UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Jennifer Noonan Edmonds, attest that I am the Director, Policy Analysis and Communications, Office of Air Quality Planning and Standards, Office of Air and Radiation of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

March 1993, Ethylene Oxide Emissions for Commercial Sterilization Fumigation Operations - Background Information for Proposed Standards. Draft EIS, 300 pages

March 1989, Alternative Control Technology Document – Ethylene Oxide Sterilization/Fumigation Operations, 100 pages

November 1994, Ethylene Oxide Emissions Standards for Commercial Sterilization and Fumigation Operations Background Information for Final Standards: Summary of Public Comments and Responses, 90 pages

April 5, 1988, Sampling/Analytical Method Evaluation for EO Emission and Control Unit Efficiency Determinations, 113 pages

August 2018, 2014 NATA Technical Support Document, 211 pages

November 2022, DRAFT Test Data for Sterilization Chamber Vents at Facilities in the Ethylene Oxide Commercial Sterilization Facilities Source Category – Proposal Review for Ethylene Oxide Commercial Sterilization Source Category, 15 pages

Table A.1. Full List of Facilities with SCV, at Facilities where ETO is at least 40 tpy , 1 page

Appendix A.2 Final Run-by-Run Values for SCVs Sources Using 40+ Tons , 3 pages

October 1992, Background Information for Proposed Standards, 300 pages

February 23, 2021, Use of Stand-Alone Timers for Volatile Organic Compound (VOC) Sample Collection in Canisters, 3 pages

May 7, 2021, Effect of Canister Type on Background Ethylene Oxide Concentration, 2 pages

May 25, 2021, Technical Note: The Ethylene Oxide Canister Effect, 2 pages

April 2004, Volume 1 Technical Resource Manual, 899 pages

July 18, 1997, Subpart O – Ethylene Oxide Commercial Sterilization Plant Explosions, 2 pages

September 23, 2005, Residual Risk Assessment for EO Commercial Sterilization Source Category, 85 pages

Subscribed under the penalty of perjury on this 17th day of July, 2023.

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CERTIFICATION OF TRUE COPY

I, Jennifer Clark, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

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October 1992

Air

EPA

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations

DRAFT EIS

Background Information for Proposed Standards

NESHAP

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ETHYLENE OXIDE EMISSIONS FROM COMMERCIAL STERILIZATION/FUMIGATION OPERATIONS --

BACKGROUND INFORMATION FOR PROPOSED STANDARDS

Final

ETHYLENE OXIDE EMISSIONS FROM COMMERCIAL STERILIZATION/FUMIGATION OPERATIONS -- BACKGROUND INFORMATION FOR PROPOSED STANDARDS

Emission Standards Division

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina 27711

March 1993

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Publication No. EPA-435/D-93-016

ENVIRONMENTAL PROTECTION AGENCY

Background Information
and Draft
Environmental Impact Statement
for Commercial Sterilization/Fumigation Operations

Prepared by:

for Bruce Jordan
Director, Emission Standards Division
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

6-7-93
(Date)

1. The proposed national emission standard would limit emissions of ethylene oxide from existing and new commercial sterilization/fumigation operations. The proposed standards implement Section 112 of the Clean Air Act as amended in 1990 and are based on the Administrator's determination of July 16, 1992 (57 FR 31576) that commercial sterilization sources generate a large amount of ethylene oxide, a hazardous air pollutant listed in Section 112(b) of the Act.

2. Copies of this document have been sent to the following Federal Departments: Labor, Health and Human Services, Defense, Transportation, Agriculture, Commerce, Interior, and Energy; the National Science Foundation; the Council on Environmental Quality; members of the State and Territorial Air Pollution Program Administrators; the Association of Local Air Pollution Control Officials; EPA Regional Administrators; Office of Management and Budget; and other interested parties.

3. The comment period for review of this document is 60 days. Mr. David Markwordt, Chemicals and Petroleum Branch, telephone (919) 541-0837, may be contacted regarding the date of the comment period.

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1.0 SUMMARY

1.1 STATUTORY AUTHORITY

National emission standards for hazardous air pollutants are established in accordance with Section 112(b)(1)(B) of the Clean Air Act (42 U.S.C. 7412), as amended. Emission standards under Section 112 apply to new and existing sources of a substance that has been listed as a hazardous air pollutant. This study examines emissions of ethylene oxide (EO) from commercial sterilization and fumigation industries.

1.2 REGULATORY ALTERNATIVES

Five regulatory alternatives representing selected combinations of control options were developed to evaluate the environmental and cost impacts of differing control strategies.

Regulatory Alternative A represents the maximum level of control with 99 percent of the EO emissions from all emissions points associated with commercial sterilization operations captured and controlled. Regulatory Alternative B represents the maximum level of control of all emissions points that exceed an EO use cutoff. Regulatory Alternative C represents control of the sterilizer vent, vacuum pump drain, and aeration room emissions at this same level of EO use. Additional controls on chamber exhaust emissions are not anticipated under this alternative. Regulatory Alternative D represents control of only the sterilizer vent and vacuum pump drain emissions for facilities using 270 kilograms per year (kg/yr) (600 pounds per year [lb/yr]) or more of EO. Regulatory Alternative E represents control of these same two emissions points for facilities using 900 kg/yr (2,000 lb/yr) or more of EO. Regulatory Alternative E

represents the maximum achievable control technology (MACT) floor determination.

1.3 ENVIRONMENTAL IMPACT

Table 1-1 summarizes the environmental impacts of the regulatory alternatives. At the MACT floor (Regulatory Alternative E), the nationwide EO emissions are estimated at 120 megagrams per year (Mg/yr) (132 tons per year [tons/yr]). The lower EO use cutoff proposed under Regulatory Alternative D reduces the estimated nationwide EO emissions to 109 Mg/yr (120 tons/yr). The control options under Regulatory Alternative C reduce the nationwide emissions to 68 Mg/yr (75 tons/yr). Under Regulatory Alternatives B and A, the control options proposed would reduce the nationwide emissions of EO to 30 Mg/yr and 11 Mg/yr (33 tons/yr and 12 tons/yr), respectively.

The potential impacts of these regulatory alternatives on wastewater, solid waste, and energy are also shown in Table 1-1. It is expected that the wastewater and solid waste impacts will be insignificant because of the recycling of ethylene glycol and reactant.

1.4 COST IMPACT

The nationwide cost impacts of the regulatory alternatives are summarized in Table 1-2. The costs associated with Regulatory Alternative E (MACT floor regulation) may require a nationwide capital investment of about $3.8 million. The control measures in Regulatory Alternatives D, C, B, and A may each require a nationwide capital investment of about $4.3 million, $6.4 million, $9.2 million, and $12 million respectively. These cost figures were determined using fourth quarter 1987 dollars.

1.5 ECONOMIC IMPACT

The economic impacts associated with the regulation of commercial sterilizers are not significant. In general, sterilization costs represent a small fraction of total production costs for facilities in industries in which sterilization is not the main source of revenue. Thus, any cost increases caused by the regulation will not significantly increase total production costs. Furthermore, because total

TABLE 1-1. POTENTIAL NATIONWIDE PERCENT EMISSIONS REDUCTION AND NATIONWIDE AIR, WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS

Regulatory Alternative	Nationwide emission reduction, %	EO air emission reduction Mg/yr (tons/yr)	Total annual wastewater production, m^3 (gal)[a,b]	Total annual solid waste production, Mg/(tons)[c,d]	Total annual electricity consumption, Kw/h (000's)
A	99	1,061 (1,170)	2,150 (569,000)	190 (209)	4,600
B	97	1,042 (1,148)	2,140 (566,000)	137 (151)	2,700
C	94	1,004 (1,107)	2,140 (566,000)	137 (151)	2,700
D	90	963 (1,062)	2,140 (566,000)	0	0
E	89	952 (1,049)	2,120 (561,000)	0	0

[a]Actual impacts anticipated to be zero because of recycling of ethylene glycol.
[b]Approximately 60 percent (by volume) of wastewater is composed of ethylene glycol.
[c]Actual impacts anticipated to be zero because of recycling of reactant.
[d]Based on the use of gas/solid reactor.

Source: U. S. EPA Ethylene Oxide Commercial Sterilization Data Base, 1986, 1988.

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TABLE 1-2. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS

Regulatory Alternative	Emission reduction, %	Total annual costs, $/MM	Emission reduction, Mg/yr (tons/yr)	Cost effectiveness $/Mg ($/ton)	Incremental cost effectiveness, $/Mg ($/ton)
A	99	12	1,061 (1,170)	11,300 (10,300)	147,000 (133,000)
B	97	9.2	1,042 (1,149)	8,800 (8,000)	74,000 (67,000)
C	94	6.4	1,004 (1,107)	6,400 (5,800)	51,000 (46,000)
D	90	4.3	963 (1,062)	4,500 (4,050)	45,000 (41,000)
E	89	3.8	952 (1,049)	4,000 (3,600)	N/A

[a]Ethylene oxide use cutoff same as for sterilizer vent.
[b]Status quo means that baseline chambers exhaust emissions are not exceeded.

production costs will not increase substantially, the price increases required to recover control also will be low.

In the contract sterilization industry, sterilization is nearly the entire product, and thus is the main source of revenue. Therefore, increased sterilization costs due to the regulation may cause total production costs and prices to increase significantly. However, as a result of the regulation, these facilities should experience an increase in demand for their services through facilities switching from in-house sterilization to contract sterilization. This increase in demand should allow them to recover control costs and may even increase profits for facilities in the contract sterilization industry. Thus, contract sterilizers are not adversely impacted by the regulation of commercial sterilizers.

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2.0 INTRODUCTION

2.1 BACKGROUND AND AUTHORITY FOR STANDARDS

According to industry estimates, more than 2.4 billion pounds of toxic pollutants were emitted to the atmosphere in 1988 ("Implementation Strategy for the Clean Air Act Amendments of 1990," Environmental Protection Agency [EPA] Office of Air and Radiation, January 15, 1991). These emissions may result in a variety of adverse health effects, including cancer, reproductive effects, birth defects, and respiratory illnesses. Title III of the 1990 Amendments to the Clean Air Act provides the tools for controlling emissions of these pollutants. Emissions from both large and small facilities that contribute to air toxics problems in urban and other areas will be regulated. The primary consideration in establishing national industry standards must be demonstrated technology. Before national emission standards for hazardous air pollutants (NESHAP) are proposed as Federal regulations, air pollution prevention and control methods are examined in detail with respect to their feasibility, environmental impacts, and costs. Various control options based on different technologies and degrees of efficiency are examined, and a determination is made regarding whether the various control options apply to each emissions source or if dissimilarities exist between the sources. In most cases, regulatory alternatives are subsequently developed and are then studied by EPA as a prospective basis for a standard. The alternatives are investigated in terms of their impacts on the environment, the economics and well-being of the industry, the national economy, and energy and other impacts. This document summarizes the information obtained through these studies so that interested

persons will be able to evaluate the information considered by EPA in developing the proposed standards.

National emission standards for hazardous air pollutants for new and existing sources are established under Section 112 of the Clean Air Act as amended in 1990 [42 U.S.C. 7401 et seq., as amended by PL 101-549, November 15, 1990], hereafter referred to as the Act. Section 112 directs the EPA Administrator to promulgate standards that "require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition of such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reductions, and any non-air quality health and environmental impacts and energy requirements, determines is achievable ... ." The Act allows the Administrator to set standards that "distinguish among classes, types, and sizes of sources within a category or subcategory."

The Act differentiates between major sources and area sources. A major source is defined as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." The Administrator, however, may establish a lesser quantity cutoff to distinguish between major and area sources. The level of the cutoff is based on the potency, persistence, or other characteristics or factors of the air pollutant. An area source is defined as "any stationary source of hazardous air pollutants that is not a major source." For new sources, the 1990 Amendments state that the "maximum degree of reduction in emissions that is deemed achievable for new sources in a category or subcategory shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator." Emission standards for existing sources "may be less stringent than the standards for new sources in the same

category or subcategory but shall not be less stringent, and may be more stringent than--

(A) the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information), excluding those sources that have, within 18 months before the emission standard is proposed or within 30 months before such standard is promulgated, whichever is later, first achieved a level of emission rate or emission reduction which complies, or would comply if the source is not subject to such standard, with the lowest achievable emission rate (as defined by Section 171) applicable to the source category and prevailing at the time, in the category or subcategory for categories and subcategories with 30 or more sources, or

(B) the average emission limitation achieved by the best performing five sources (for which the Administrator has or could reasonably obtain emissions information) in the category or subcategory for categories or subcategories with fewer than 30 sources."

The Federal standards are also known as "MACT" standards and are based on the maximum achievable control technology previously discussed. The MACT standards may apply to both major and area sources, although the existing source standards may be less stringent than the new source standards, within the constraints presented above. The MACT is considered to be the basis for the standard, but the Administrator may promulgate more stringent standards that have several advantages. First, they may help achieve long-term cost savings by avoiding the need for more expensive retrofitting to meet possible future residual risk standards, which may be more stringent (discussed in Section 2.6). Second, Congress was clearly interested in providing incentives for improving technology. Finally, in the 1990 Amendments, Congress gave EPA a clear mandate to reduce the health and environmental risk of air toxics emissions as quickly as possible.

For area sources, the Administrator may "elect to promulgate standards or requirements applicable to sources in such categories or subcategories which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants." These area source standards are also known as "GACT" (generally available control technology) standards, although MACT may be applied at the Administrator's discretion, as discussed previously.

The standards for hazardous air pollutants (HAP's), like the new source performance standards (NSPS) for criteria pollutants required by Section 111 of the Act (42 U.S.C. 7411), differ from other regulatory programs required by the Act (such as the new source review program and the prevention of significant deterioration program) in that NESHAP and NSPS are national in scope (versus site-specific). Congress intended for the NESHAP and NSPS programs to provide a degree of uniformity to State regulations to avoid situations where some States may attract industries by relaxing standards relative to other States. States are free under Section 116 of the Act to establish standards more stringent than Section 111 or 112 standards.

Although NESHAP are normally structured in terms of numerical emissions limits, alternative approaches are sometimes necessary. In some cases, physically measuring emissions from a source may be impossible or at least impracticable due to technological and economic limitations. Section 112(h) of the Act allows the Administrator to promulgate a design, equipment, work practice, or operational standard, or combination thereof, in those cases where it is not feasible to prescribe or enforce an emissions standard. For example, emissions of volatile organic compounds (many of which may be HAP's, such as benzene) from storage vessels for volatile organic liquids are greatest during tank filling. The nature of the emissions (i.e, high concentrations for short periods during filling and low concentrations for longer periods during storage) and the configuration of storage tanks make direct emission measurement

impractical. Therefore, the MACT or GACT standards may be based on equipment specifications.

Under Section 112(h)(3), the Act also allows the use of alternative equivalent technological systems: "If, after notice and opportunity for comment, the owner or operator of any source establishes to the satisfaction of the Administrator that an alternative means of emission limitation" will reduce emissions of any air pollutant at least as much as would be achieved under the design, equipment, work practice, or operational standard, the Administrator shall permit the use of the alternative means.

Efforts to achieve early environmental benefits are encouraged in Title III. For example, source owners and operators are encouraged to use the Section 112(i)(5) provisions, which allow a 6-year compliance extension of the MACT standard in exchange for the implementation of an early emission reduction program. The owner or operator of an existing source must demonstrate a 90-percent emission reduction of HAP's (or 95 percent if the HAP's are particulates) and meet an alternative emission limitation, established by permit, in lieu of the otherwise applicable MACT standard. This alternative limitation must reflect the 90- (95-) percent reduction and is in effect for a period of 6 years from the compliance date for the otherwise applicable standard. The 90- (95-) percent early emission reduction must be achieved before the otherwise applicable standard is first proposed, although the reduction may be achieved after the standard's proposal (but before January 1, 1994) if the source owner or operator makes an enforceable commitment before the proposal of the standard to achieve the reduction. The source must meet several criteria to qualify for the early reduction standard, and Section 112(i)(5)(A) provides that the State may require additional reductions.

2.2 SELECTION OF POLLUTANTS AND SOURCE CATEGORIES

As amended in 1990, the Act includes a list of 189 HAP's. Petitions to add or delete pollutants from this list may be submitted to EPA. Using this list of pollutants, EPA will publish a list of source categories (major and area sources) for

which emission standards will be developed. Within 2 years of enactment (November 1992), EPA will publish a schedule establishing dates for promulgating these standards. Petitions also may be submitted to EPA to remove source categories from the list. The schedule for standards for source categories will be determined according to the following criteria:

"(A) the known or anticipated adverse effects of such pollutants on public health and the environment;

(B) the quantity and location of emissions or reasonably anticipated emissions of hazardous air pollutants that each category or subcategory will emit; and

(C) the efficiency of grouping categories or subcategories according to the pollutants emitted, or the processes or technologies used."

After the source category has been chosen, the types of facilities within the source category to which the standard will apply must be determined. A source category may have several facilities that cause air pollution, and emissions from these facilities may vary in magnitude and control cost. Economic studies of the source category and applicable control technology may show that air pollution control is better served by applying standards to the more severe pollution sources. For this reason, and because there is no adequately demonstrated system for controlling emissions from certain facilities, standards often do not apply to all facilities at a source. For the same reasons, the standards may not apply to all air pollutants emitted. Thus, although a source category may be selected to be covered by standards, the standards may not cover all pollutants or facilities within that source category.

2.3 PROCEDURE FOR DEVELOPMENT OF NESHAP

Standards for major and area sources must (1) realistically reflect MACT or GACT; (2) adequately consider the cost, the non-air quality health and environmental impacts, and the energy requirements of such control; (3) apply to new and existing sources; and (4) meet these conditions for all variations of industry operating conditions anywhere in the country.

The objective of the NESHAP program is to develop standards to protect the public health by requiring facilities to control emissions to the level achievable according to the MACT or GACT guidelines. The standard-setting process involves three principal phases of activity: (1) gathering information, (2) analyzing the information, and (3) developing the standards.

During the information-gathering phase, industries are questioned through telephone surveys, letters of inquiry, and plant visits by EPA representatives. Information is also gathered from other sources, such as a literature search. Based on the information acquired about the industry, EPA selects certain plants at which emissions tests are conducted to provide reliable data that characterize the HAP emissions from well-controlled existing facilities.

In the second phase of a project, the information about the industry, the pollutants emitted, and the control options are used in analytical studies. Hypothetical "model plants" are defined to provide a common basis for analysis. The model plant definitions, national pollutant emissions data, and existing State regulations governing emissions from the source category are then used to establish "regulatory alternatives." These regulatory alternatives may be different levels of emissions control or different degrees of applicability or both.

The EPA conducts studies to determine the cost, economic, environmental, and energy impacts of each regulatory alternative. From several alternatives, EPA selects the single most plausible regulatory alternative as the basis for the NESHAP for the source category under study.

In the third phase of a project, the selected regulatory alternative is translated into standards, which, in turn, are written in the form of a Federal regulation. The Federal regulation limits emissions to the levels indicated in the selected regulatory alternative.

As early as is practical in each standard-setting project, EPA representatives discuss the possibilities of a standard and the form it might take with members of the National Air Pollution

Control Techniques Advisory Committee, which is composed of representatives from industry, environmental groups, and State and local air pollution control agencies. Other interested parties also participate in these meetings.

The information acquired in the project is summarized in the background information document (BID). The BID, the proposed standards, and a preamble explaining the standards are widely circulated to the industry being considered for control, environmental groups, other government agencies, and offices within EPA. Through this extensive review process, the points of view of expert reviewers are taken into consideration as changes are made to the documentation.

A "proposal package" is assembled and sent through the offices of EPA Assistant Administrators for concurrence before the proposed standards are officially endorsed by the EPA Administrator. After being approved by the EPA Administrator, the preamble and the proposed regulation are published in the Federal Register.

The public is invited to participate in the standard-setting process as part of the Federal Register announcement of the proposed regulation. The EPA invites written comments on the proposal and also holds a public hearing to discuss the proposed standards with interested parties. All public comments are summarized and incorporated into a second volume of the BID. All information reviewed and generated in studies in support of the standards is available to the public in a "docket" on file in Washington, D.C. Comments from the public are evaluated, and the standards may be altered in response to the comments.

The significant comments and EPA's position on the issues raised are included in the preamble of a promulgation package, which also contains the draft of the final regulation. The regulation is then subjected to another round of internal EPA review and refinement until it is approved by the EPA Administrator. After the Administrator signs the regulation, it is published as a "final rule" in the Federal Register.

2.4 CONSIDERATION OF COSTS

The requirements and guidelines for the economic analysis of proposed NESHAP are prescribed by Presidential Executive Order 12291 (EO 12291) and the Regulatory Flexibility Act (RFA). The EO 12291 requires preparation of a Regulatory Impact Analysis (RIA) for all "major" economic impacts. An economic impact is considered to be major if it satisfies any of the following criteria:

1. An annual effect on the economy of $100 million or more;
2. A major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions; or
3. Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

An RIA describes the potential benefits and costs of the proposed regulation and explores alternative regulatory and nonregulatory approaches to achieving the desired objectives. If the analysis identifies less costly alternatives, the RIA includes an explanation of the legal reasons why the less costly alternatives could not be adopted. In addition to requiring an analysis of the potential costs and benefits, EO 12291 specifies that EPA, to the extent allowed by the Act and court orders, demonstrate that the benefits of the proposed standards outweigh the costs and that the net benefits are maximized.

The RFA requires Federal agencies to give special consideration to the impact of regulations on small businesses, small organizations, and small governmental units. If the proposed regulation is expected to have a significant impact on a substantial number of small entities, a regulatory flexibility analysis must be prepared. In preparing this analysis, EPA takes into consideration such factors as the availability of capital for small entities, possible closures among small entities, the increase in production costs due to compliance, and a comparison

of the relative compliance costs as a percent of sales for small versus large entities.

The prime objective of the cost analysis is to identify the incremental economic impacts associated with compliance with the standards based on each regulatory alternative compared to baseline. Other environmental regulatory costs may be factored into the analysis wherever appropriate. Air pollutant emissions may cause water pollution problems, and captured potential air pollutants may pose a solid waste disposal problem. The total environmental impact of an emission source must, therefore, be analyzed and the costs determined whenever possible.

A thorough study of the profitability and price-setting mechanisms of the industry is essential to the analysis so that an accurate estimate of potential adverse economic impacts can be made for proposed standards. It is also essential to know the capital requirements for pollution control systems already placed on plants so that the additional capital requirements necessitated by these Federal standards can be placed in proper perspective. Finally, it is necessary to assess the availability of capital to provide the additional control equipment needed to meet the standards.

2.5 CONSIDERATION OF ENVIRONMENTAL IMPACTS

Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969 requires Federal agencies to prepare detailed environmental impact statements on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment. The objective of NEPA is to build into the decision-making process of Federal agencies a careful consideration of all environmental aspects of proposed actions.

In a number of legal challenges to standards for various industries, the United States Court of Appeals for the District of Columbia Circuit has held that environmental impact statements need not be prepared by EPA for proposed actions under the Act. Essentially, the Court of Appeals has determined that the best system of emissions reduction requires the Administrator to take into account counterproductive environmental effects of proposed

standards as well as economic costs to the industry. On this basis, therefore, the Courts established a narrow exemption from NEPA for EPA determinations.

In addition to these judicial determinations, the Energy Supply and Environmental Coordination Act (ESECA) of 1974 (PL-93-319) specifically exempted proposed actions under the Act from NEPA requirements. According to Section 7(c)(1), "No action taken under the Clean Air Act shall be deemed a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969" (15 U.S.C. 793(c)(1)).

Nevertheless, EPA has concluded that preparing environmental impact statements could have beneficial effects on certain regulatory actions. Consequently, although not legally required to do so by Section 102(2)(C) of NEPA, EPA has adopted a policy requiring that environmental impact statements be prepared for various regulatory actions, including NESHAP developed under Section 112 of the Act. This voluntary preparation of environmental impact statements, however, in no way legally subjects the EPA to NEPA requirements.

To implement this policy, a separate section is included in this document that is devoted solely to an analysis of the potential environmental impacts associated with the proposed standards. Both adverse and beneficial impacts in such areas as air and water pollution, increased solid waste disposal, and increased energy consumption are discussed.

2.6 RESIDUAL RISK STANDARDS

Section 112 of the Act provides that 8 years after MACT standards are established (except for those standards established 2 years after enactment, which have 9 years), standards to protect against the residual health and environmental risks remaining must be promulgated, if necessary. The standards would be triggered if more than one source in a category or subcategory exceeds a maximum individual risk of cancer of 1 in 1 million. These residual risk regulations would be based on the concept of providing an "ample margin of safety to protect public health."

The Administrator may also consider whether a more stringent standard is necessary to prevent--considering costs, energy, safety, and other relevant factors--an adverse environmental effect. In the case of area sources controlled under GACT standards, the Administrator is not required to conduct a residual risk review.

3.0 ETHYLENE OXIDE STERILIZATION/FUMIGATION PROCESSES AND EMISSIONS

3.1 BACKGROUND INFORMATION

The commercial sterilization (CS) source category covers the use of ethylene oxide (EO) as a sterilant/fumigant in the production of medical equipment supplies and in miscellaneous sterilization and fumigation operations. Commercial sterilization facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. These materials may be sterilized at the facility that produces or uses the product or by contract sterilizers (i.e., firms under contract to sterilize products manufactured by other companies). Libraries and museums use EO to fumigate books and other historical items. State departments of agriculture control diseases of bees by fumigating beehives with EO.

Information about facilities that use EO as a sterilant/fumigant was obtained from two sources: (1) a survey of medical equipment suppliers (Health Industry Manufacturers' Association [HIMA] members) conducted by HIMA in November 1985 and (2) an information collection request (ICR) submitted by EPA under Section 114 of the Act to miscellaneous sterilizers and fumigators (identified during an extensive survey of potential users) in July 1986. A total of 203 CS facilities responded to the HIMA survey and the July 1986 EPA information request to complete the 1986 data base.[1,2]

Additional information to the 1986 data base was obtained from two Section 114 letters (July 1988 and July 1989). The July 1988 Section 114 letter was sent to 44 (9 parent companies) of the 203 facilities represented in the 1986 data base.[3] These 44 facilities were chosen because they represent the diversity of sterilizer chamber sizes, annual EO use, and industries associated with the commercial sterilization category. Although these facilities represent only 22 percent of the number of facilities in the CS data base, the emissions from these facilities account for 64 percent of the total emissions from commercial sterilization facilities. The July 1988 Section 114 letter was used to obtain detailed operating parameters for a short-term health risk assessment analysis; data on vacuum pumps, gas types, control devices, and aeration rooms were also obtained from this ICR. The July 1989 Section 114 letter was sent to 39 of the 203 facilities in the 1986 data base (i.e., those with a maximum individual risk [MIR] of cancer incidence greater than 10^{-3}).[4] The purpose of this Section 114 letter was to update EPA's Air Toxics Exposure and Risk Information System (ATERIS) data base. The July 1989 Section 114 letter was also used to obtain updated information regarding EO use, emission controls, and vacuum pumps. The responses to the July 1989 Section 114 letter indicated that 7 of the 39 facilities had ceased EO use. Therefore, 196 facilities comprise the EPA 1989 CS data base.

As shown in Table 3-1, the facilities represented in the EPA commercial sterilization data base are located in 41 States and Puerto Rico. These facilities were grouped by Standard Industrial Classification (SIC) into the following categories:

1. medical equipment suppliers;
2. pharmaceuticals;
3. other health-related industries;
4. spice manufacturers;
5. contract sterilizers;
6. libraries, museums, and archives;

TABLE 3-1. LOCATIONS OF FACILITIES--EPA COMMERCIAL STERILIZATION DATA BASE[1-4]

State	No. of facilities	State	No. of facilities
Arizona	3	Missouri	5
Arkansas	2	New Hampshire	2
California	19	New Jersey	17
Colorado	3	New York	13
Connecticut	6	North Carolina	7
Delaware	2		
Florida	5	Ohio	2
Georgia	4	Pennsylvania	9
Illinois	8	Puerto Rico	14
Indiana	4	Rhode Island	2
Iowa	3	South Carolina	2
Maryland	5	Tennessee	3
Massachusetts	9	Texas	12
Michigan	8	Utah	1
Minnesota	6	Virginia	5
Mississippi	2	Washington	2
Subtotal	89	Subtotal	96

The commercial sterilization data base includes one facility located in each of the following States: Alabama, Hawaii, Kentucky, Maine, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Wisconsin, and West Virginia.

Subtotal	11
Total No. of facilities	196

7. laboratories (research, testing, and animal breeding); and

8. State departments of agriculture.[5]

Table 3-2 shows the number of facilities in the EPA commercial sterilization data base for the eight categories listed above and the SIC codes represented by these industry categories.

3.2 PROCESS DESCRIPTION

There are two main types of EO sterilization processes: (1) bulk sterilization and (2) single-item sterilization. These processes are described below followed by discussions about spice fumigators, library and museum fumigators, and beehive fumigators used by State departments of agriculture. (In addition to using the bulk sterilization process, one facility also sterilizes within 55-gallon drums.[2] This process, which is neither bulk nor single-item sterilization, is not discussed.)

3.2.1 Bulk Sterilization

Bulk sterilization is the more commonly used EO sterilization process; 98 percent of the commercial sterilization facilities represented in the EPA data base use this process.[1-4] The products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas at a predetermined temperature, humidity level, and pressure. The equipment, sterilant gases, and sterilization cycle used for bulk sterilization processes are described below.

3.2.1.1 Equipment. A schematic of a gas sterilizer is shown in Figure 3-1. The main components of the sterilizer are the chamber and vacuum pump. Chambers used by commercial sterilization facilities typically range in volume from 2.8 cubic meters (m^3) (100 cubic feet [ft^3]) to 28 m^3 (1,000 ft^3).[1,2] Table 3-3 presents size data for the chambers in the EPA commercial sterilization data base.

A vacuum pump is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete. In the past, once-through, water-ring vacuum pumps were used. However, many facilities are converting to full sealant recovery (i.e., oil-sealed or

TABLE 3-2. NUMBER OF FACILITIES AND STANDARD INDUSTRIAL CLASSIFICATION (SIC) PER INDUSTRY CATEGORY--EPA COMMERCIAL STERILIZATION DATA BASE[5]

Industry category	No. of facilities	SIC
Medical equipment suppliers	61	3841, 3842
Pharmaceuticals	39	2834, 5122, 2831, 2833
Other health-related industries	24	3079, 3693, 5086, 2211, 2821, 2879, 3069, 3569, 3677, 3999
Spice manufacturers	23	2099, 5149, 2034, 2035, 2046
Contract sterilizers	17	7399, 7218, 8091
Libraries, museums, and archives	13	8411, 8231
Laboratories (research, testing and animal breeding)	11	0279, 7391, 8071, 8922, 7397
State departments of agriculture	8	9641
Total	196	

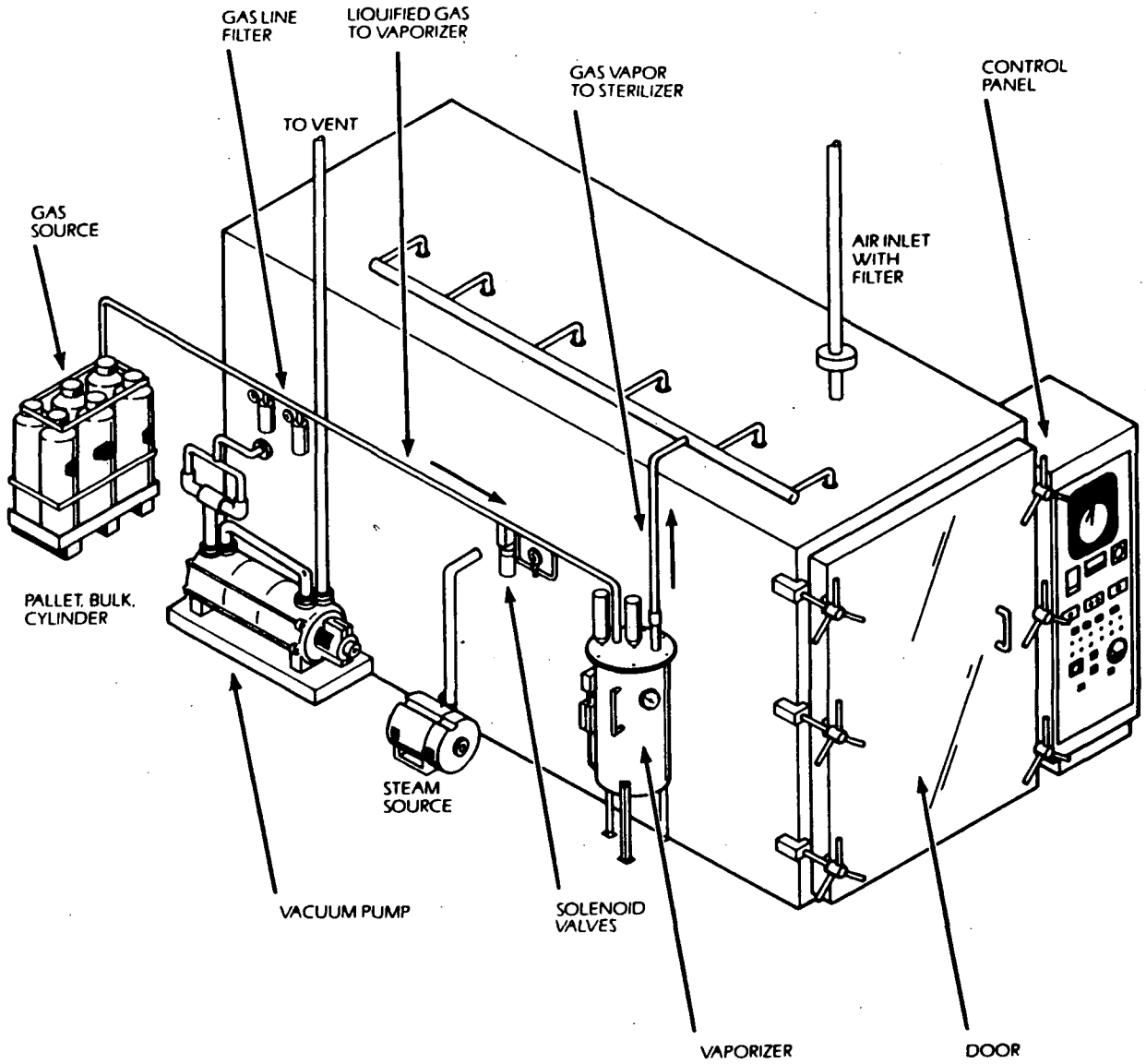

Figure 3-1. Schematic of a gas sterilizer.
(Courtesy of Union Carbide Corporation, Linde Division.)[7]

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TABLE 3-3. CHAMBER SIZES--EPA COMMERCIAL STERILIZATION DATA BASE[1,2]

Size range, m^3 (ft^3)	No. of chambers	Percent	Cumulative No. of chambers	Cumulative percent
≤1.4 (≤50)	83	20	83	20
1.5-2.8 (51-100)	29	7	112	28
2.9-14 (101-500)	113	28	225	55
15-28 (501-1,000)	116	29	341	84
29-57 (1,001-2,000)	55	14	396	98
≥58 (≥2,001)	11	2	407[a]	100

[a]This number excludes four single-item sterilization units, one 55-gal drum user, and two facilities that did not report a chamber size.

recirculating water) vacuum pumps in order to meet the 1 part per million by volume (1 ppmv) Occupational Safety and Health Administration (OSHA) worker exposure standard for EO and proposed State regulations.[3,6]

3.2.1.2 Sterilant Gases. Ethylene oxide is an extremely effective sterilant gas. The EO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping.

The most widely used sterilant gas is a mixture of 12 percent by weight EO and 88 percent by weight dichlorodifluoromethane (CFC-12), referred to as 12/88. Two other commonly used sterilant gases are (1) pure EO (i.e., 100 percent EO) and (2) a mixture of 10 percent by weight EO and 90 percent by weight carbon dioxide (CO_2), referred to as 10/90. Other sterilant gas mixtures that are used include 20/80, 30/70, and 80/20 (weight percents EO/CO_2).[1,2,4] Gas mixtures that contain 20 percent or greater EO (by weight) are considered flammable. The 80/20 (EO/CO_2) mixture has the same flammability range as pure EO.[7] Physical and chemical properties of EO, CFC-12, and CO_2 are given in Table 3-4. Table 3-5 shows the number of commercial sterilization facilities represented in the EPA data base that use a particular gas type and the amount of EO used for each gas type. Since many commercial sterilization facilities operate more than one sterilization chamber, the gas usage rates in Table 3-5 also are presented on a chamber basis.[1,2,4] The data presented in Table 3-5 are based on information from the 1985 HIMA survey and the 1986 EPA ICR.[1,2] Gas type data were collected for the 44 facilities that responded to the 1988 Section 114 letter; however, this information was not updated for the remaining facilities represented in the 1989 CS data base. Since 1986, the increased price of CFC-12 (due to EPA regulation of CFC production) could have affected the number of facilities that use 12/88.

TABLE 3-4. PHYSICAL AND CHEMICAL PROPERTIES OF ETHYLENE OXIDE, DICHLORODIFLUOROMETHANE, AND CARBON DIOXIDE [8-11]

	Ethylene oxide	Dichlorodifluoromethane	Carbon dioxide
Other designations	1,2-epoxyethane, oxirane, dimethylene oxide	CFC-12, refrigerant 12, propellant 12	Carbonic acid gas, carbonic anhydride
Appearance	Colorless liqud or gas	Colorless gas, readily liquified under pressure and/or cooling	Colorless gas
Chemical formula	C_2H_4O	CCl_2F_2	CO_2
Molecular weight	44.0	120.9	44.0
Vapor pressure at 20°C (68°F)	146.0 kPa (21.2 psia)	567.6 kPa (82.3 psia)	5,731.0 kPa (831 psia)
Boiling point at 101.3 kPa (14.7 psi)	10.4°C (50.7°F)	-29.8°C (-21.6°F)	-78.5°C (-109.3°F)
Flammability limits in air	Lower 3 percent by volume Upper 80+ percent by volume[a]	Nonflammable	Nonflammable
Water solubility	Completely miscible	Low solubility	--
Heat of combustion, vapor at 25°C (77°F)	1,306 kJ/mol (12,760 Btu/lb)	111 kJ/mol (396 Btu/lb)	--
Threshold limit value (TLV) 8-hr time weighted average (TWA)	1 ppmv	1,000 ppmv	5,000 ppmv

[a]Pure EO explodes by decomposition at 560°C (1040°F) with ignition.

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TABLE 3-5. STERILANT GAS TYPE USAGE--EPA COMMERCIAL STERILIZATION DATA BASE [1-4]

Sterilant gas	No. of facilities[a]	Percent of facilities	No. of chambers[b]	Percent of chambers	EO use, Mg/yr[c]	Percent of total EO use
12/88 (EO/CFC-12)	151	77	282	64	639	33
Pure EO	40	20	113	26	1,027	54
10/90 (EO/CO_2)	14	7	19	4	4	<0.01
Other mixtures[d]	16	8	25	6	249	13

[a]There are 196 commercial sterilization facilities in the EPA data base. Approximately 10 percent of these facilities use more than one type of sterilant gas.

[b]There are 434 operational sterilization "chambers" (the four single-item sterilization systems are counted as chambers) in the EPA commercial sterilization data base. More than one type of sterilant gas is used in 5 percent of these chambers.

[c]Amount of EO in the sterilant gas mixture.

[d]Includes mixture of EO and CO_2 with a weight percent of EO ranging from 20 to 80 percent and custom mixes.

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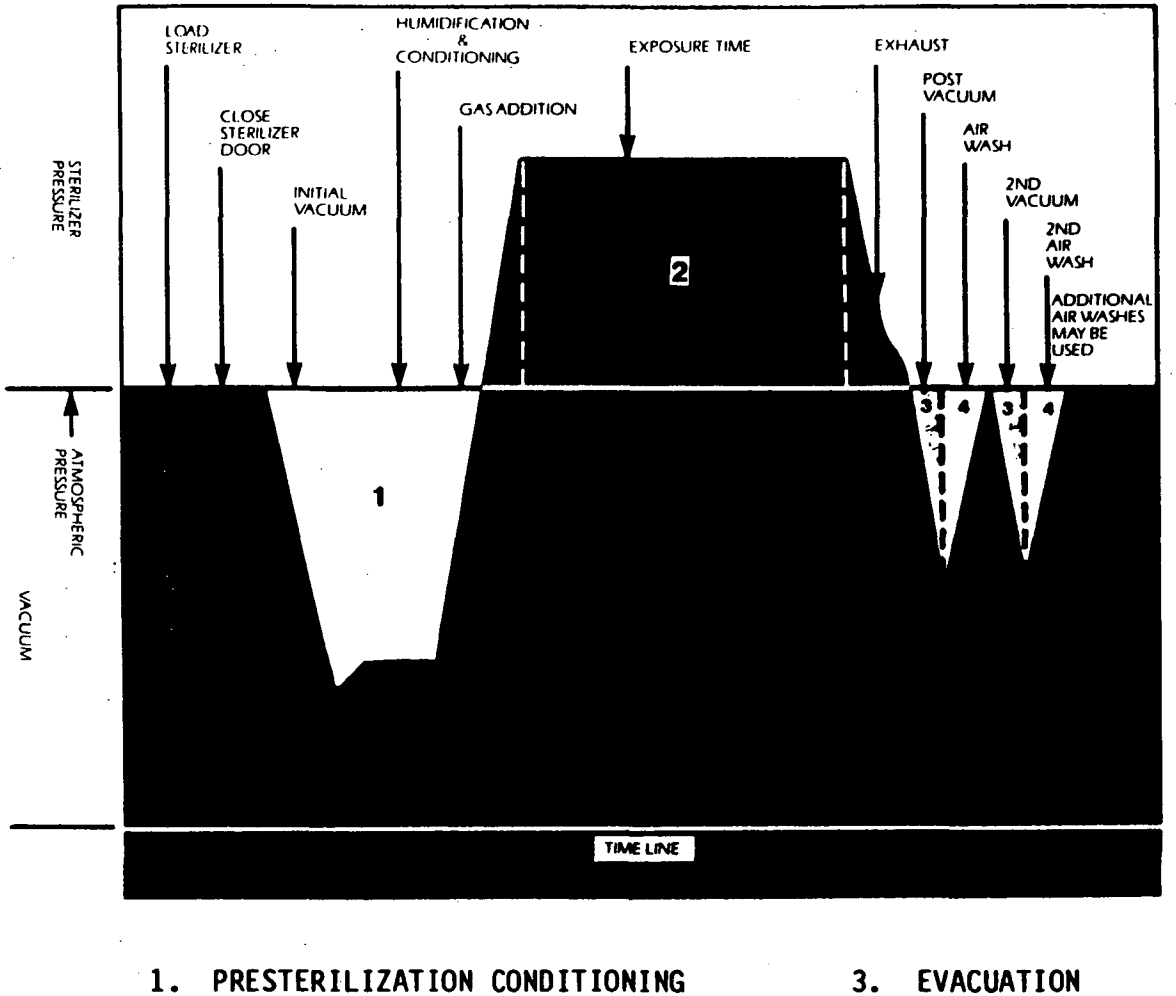
The 12/88 mixture is popular for several reasons. Unlike pure EO, 12/88 is nonflammable and nonexplosive. Therefore, the use of 12/88 does not require explosion-proof rooms and additional safety precautions that are necessary when pure EO is used. The 10/90 mixture also is nonflammable and nonexplosive.[7] But, because 10/90 is only 10 percent EO by volume whereas 12/88 is 27.3 percent EO by volume, 10/90 requires higher operating pressures to obtain an EO concentration that is sufficient for effective sterilization (approximately 304 kilopascals [kPa], or 44 pounds per square inch absolute [psia], for 10/90, as compared to 170 kPa [24.7 psia] for 12/88).[12] The chambers used for 10/90 sterilization must be ASME-rated pressure vessels, (i.e., manufactured in accordance with Section VIII, Division I, of the American Society of Mechanical Engineers [ASME] Pressure Vessel Code) and are, therefore, more expensive to construct than the chambers used with 12/88. However, because of insurance requirements, many commercial sterilization facilities use chambers that meet requirements for ASME-rated pressure vessels when sterilizing with 12/88 or with explosive mixtures below ambient pressure.[13]

3.2.1.3 Sterilization Cycle. The typical sterilization cycle consists of five phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, (4) air wash, (5) chamber exhaust, and (6) aeration. Figures 3-2 and 3-3 show pressure/time curves for the first four phases of the 12/88 sterilization cycle and the pure EO sterilization cycle, respectively. Steps 1 through 4 typically require about 8 hours.

3.2.1.3.1 Presterilization conditioning. After the products have been loaded into the chamber and the airtight door sealed, a partial vacuum is drawn inside the chamber. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable sterilant gases are used, the removal of air reduces the potential for ignition.[7] The chamber pressure is reduced to a pressure of about 6.9 to 69 kPa (1 to 10 psia) for 12/88 and 3 kPa (0.4 psia) for pure EO. The initial drawdown takes from about 5 to 45 minutes, depending on the product being



1. PRESTERILIZATION CONDITIONING
2. STERILIZATION
3. EVACUATION
4. AIR WASH

Figure 3-2. Sterilization cycle for 12/88.
(Courtesy of Union Carbide Corporation, Linde Division.)[7]

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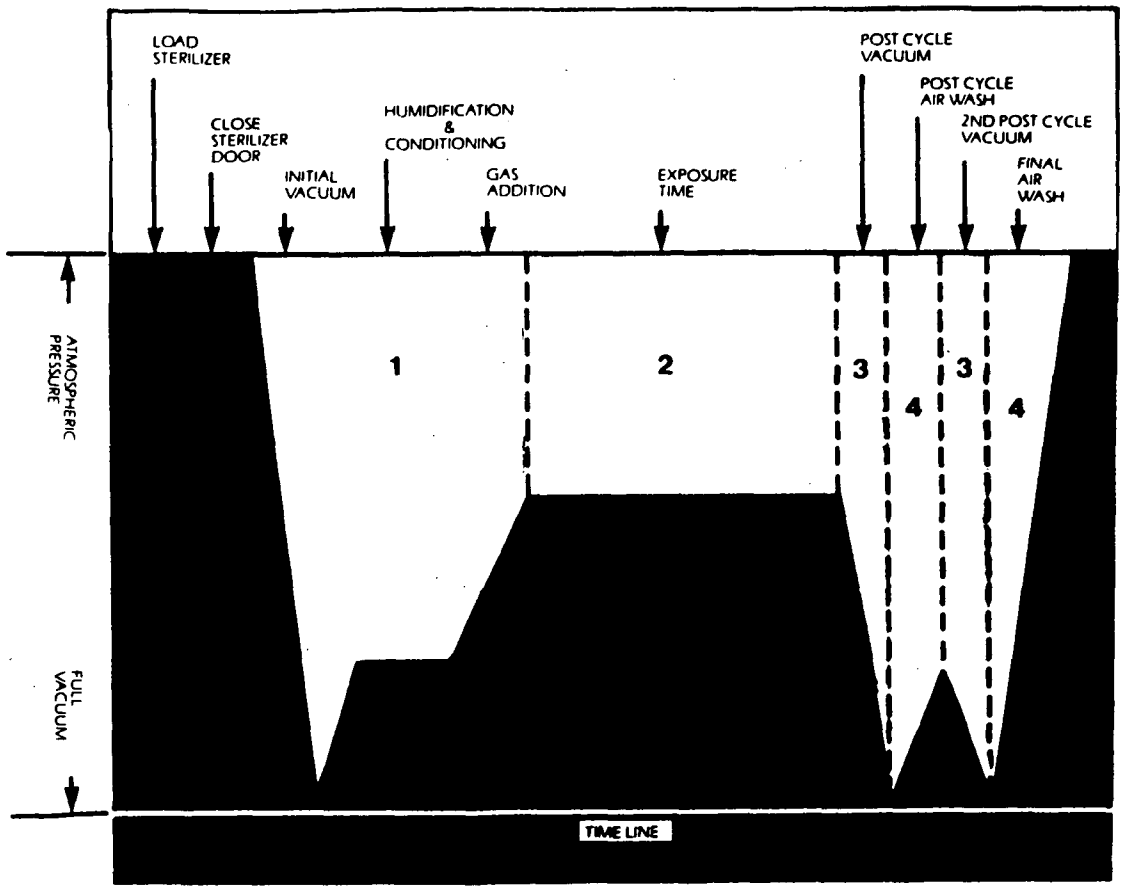

1. PRESTERILIZATION CONDITIONING
2. STERILIZATION
3. EVACUATION
4. AIR WASH

Figure 3-3. Sterilization cycle for pure EO.
(Courtesy of Union Carbide Corporation, Linde Division.)[7]

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sterilized. Certain products require a longer drawdown time because they are damaged by sudden pressure changes. The chamber temperature is then adjusted to between 38° and 54°C (100° and 130°F). A higher temperature increases the diffusion rate of EO into the products and, thus, reduces the time the products must be exposed to the sterilant gas to ensure proper sterilization. Finally, the relative humidity is raised to about 45 percent by injecting steam. Proper humidification is important to the process because the susceptibility of microorganisms to the sterilant gas is increased under moist conditions.[7]

3.2.1.3.2 Sterilization. The sterilant, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration of EO (600 parts per million [ppm]).[7] The chamber pressure depends on the type of sterilant gas used. Pure EO is used under vacuum pressures of about 51 kPa (7.35 psia); the 12/88 mixture is used at pressures of about 170 kPa (24.7 psia). The pressure is held for about 4 to 6 hours. This exposure time is dependent on the temperature, pressure, humidity level, type of sterilant gas, and products being sterilized. For example, porous products require shorter exposures than nonporous products. Also, some bacteria are more resistant to EO and take longer to destroy.

3.2.1.3.3 Evacuation. Following sufficient exposure time, the sterilant gas is evacuated from the chamber with a vacuum pump. (If sterilization is performed at a pressure greater than atmospheric, the chamber is often allowed to vent to atmospheric pressure before using the vacuum pump to evacuate the chamber.) Typical evacuation pressures are 13 kPa (1.9 psia) for 12/88 gas and 3 kPa (0.4 psia) for pure EO. This postcycle vacuum phase typically lasts about 10 minutes.

3.2.1.3.4 Air wash. The pressure in the chamber is brought to atmospheric pressure by introducing air (when nonflammable sterilant gases are used) or either nitrogen or CO_2 (when flammable sterilant gases are used). The combination of evacuation and air wash phases is repeated from two to four times

to remove as much of the EO from the product as possible. Each air wash typically lasts 2 to 15 minutes.

The purpose of the air wash is to allow residual EO to diffuse from the product. Removal of EO from the product during the air wash helps meet Food and Drug Administration (FDA) guidelines on residual EO levels for medical devices, EPA residual tolerances for agricultural products, and the OSHA standard for exposure in the workplace.

3.2.1.3.5 Chamber exhaust. Prior to unloading the sterilizer, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust is an exhaust system that evacuates EO-laden air from the chamber prior to unloading and while the chamber is being unloaded (and reloaded). The chamber exhaust typically consists of a butterfly valve in the ductwork that opens automatically and a roof-mounted blower that automatically switches on and pulls fresh air through the chamber. A chamber face velocity of 30.5 m/min (100 ft/min) is generally maintained, producing a chamber exhaust flow rate of 28 to 85 m^3/min (1,000 to 3,000 ft^3/min), depending on chamber size. This process usually begins 15 minutes prior to unloading and continues during loading and reloading.[14]

The chamber exhaust is responsible for removing EO from the void space in the sterilizer chamber, not the product. Use of the chamber exhaust assists some facilities in meeting the EO worker exposure levels set by OSHA. Facilities that use conveyors to load and unload the chamber, as well as facilities that do not have problems meeting OSHA worker exposure levels, may not use chamber exhausts.

3.2.1.3.6 Aeration. After the last air wash, the sterile products are placed in an aeration room and kept there for several hours to days depending on the product. The purpose of aeration is to allow further diffusion of residual EO from the products prior to shipping in order to comply with the FDA and EPA residual EO guidelines. Ethylene oxide concentrations in the aeration room are maintained at relatively low levels by ventilating the room at a rate of about 20 air changes per hour.

Recent information from industry contacts indicates that some commercial sterilization facilities are aerating some or all of the sterile products in heated enclosed aeration units. In comparison to traditional warehouse-type aeration rooms, these units are smaller in volume (<70 m^3 [2500 ft^3]) with much lower ventilation rates. Consequently, the EO concentrations are usually higher than the 1 ppmv OSHA standard. However, worker exposure is reduced by not opening the door until the EO concentration drops and by limiting the frequency of opening the aeration room door. The main purpose of this type of aeration process is to increase the diffusion rate of EO out of the sterile product (by increasing the temperature) and, thus, reduce the aeration time.

Facilities that sterilize products infrequently may aerate in the sterilization chamber. Two basic chamber aeration processes are used. The first process involves cycling the chamber between atmospheric pressure and a slight vacuum pressure (i.e., a pressure of about 94 kPa [13.7 psia]) several times over a 12- to 24-hour period. The length of these cycles depends on the chamber size and vacuum pump capacity. The second process involves drawing an extreme vacuum (about 0.6 kPa [0.1 psia]) in the chamber and holding the vacuum for 24 to 48 hours.

Some commercial sterilization facilities with small sterilizers (less than 1 m^3 [40 ft^3]) use aeration chambers (or cabinets), which are similar to the sterilization chambers in size and design. These facilities typically aerate products for about 24 hours.

3.2.2 Single-Item Sterilization System

Four of the 196 commercial sterilization facilities represented in the 1989 EPA CS data base (2 percent) reported the use of a single-item sterilization system.[1,2] Three of these facilities use the Sterijet® system manufactured by H. W. Andersen Products; one facility uses another patented system that is similar to the Sterijet® system.[2] In contrast to the bulk sterilization chambers used by most commercial sterilization facilities, these systems are designed to sterilize

small individual items (such as medical equipment supplies) in sealed pouches. Marketing of these systems is primarily focused on hospital sterilization.[15]

These single-item sterilization systems consist of (1) a machine that delivers the sterilant gas through a nozzle, (2) flexible plastic pouches, and (3) an aeration cabinet. The process involves the following steps. The product to be sterilized is placed in a plastic pouch. With the open ends of the pouch sealed around the nozzle, a slight vacuum is drawn in the pouch followed by injection of a premeasured quantity of sterilant gas. The amount of sterilant gas injected depends on the size of the pouch. After the gas is injected, the nozzle is automatically withdrawn, and the pouch is heat sealed. The sealed pouches are placed directly into an aeration cabinet or temperature-controlled aeration room. The enclosed product is sterilized prior to the escape of the gas through the pouch, which is designed to retain the EO long enough to ensure proper sterilization. The products are sterilized for approximately 12 hours at about 50°C (122°F) and aerated for 36 hours.[15]

Another type of single item sterilization system consists of (1) ampule-delivered EO sterilant gas, (2) flexible plastic pouches, (3) a sterilization cabinet, and (4) an optional aeration cabinet.[16] This process involves the following steps. The product to be sterilized is wrapped in gas permeable packaging and placed in a plastic pouch along with an ampule containing the sterilant gas. The pouch is placed in the sterilization cabinet, and the ampule is broken to release the sterilant gas. The pouch is then sealed, and the cabinet closed to allow sufficient time for sterilization of the materials. After the sterilization cycle is complete, the cabinet door and plastic pouch are opened, and the materials are unloaded. Depending on the characteristics of the materials sterilized, they may be placed in an aeration cabinet to allow for the offgassing of residual EO. The products are typically sterilized for approximately 12 hours at room temperature and atmospheric

pressure, and aerated for approximately 12 hours at 50°C (122°F) at atmospheric pressure (if an aeration cabinet is used).[16]

At least one vendor does offer an optional or retrofit ventilation hood to control worker exposure to EO when loading/unloading the sterilizer, and while sterilization occurs. This device causes fresh air to be pulled past the chamber by a roof-mounted blower; however, this system does not provide any evacuation of the sterilization cabinet itself.[16]

3.2.3 Spice Fumigators

The process for spice fumigators is essentially the same as bulk sterilization.[17] The spices are typically stored in fiber drums lined with a plastic insert, which is closed with twist tie; lids are then placed on the drums. Alternatively, the spices may be stored in large bags or totes. The drums, bags, or totes are loaded into the sterilization chamber on wooden pallets, typically via a conveyor. Depending on how densely packed the spice is, a long, hollow spike punctured with many holes may be driven into the spice to allow the EO to penetrate through the bag drum, or tote. Ethylene oxide is then added to the chamber. The length of the sterilization cycle depends on the product's susceptibility to adequate kill rates. Ethylene oxide's effectiveness is different for different spices. Following evacuation of the sterilization chamber, and subsequent air washes, the spices are removed from the sterilization chamber and placed in an aeration room. Aeration typically takes 2 hours.[17]

3.2.4 Library and Museum Fumigators

Library and museum fumigation is accomplished using essentially the same process as for bulk sterilization. However, the amount of ethylene oxide used each year by these facilities is much lower than that used by the typical bulk sterilizers. These library and museum fumigators are typically operated only one to two times a month.[18-21] Additionally, several museums and libraries are discontinuing their use of ethylene oxide for fumigation because of (1) the recent OSHA worker exposure regulations and (2) problems associated with the long aeration

times needed when fumigating organic materials with EO (most museums and libraries do not have the space needed for adequate aeration of organic materials, such as wood [up to 1 month], because these materials readily absorb much of the EO used in the fumigation process).[22-24] Some museums have switched to using sulfuryl fluoride as a fumigant.[22,23] Other museums are accepting objects from other museums and libraries to be fumigated with EO in their fumigator.[25]

3.2.5 Beehive Fumigators

The process for beehive fumigators is essentially the same as bulk sterilization; however, a unique feature of the fumigators warrants a separate discussion. Whereas the sterilization processes described above are performed at one location, the eight State departments of agriculture represented in the EPA sterilization data base use portable chambers to fumigate beehives at numerous and variable locations in each of the six States.[2] The State departments of agriculture use an EO/CO_2 sterilant gas mixture. Typically, a garden hose is connected to the fumigation chamber and is placed along the ground for venting the sterilant gas during the evacuation phase of the sterilization cycle. After the evacuation, the beehive is removed from the chamber and aerated in the open air.

3.3 EMISSION SOURCES

The four principal sources of EO emissions from sterilization/fumigation processes are (1) the sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator), (2) the sterilization chamber vacuum pump drain (assuming that a once-through, water-ring vacuum pump is used), (3) the chamber exhaust vent(s), and (4) the aeration room vent(s). A schematic of these emission sources is shown in Figure 3-4. Other potential emission sources are equipment leaks and storage and handling. (For the purposes of developing emission estimates, and because bulk sterilization processes are the main source of emissions, emission sources were assumed to be the same for all stationary sterilization processes [i.e., bulk and single-item and the 55-gallon drums]).

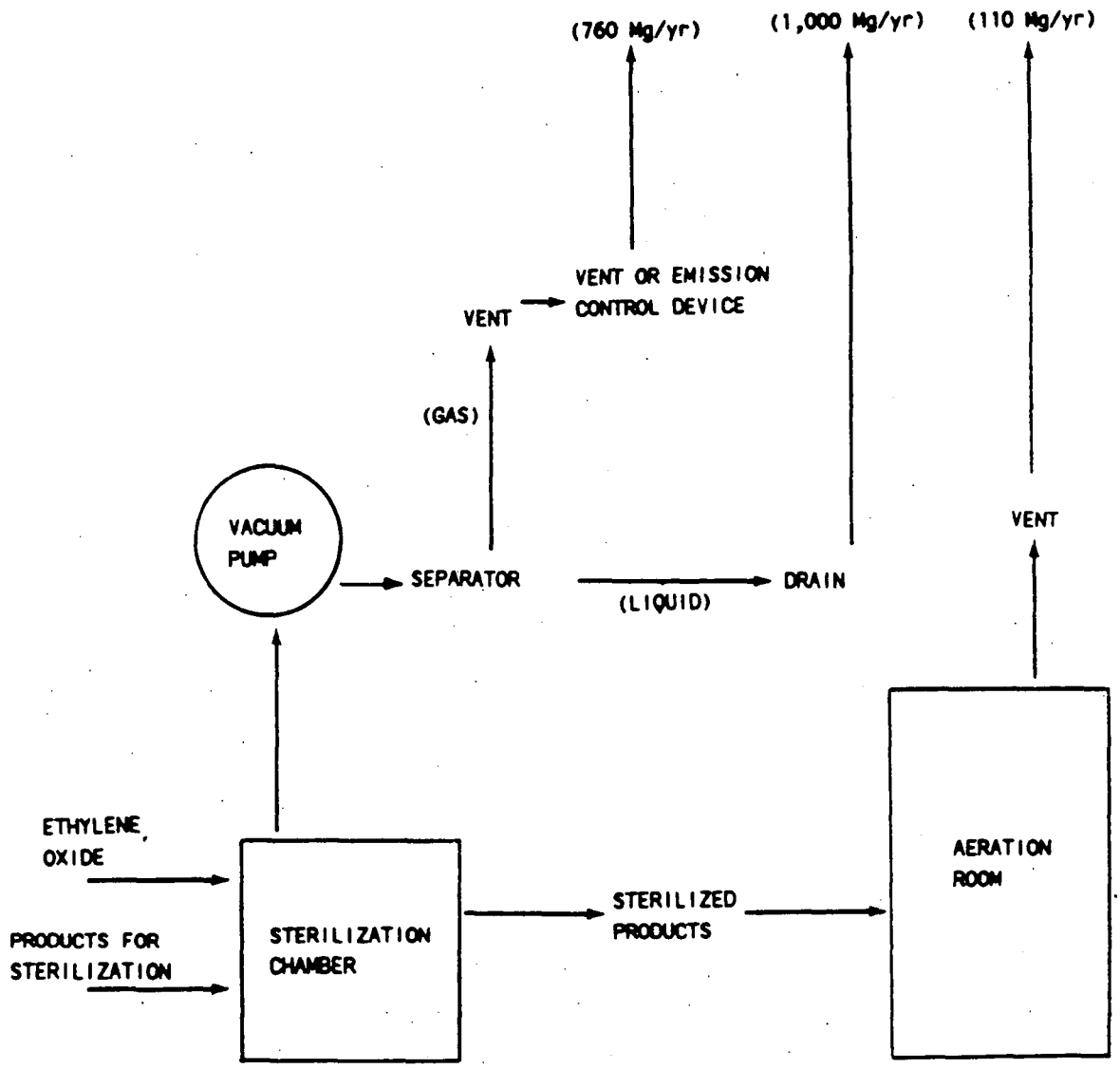

Figure 3-4. Schematic of emission sources at commercial sterilization facilities.

3.3.1 Sterilization Chamber Vents

Sterilization chamber vent emissions are dependent on the type of vacuum pump used to evacuate the sterilizer. Once-through, liquid-ring design vacuum pumps that use water as the working fluid discharge a mixture of chamber gas and water to a centrifugal gas/liquid separator. In the separator, gaseous EO is directed to a vent and emitted to the atmosphere. The liquids from the separator are discharged to a drain. (Full-sealant recovery [i.e., oil-sealed or recirculating water] vacuum pumps do not produce drain emissions of EO.) Sterilizer vent emissions also include emissions associated with venting the chamber from a positive pressure before evacuating with a vacuum pump.

3.3.2 Sterilization Chamber Vacuum Pump Drains

If a once-through, water-ring vacuum pump is used to evacuate the chamber, some of the EO evacuated from the chamber enters the liquid-phase separator line with the vacuum pump water. Although some EO may be hydrolyzed to ethylene glycol, the conversion rate at ambient temperatures is extremely slow, requiring weeks for completion (see Figure 3-5).[8] Also, EO is rapidly released from an aqueous solution when agitated.[26] Therefore, virtually all of the EO that dissolves in the vacuum pump water is emitted from the water. The absorbed EO may be released at the 1-inch air break between the liquid pipe and drain (required by local plumbing codes) or may diffuse into other areas of the building as the water passes through the drain system. Any remaining EO would desorb into the head space of the sewer pipes (possibly creating flammable mixtures with air) and be emitted as it passes through the sewer or waste treatment systems.[6,8]

3.3.3 Chamber Exhaust Vent

Chamber exhaust emissions consist of EO that remains in the sterilizer chamber void space (surrounding the product) after the sterilization cycle is completed. Product off-gassing in the sterilizer is a negligible contributor to this emission source.[27] Therefore, the chamber exhaust emissions are assumed to be only EO trapped in the sterilizer void space.

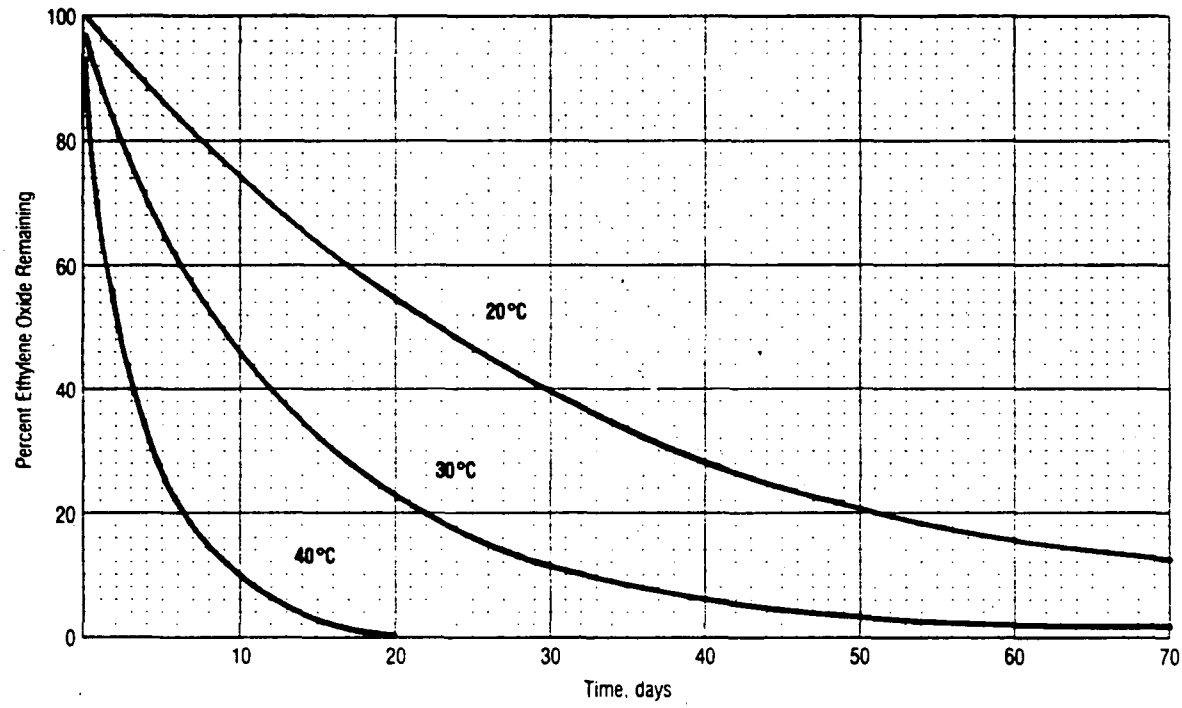

Figure 3-5. Hydrolysis rates of dilute, neutral aqueous solutions of ethylene oxide. (Courtesy of Union Carbide Corporation, Ethylene Oxide/Glycol Division.)[8]

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3.3.4 Aeration Room Vent

All emissions from residual EO in the product are referred to as aeration room vent emissions. As residual EO diffuses out of the sterile products in the aeration room or is emitted to the sterilization room when the chamber door is opened, it is emitted to the atmosphere via room ventilation. High ventilation airflow rates are used to maintain EO concentrations below the OSHA limit.

3.3.5 Equipment Leaks

Although equipment component counts (number of flanges, valves, etc.) were not obtained for the commercial sterilization facilities, observations made during site visits indicated that the number of components is small. However, control of equipment leaks may be important to meet the 1 ppmv OSHA standard. For the purposes of this analysis, equipment leak emissions are assumed to be negligible.

3.3.6 Storage and Handling

Ethylene oxide at commercial sterilization facilities is typically stored in pressurized cylinders rather than bulk containers. Therefore, material losses associated with loading and unloading bulk quantities of EO and storage tank breathing losses would not occur. Although bulk storage of sterilant gas at sterilization facilities is rare, at least one commercial sterilization facility stores bulk quantities of 12/88 in a pressure vessel. During transfer of the 12/88 from the tank truck to the pressure vessel, the vessel and the tank truck are vapor balanced. Therefore, emissions during transfer are expected to be negligible. Also, because the storage tank is a pressure vessel, no emissions should occur during routine operation. Consequently, commercial sterilization facilities are likely to have negligible storage and handling emissions.

3.4 EMISSION ESTIMATES

3.4.1 Commercial Sterilization Facilities

The emission estimate for commercial sterilization facilities is based on the facility-specific annual EO usages and emission control levels reported in the 196 responses to the HIMA survey, the 1986 EPA ICR, and the July 1989 Section 114

letter.[1,2] Eight of the 196 facilities are State departments of agriculture that operate a total of 10 mobile beehive fumigator units; these units are not included in these or subsequent analyses unless otherwise stated. (These 10 fumigation units use a total of 0.46 megagrams per year (Mg/yr) (1,015 pounds per year [lb/yr]) of EO, all of which is reportedly uncontrolled.) Average EO emissions from the remaining 188 commercial sterilization facilities, based on total sterilizer volume, are presented in Table 3-6. The total amount of EO used by these 188 commercial sterilization facilities is 1,920 Mg/yr (4.23 million lb/yr); approximately 42 percent (i.e., 809 Mg/yr [1.78 million lb/yr]) of this amount is controlled. Therefore, the EO emission estimate for the 188 facilities represented in the 1989 EPA CS data base is 1,111 Mg/yr (2.45 million lb/yr).[1-4] Of this amount, it is estimated that 667 Mg/yr (1.47 million lb/yr) are emitted from sterilizer vents; 312 Mg/yr (688,000 lb/yr) are emitted from sterilization chamber vacuum pump drains; 38 Mg/yr (84,000 lb/yr) are emitted from chamber exhaust vents; and 57 Mg/yr (126,000 lb/yr) are emitted from aeration room vents (see Figure 3-4). These estimates were developed using the HIMA survey, the EPA ICR responses, the Section 114 letter (July 1988 and July 1989) responses, and the following assumptions:

1. All of the EO used in the sterilization process is evacuated from the sterilization chamber or released from the product during postevacuation processes.

2. Within each facility, EO emissions are distributed among four emission points. The four emission points and the percentage of total EO emissions allocated to each are:

a. Sterilizer vent(s)--50 percent;

b. Sterilization chamber vacuum pump drain (if applicable)--45 percent;

c. Chamber exhaust vent(s)--2 percent; and

d. Aeration room vent(s)--3 percent.

This 50/45/2/3-percent split is based on industry estimates, limited test data, and engineering judgment.[28,29]

TABLE 3-6. AVERAGE EMISSIONS FROM COMMERCIAL STERILIZATION FACILITIES--EPA COMMERCIAL STERILIZATION DATA BASE[1-4]

Total chamber volume at facility, m^3 (ft^3)	No. of facilities	Mean EO use, kg/yr (lb/yr)	Mean EO emissions, kg/yr (lb/yr)[a] [b]
<11 (<400)	87	580 (1,300)	520 (1,200)
11-56 (400-2,000)	71	6,500 (14,000)	4,200 (9,300)
>56 (>2,000)	38	37,000 (82,000)	20,000 (45,000)

[a]Mean emissions are less than mean EO use because of existing controls.
[b]Emissions from all sources (i.e., sterilizer vent, vacuum pump drain, aeration).

3. For the uncontrolled sterilization chambers, all of the EO that enters the chamber (except 3 percent, if the aeration room is controlled) is released to the atmosphere. For the 79 sterilization chambers with emission control devices, the chamber vent emissions are assumed to be controlled at the following efficiencies:

a. 99.0 percent for acid/water scrubbers and catalytic oxidizers;

b. 99.0 percent for flares (given the chemical/ physical characteristics of ethylene oxide, its high combustability, and the extremely weak nature of the oxide bond, it is reasonable to assume that emissions of ethylene oxide will be controlled at an efficiency of 99 percent in flares rather than the generally EPA-accepted efficiency for flares of 98 percent); and

c. The facility-reported efficiency for other control devices.

4. All facilities that control sterilizer vent emissions with acid/water scrubbing, catalytic oxidation, flaring, or condensation/ reclamation control devices are assumed to have recirculating-fluid vacuum pumps and, thus, no drain emissions from those chambers. (One facility that uses a different control technology than those described above is assumed to have a once-through water-sealed pump). All uncontrolled facilities are assumed to have once-through water-sealed pumps unless data are available to indicate otherwise.

5. At facilities that have once-through water-sealed vacuum pumps, all of the EO that dissolves in the vacuum pump water subsequently enters the drain and is assumed to be emitted uncontrolled to the atmosphere at an outdoor ground-level drain near the facility. This assumption is consistent with test data that suggest EO is rapidly released from an aqueous solution when agitated.[26]

6. Facilities that have a total sterilizer volume greater than 7 m^3 (>250 ft^3) are assumed to have chamber exhausts on all sterilizers. Chamber exhaust emissions are assumed to equal

2 percent of the total EO use and to be released uncontrolled to the atmosphere.[29]

7. At each facility (except for three facilities that have aeration room controls), all of the EO that enters the aeration room(s) vent is released uncontrolled to the atmosphere.

3.5 CURRENT REGULATIONS

3.5.1 Occupational Safety and Health Administration Standard

In 1984, OSHA established a permissible exposure limit for occupational exposure to EO of 1 ppmv determined as an 8-hour time-weighted average (TWA) concentration. In addition, an action level of 0.5 ppmv as an 8-hour TWA was established as the level above which employers must monitor employee exposure.[30] In April 1988, OSHA established a short-term excursion limit (EL) for occupational exposure to EO emissions of 5 ppmv averaged over a 15-minute sampling period.[31]

3.5.2 State Regulations

Existing State regulations for EO are summarized in Table 3-7. Several States are currently regulating EO or developing air toxics programs.[32-38]

TABLE 3-7. STATE REGULATIONS FOR ETHYLENE OXIDE EMISSIONS[22-28]

State	Regulatory description
California[a]	• Control is based on annual EO usage

Annual usage, lb	Sterilizer control	Aeration control
<25	No control	No control
25-600	99%	No control
600-5,000	99.9%	95%
>5,000	99.9%	99%

State	Regulatory description
Colorado	• Regulate as a volatile organic compound (VOC).
	• Reasonably available control technology (RACT) required for new sources.
Connecticut	• Best available control technology (BACT) required for all new or modified sources exceeding a maximum allowable stack concentration (MASC).
	• MASC is calculated using exhaust gas flow rate, stack height, and the distance from the discharge point to the property line. MASC would be exceeded for industrial sterilizers using typical sterilization cycles. Therefore, BACT required on new or modified sources. Existing sources exceeding the maximum allowable ambient concentration of 0.01 ppm have 3 years to comply with orders given by the Connecticut Department of Environmental Protection.
Florida[a]	• Maximum risk level of 10^{-6} for new or modified sources.
Michigan[a]	• BACT for all new sources. Requires emissions be indectable or subjected to risk analysis (maximum allowable risk level is 10^{-6}). For industrial sterilizers using typical sterilization cycles, a control efficiency based on a risk assessment analysis would be greater than 99 percent by weight.
Missouri	• Regulate as a VOC.
New Jersey	• Regulate as a VOC.
	• BACT required for new or modified sources.
New York[b]	• New or modified sources must receive 99 percent control or greater, or BACT (also at permit reviews)
	• Maximum annual impact must not exceed guideline Acceptable Ambient Level (AAL) of 6.67 $\mu g/m^3$ (a revised AAL of 0.019 $\mu g/m^3$ is anticipated for the next edition of Air Guide-1 [to be released by 01/90].
	• Certificate of operation includes the following statement: "Should significant new scientific evidence from a recognized institution result in the decision by DEC that lower ambient levels must be established, it may be necessary to reduce emissions from this source prior to the expiration of this Certification of Operation."
Oklahoma	• Maximum ambient air concentration at property line is 1/100 of TLV.
Puerto Rico	• Regulate as a VOC.
	• Emission controls required for emissions greater than 3 lb/h or 15 lb/d.
Rhode Island[b]	• Maximum risk level of 10^{-6} for new and existing sources.
	• If BACT is used, may consider 10^{-5} risk level.
Tennessee	• Regulate under standards for process and nonprocess emissions.
Texas	• BACT required for all new sources.
Utah	• BACT required for all new or modified sources. BACT requirements to go into effect for existing sources.
	• Following the programs developed in New York.
Vermont	• Regulate as a VOC.
Virginia	• For any 24-hour concentration exceeding 1/100 of the TLV-TWA both existing and new facilities are required to control emissions as directed by the Virginia Air Pollution Control Board.
Wyoming	• BACT required for all new sources.
	• Controls must meet AAL at property line.

[a]Information obtained from State contacts in May 1990.
[b]Information obtained from State contacts in February 1989. All other information is from 1986 through 1987 data.

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4.0 EMISSION CONTROL TECHNIQUES

This chapter describes the techniques available to control ethylene oxide (EO) emissions from bulk sterilization and single-item sterilization processes. Alternatives to EO sterilization, retrofit considerations, and the impacts of chlorofluorocarbon (CFC) regulation on EO emission controls are also discussed.

4.1 BULK STERILIZATION PROCESSES

Discussed below are techniques available to control emissions of ethylene oxide (EO) from the four principal sources of emissions from bulk sterilization processes:

1. The sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
2. The sterilization chamber vacuum pump drain;
3. The chamber exhaust vent; and
4. The aeration room vent.

4.1.1 Sterilization Chamber Vent Emissions

Three primary techniques are used to control EO emissions from sterilizer vents: hydrolysis, oxidation, and condensation. Ethylene oxide is catalytically hydrolyzed to form ethylene glycol; thermal or catalytic oxidation decomposes EO into carbon dioxide and water; and condensation allows the recovery of the sterilant gas mixture. A fourth control technique for sterilizer vents is a gas/solid reactor system that chemically reacts with EO and binds it to the solid packing of the reactor.[1]

Table 4-1 shows the emission control techniques and devices for sterilizer vent emissions used by the controlled facilities represented in the EPA data base (refer to Chapter 3 for a description of the contents and origin of the data base). Forty of the 188 commercial sterilization facilities (21 percent) in

TABLE 4-1. ETHYLENE OXIDE EMISSION CONTROL DEVICES FOR STERILIZER VENTS--EPA COMMERCIAL STERILIZATION DATA BASE[2,3,5]

Emission control technique and device	Control efficiency, (percent)[a]	No. of facilities (percent)	No. of chambers (percent)	Cumulative chamber size, m^3 (ft^3)	EO usage/facility, Mg/yr (lb/yr)
Hydrolysis					
Packed scrubber	99.0[b]	21 (11)	78 (19)	7 - 274 (350 - 9,900)	0.8 - 84 (1,800 - 180,000)
Reaction/detoxification tower	99.0[b]	7 (4)	15(4)	8 - 45 (300 - 1,600)	2.1 - 49 (5,000 - 110,000)
Caustic scrubber	50	1 (0.5)	2 (0.5)	9 (320)	0.2 (400)
Oxidation					
Flare	98.0[c]	3 (2)	6 (1.5)	11 - 229 (400 - 8,180)	25 - 90 (54,000 - 197,000)
Catalytic oxidizer	99.0	2 (1)	2 (0.5)	4 - 18 (130 - 660)	0.5 - 7 (1,000 - 15,000)
Condensation					
Condensation/ reclamation system	50.0 - 83.0	6 (3)	16 (4)	32 - 132 (1,160 - 4,720)	7 - 127 (15,000 - 280,000)
Total		40 (21)[d]	119 (29)[e]		1,020 (2,240,000)[f]

[a]Control efficiencies are those reported by the 188 commercial sterilization facilities represented in the EPA data base and are not necessarily supported by EPA-sponsored test data.

[b]Although the 21 commercial sterilization facilities that use scrubbers reported control efficiencies ranging from 96.0 to 99.9 percent, a detailed review of the available test data for acid-water scrubbers indicates that 99.0 percent is the maximum removal efficiency that can be achieved on a continuous basis.[16]

[c]Although the two commercial sterilization facilities that use flares reported destruction efficiencies of 99.0 and 99.7 percent, the EPA's position is that flares operated within specified conditions of waste gas heat content and flare exit velocity will achieve at least 98 percent destruction efficiency.[25]

[d]Total number of facilities = 188.

[e]Total number of chambers = 404.

[f]Represents 53 percent of the total EO used by the 188 commercial sterilization facilities represented in the EPA data base.

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the data base reported the use of a control device for sterilizer vent emissions. Twenty-eight of these 40 facilities use one emission control device for multiple chambers by manifolding the chamber vents and staggering the evacuation of the sterilant gas from the chambers. The remaining 12 facilities control emissions from single chambers.[2-5]

Nine additional commercial sterilization facilities reported the use of a neutral-water scrubber to control EO vent emissions. Neutral-water scrubbers reduce EO vent emissions by "washing" a portion of the EO to the drain (facilities reported 20 to 100 percent of the total EO emissions from the sterilizer chamber were "controlled" by a neutral-water scrubber).[2-5] Some of the EO that is washed to the drain may be converted by hydrolysis to ethylene glycol; however, the conversion rate of EO to ethylene glycol in neutral water at ambient temperatures is extremely slow, requiring weeks for completion.[6] Since EO is rapidly released from an aqueous solution when agitated, the vast majority of the EO washed to the drain is expected to off-gas uncontrolled from the air break in the drain line, sewer lines, or the waste water treatment system.[6-8] Because the use of neutral-water scrubbers merely changes the EO emission source, these scrubbers are not discussed here as a control technique.

4.1.1.1 <u>Hydrolysis</u>. Hydrolysis is the most common EO emission control technique used by commercial sterilization facilities.[2-5] This technique is applicable for both pure EO and EO/inert gas mixtures such as 12/88 (12 percent by weight EO and 88 percent by weight dichlorodifluoromethane [CFC-12]) and 10/90 (10 percent by weight EO and 90 percent by weight carbon dioxide [CO_2]).

Ethylene oxide can be hydrolyzed under relatively mild conditions to ethylene glycol products (without affecting the inert gas) as shown in the following reaction:

$$C_2H_4O + H_2O \xrightarrow[H+ \text{ or } OH-]{} HOCH_2CH_2OH + HO(CH_2CH_2)_nOH$$

Ethylene oxide	Ethylene glycol	Polyethylene glycols

Ethylene oxide will hydrolyze in neutral water, but this reaction is very slow. (The half-life of EO in neutral water at ambient temperatures is approximately 14 days.)[8] The reaction rate is increased in an acidic or basic solution. The reaction is approximately two orders of magnitude faster under acidic conditions than under basic conditions, making acid hydrolysis the preferred method. Twenty-eight of the 188 commercial sterilization facilities represented in the EPA data base reported using acid-water scrubbers; one facility reported using caustic scrubbers to control EO emissions.[2-5]

4.1.1.1.1 Packed scrubbers. Figure 4-1 is a schematic of a packed scrubbing system used to control EO emissions. The system consists of a countercurrent packed tower, a reaction vessel, and a holding tank. In the countercurrent tower, the sterilant gas is contacted with an acidic water solution, generally aqueous sulfuric acid. Because EO is extremely water soluble, most of the EO is absorbed into the scrubber liquor. Next, the liquor is sent to the reactor vessel, which is a small storage tank operated at atmospheric pressure, to complete the hydrolysis of EO. After the reaction is complete, the liquor is sent to the storage vessel. The liquor in the storage vessel is recirculated to operate the tower until the concentration of the ethylene glycol in the liquor reaches a predetermined weight percentage, past which point the scrubber efficiency declines. Manufacturers of packed scrubbing systems suggest that the scrubbing liquor is spent when the solution is 30 to 40 percent by weight ethylene glycol.[9,10] Possible methods of determining when the liquor needs replacing include liquid level indicators or specific gravity detectors in the tank. (Both parameters increase as the amount of ethylene glycol increases.) Alternatively, the amount of EO charged to the sterilizer can be used to determine the liquor changeout point. The spent solution is neutralized and

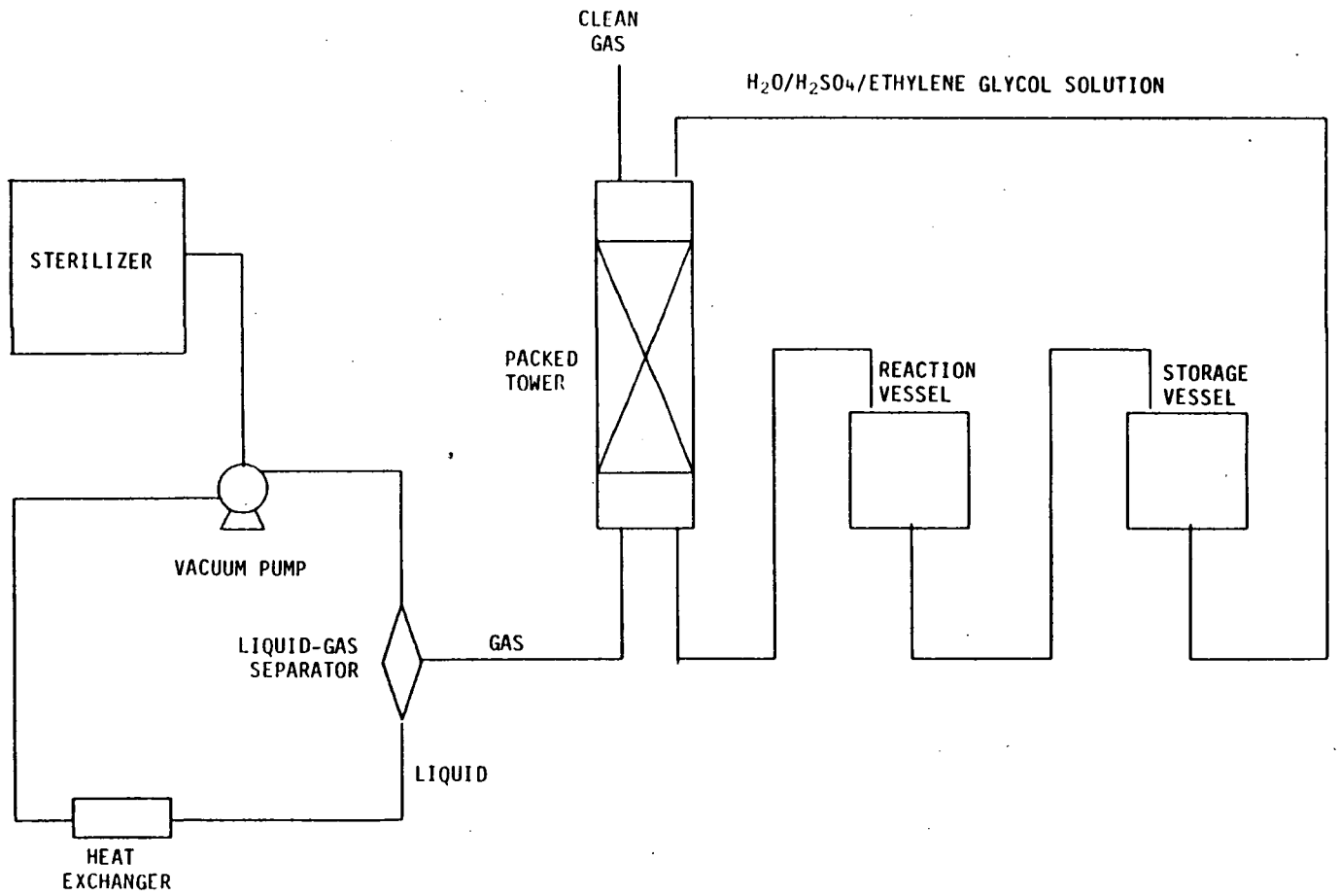

Figure 4-1. Countercurrent packed scrubbing system.

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then disposed or sold. (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Generally, sodium hydroxide is used to neutralize the glycol solution; sodium carbonate can also be used.

Countercurrent packed scrubbers are used by commercial sterilization facilities with sterilizers ranging from 1.1 cubic meters (m^3) (40 cubic feet [ft^3]) to 170 m^3 (6,000 ft^3). Ethylene oxide use at these commercial sterilization facilities ranges from 0.8 megagrams per year (Mg/yr) (2,000 pounds per year [lb/yr]) to 84 Mg/yr (180,000 lb/yr).[2,3,5]

Manufacturers of countercurrent packed scrubbers designed to control EO emissions from sterilizer vents claim EO removal efficiencies greater than 99 percent.[1,9,11] For a 12/88 sterilant-gas mixture, the average EO removal efficiency for three tests was 99.0 percent by weight (individual test results were 99.0, 98.7, and 99.4 percent).[12] These tests were conducted using a scrubber that was designed to achieve an EO removal efficiency of 99 percent. A representative from the manufacturer of the tested acid-water scrubber stated that the company can design scrubbers to achieve virtually any EO removal efficiency with any type of sterilant gas.[13] The results of an EPA-sponsored test on another acid-water scrubber designed by this company indicated an EO removal efficiency greater than 99.9 percent for 12/88.[14] For pure EO, the EO removal efficiency was greater than 99.98 percent for each of four tests performed at two facilities.[12,15] However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved on a continuous basis based on limited data at various EO concentrations.[16]

4.1.1.1.2 <u>Reaction/detoxification towers</u>. Another acid hydrolysis scrubbing technique for EO emission control is a reaction, or detoxification, tower. A schematic of this system is shown in Figure 4-2. The reaction/detoxification tank holds a sulfuric acid solution of pH 0.5 to 2.5. As the sterilant gas bubbles upward through the acidic liquor, EO is absorbed, and catalytically hydrolyzed to ethylene glycol. The gas stream then

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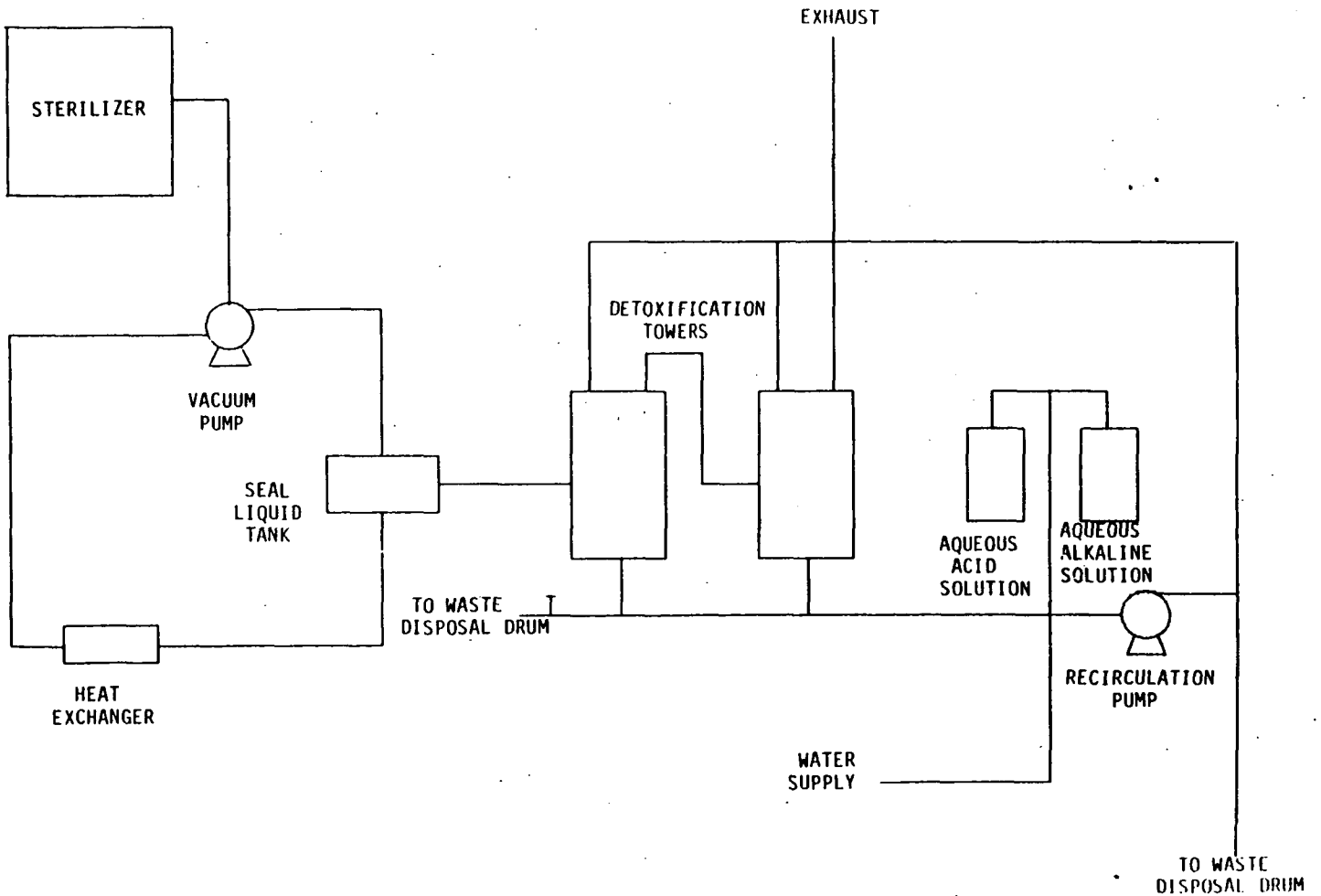

Figure 4-2. Detoxification tower control system.

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flows through the liquid surface and a demister. The demisting pad prevents acid mist from exiting with the scrubbed gas and provides a final hydrolysis reaction site for any EO remaining in the gas stream. Inert gases (i.e., CFC-12 and CO_2) are exhausted unreacted to the atmosphere. After ethylene glycol builds up in the stream to a maximum recommended level of 60 percent, the scrubber liquor is neutralized and disposed or sold.[17] (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Possible methods of determining the scrubbing liquor changeout point include (1) using liquid level indicators, (2) using specific gravity detectors, and (3) measuring the amount of EO charged to the sterilizer. Reaction towers have been installed for chambers ranging from 1.4 m^3 (50 ft^3) to 45 m^3 (1,600 ft^3).[18,19] Seven of the 188 commercial sterilization facilities represented in EPA's data base use reaction towers to control EO emissions from sterilizer vents. The sterilizers at these seven facilities range in volume from 4 m^3 (140 ft^3) to 27 m^3 (960 ft^3). Annual ethylene oxide use at these seven facilities ranges from 2.1 Mg (5,000 lb) to 49 Mg (110,000 lb).[2,3,5]

Manufacturers of reaction/detoxification towers claim 99+ percent EO removal efficiency by weight.[18,20] Third-party laboratory test results indicate that EO emission reductions greater than 99.8 percent can be achieved with reaction towers.[19] However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved by acid hydrolysis techniques on a continuous basis.[16]

4.1.1.1.3 <u>Waste disposal</u>. The spent liquor from acid hydrolysis of EO is typically 40 to 60 weight percent ethylene glycol and has a pH of 0.5 to 2.0. Because of the low pH, the solution is considered a hazardous waste and thus, requires special handling procedures for shipping. However, the spent liquor can easily be neutralized with sodium hydroxide (caustic) prior to disposal. Two recovery companies have been identified that are willing to purchase the aqueous ethylene glycol

solution.[21,22] Both of these companies require that sodium hydroxide be used for neutralization and will pick up the solution at the sterilization facility. A third recovery company will accept the spent scrubbing solution on a no cost/no payment basis, except for shipping charges.[23] Neutralized scrubbing solution may also be disposed to a landfill or incinerator.

4.1.1.2 Oxidation. Two methods of oxidizing EO are (1) thermal oxidation with flares and (2) catalytic oxidation with a solid-phase catalyst.

4.1.1.2.1 Thermal oxidation. Ethylene oxide, which has a high heating value, a relatively low ignition temperature, and a very wide range of mixtures combustible in air (see Table 3-4), can be easily and efficiently destroyed by thermal oxidation using flares. Thermal oxidation of EO produces carbon dioxide and water as follows:

$$2\ C_2H_4O + 5\ O_2 \xrightarrow[\text{thermal oxidation}]{} 4\ CO_2 + 4\ H_2O$$

Three of the 188 commercial sterilization facilities represented in the EPA data base reported using flares to control EO emissions when pure EO was used as a sterilant gas.[2,5] One of these facilities has one 76.7-m^3 (2,710-ft^3) chamber and uses 26 Mg (57,000 lb) of EO per year. Another facility has three chambers ranging in size from 75.2 to 76.9 m^3 (2,655 to 2,715 ft^3) and one smaller 1.7-m^3 (60-ft^3) chamber; this facility uses 89 Mg/yr (197,000 lb/yr) of EO.[2] The third facility has one 11-m^3 (400-ft^3) chamber and uses 25 Mg/yr (54,000 lb/yr) of EO.[5] Because of difficulties with sustaining combustion, commercially available flares are not applicable for facilities emitting only small amounts of EO.

A manufacturer of flare burners for the control of EO emissions claims greater than 99-percent control efficiency for pure EO, but no data were provided to substantiate this claim.[24] The EPA's position is that flares operated within specified

conditions of waste gas heat content and flare exit velocity will achieve at least 98-percent destruction efficiency.[25]

Flares can also be used with EO/CO_2 sterilant gas mixtures (e.g., 10/90) but are not designed for use with EO/CFC-12 mixtures (e.g., 12/88).[24,26] The EPA has not in the past and does not now recommend the use of flares to control emission streams containing halogenated compounds (e.g., CFC-12) because corrosive or toxic byproducts may form. As shown below, thermal oxidation of CFC-12 may produce the following corrosive or toxic byproducts at the high temperatures (400° to 800°C [800° to 1500°F]) associated with the use of flares:

$$CF_2Cl_2 + O_2 \xrightarrow{\text{thermal oxidation}} \begin{array}{ll} COCl_2 & \text{Phosgene} \\ COF_2 & \text{Carbonyl fluoride} \\ HCl & \text{Hydrogen chloride} \\ HF & \text{Hydrogen fluoride} \\ CF_4 & \text{Carbon tetrafluoride} \\ Cl_2 & \text{Chlorine} \\ CO & \text{Carbon monoxide} \end{array}$$

CFC-12

4.1.1.2.2 Catalytic oxidation. Catalytic oxidation of EO occurs in the presence of a solid-phase catalyst as follows:

$$2\ C_2H_4O + 5\ O_2 \xrightarrow[\text{catalytic oxidation}]{} 4\ CO_2 + 4\ H_2O$$

This control technique is applicable to pure EO, EO/CO_2 mixtures, and EO/CFC-12 mixtures. The CFC-12 does not react at the temperatures (150° to 180°C [300° to 350°F]) that occur during catalytic oxidation, and, therefore, the toxic CFC byproducts that result from the higher temperatures associated with thermal oxidation are not produced. During an EPA-sponsored test of a catalytic oxidation unit, no CFC decomposition byproducts were detected; the detection limit was 200 parts per billion (ppb) for the analyte chloride ion. The maximum operating temperature of the unit during testing was 155°C (311°F).[27]

A schematic of a catalytic oxidizer is shown in Figure 4-3. The spent sterilizer gas is first mixed with a large volume of air to reduce the control device inlet EO concentration to 5,000 parts per million by volume (ppmv) or less. This dilution

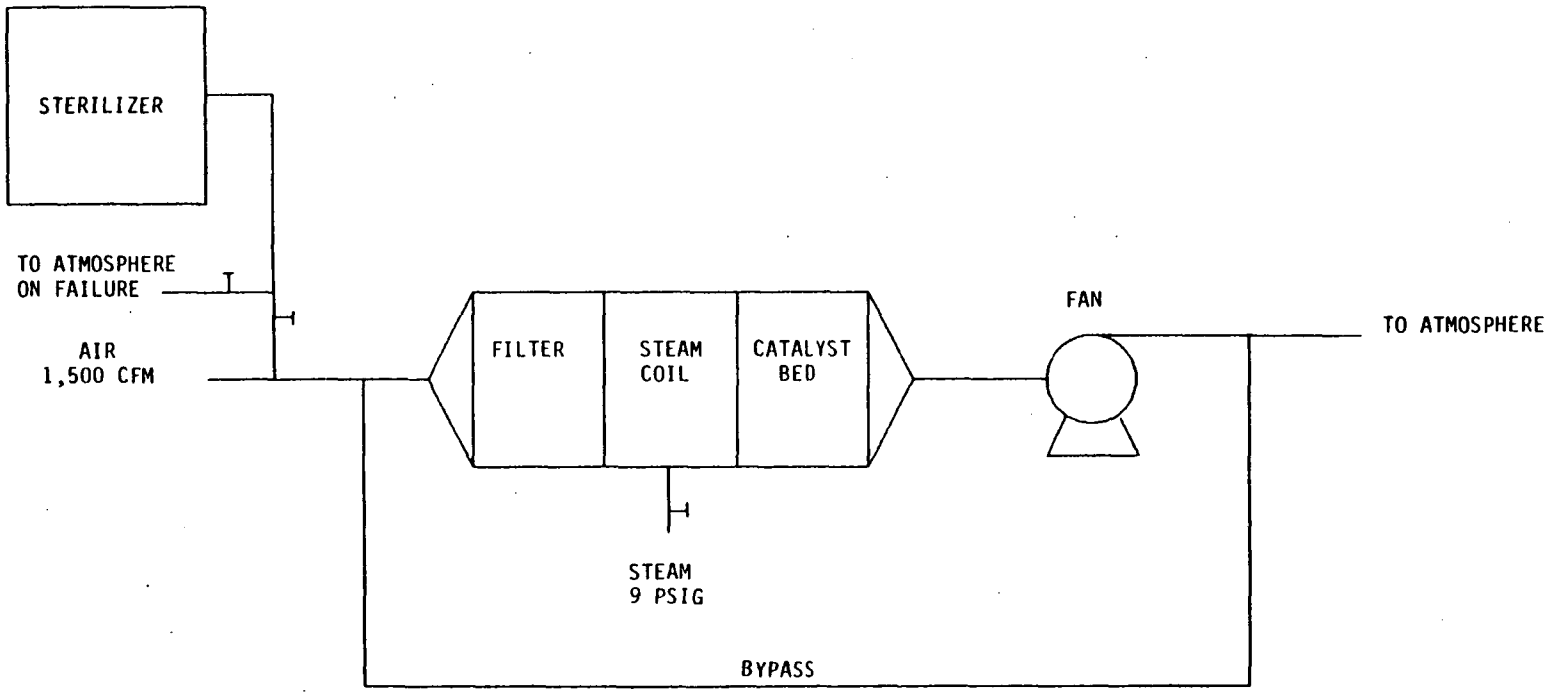

Figure 4-3. Catalytic oxidation system.

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prevents excessive catalyst bed temperatures (which can damage the catalyst) from occurring during the oxidation of EO. The gas stream passes through a filter for dust removal and then is preheated to the reaction temperature with steam or electricity. The gas then enters the catalyst bed(s), where the EO is oxidized. Part of the exiting gas stream may be recycled for heat recovery before being vented to the atmosphere. One manufacturer also sells a catalytic oxidizer that uses excess catalyst, instead of diluent air, to absorb the heat of oxidation.[28] Because of cost considerations, the excess-catalyst system has been used, thus far, only for chambers less than 1 m^3 [40 ft^3]) in volume.[28]

Two of the 188 commercial sterilization facilities represented in the EPA data base reported the use of a catalytic oxidizer to control EO emissions from the chamber vent.[2,4] One facility has one 4-m^3 (130-ft^3) chamber and uses 0.5 Mg/yr (1,000 lb/yr) of EO in an EO/CO_2 sterilant-gas mixture.[2] The other facility has an 18-m^3 (600-ft^3) sterilizer and uses 7 Mg (15,000 lb) of EO annually; the EO concentration to the control unit at this facility is regulated by throttles.[4]

Because catalytic oxidation is applicable to the control of low EO concentrations, facilities can manifold other EO emission sources (e.g., aeration chambers or rooms, sterilizer hood and door vent, and the gas cylinder room) to the control device. In addition, if the catalytic oxidizer requires diluent air, these low-concentration emission sources can provide part or all of the necessary diluent.

Manufacturers of catalytic oxidation units claim EO destruction efficiencies greater than 99.9 percent.[29,30] Third-party testing and an EPA-sponsored test support these claims for small (<0.85 m^3 [<30 ft^3]) sterilizers.[27,29]

4.1.1.3 Condensation/Reclamation Systems. Recovery of sterilant gas mixtures is possible using a reclamation system. The sterilant gas mixtures will condense under conditions of

reduced temperature and increased pressure, but precautions are necessary to avoid explosions.

Figure 4-4 is a schematic of a condensation/reclamation system for a 12/88 sterilant-gas mixture. (See Table 3-4 for physical and chemical properties of CFC-12.) After each sterilization cycle, the 12/88 gas is withdrawn and passed through one of the two desiccant beds next to the chamber. (One of the desiccant beds is regenerated while the other is in use.) The dried 12/88 gas then passes to a compressor where it is compressed to 345 kilopascals (65 psia) to improve condensation efficiency.[31] The compressed gas is piped to a separate explosion-proof room, where it passes through a pressurized condenser that is chilled by ethylene glycol to about -18°C (0°F).[31] The liquid 12/88 mixture is collected in a pressurized, chilled holding tank. The noncondensed gas is recirculated to the chamber and back through the condenser. The liquid collected in the holding tank is transferred to a pressurized reblending tank where the liquid is mixed and its composition determined by infrared analysis. The liquid is then adjusted to the 12/88 (weight percent) ratio by adding the necessary amount of EO or CFC-12. When the correct ratio is obtained, the liquid is transferred to a pressurized storage tank in the chamber room.[31]

Although the reclamation cycle could be continued indefinitely, the amount of EO recovered declines to the point where it is not cost effective to continue the reclamation cycle after about three passes through the system (i.e., typically 60 to 90 minutes). The majority of the EO (80 to 85 percent) is recovered during this time. Also, increasing the reclamation time would require that products spend additional time in the sterilizer and could affect the plant's operating schedule. However, even if the reclamation time was increased, this system is not designed for low EO concentrations. Therefore, if this type of control system is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete.

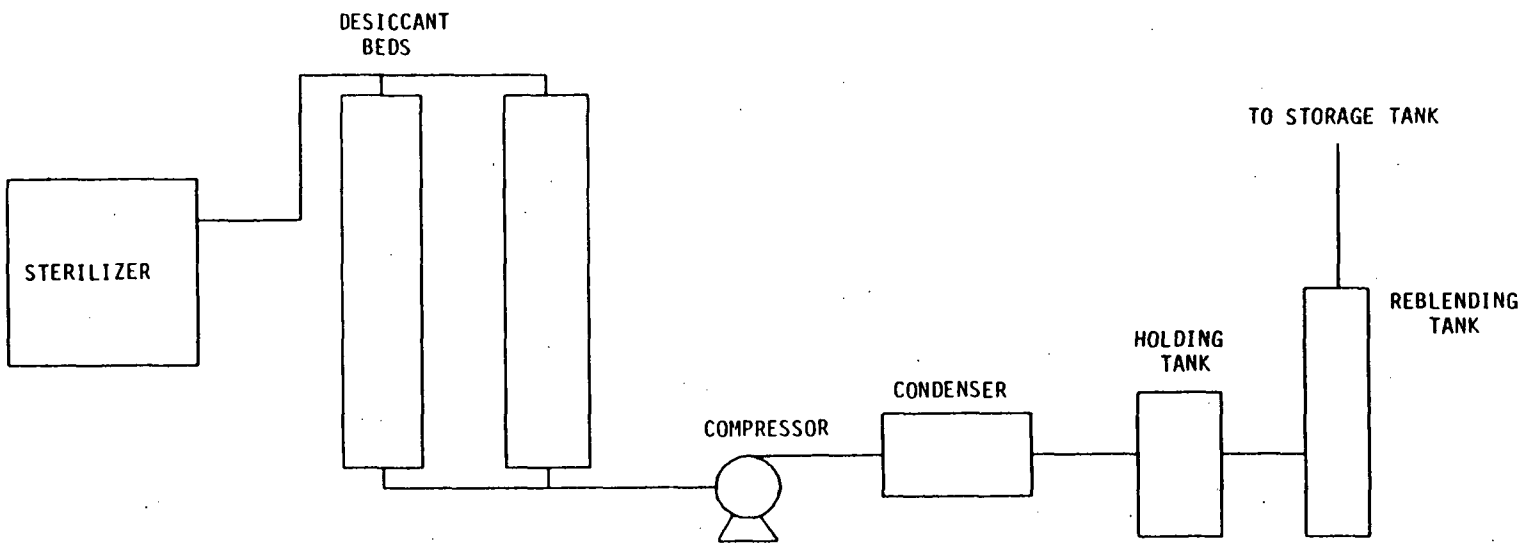

Figure 4-4. Condensation/reclamation system.

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Six of the 188 commercial sterilization facilities represented in the EPA data base reported the use of condensation/reclamation systems; one of these facilities reported an 83-percent EO recovery efficiency, four reported 80 percent, and one reported 50 percent.[2,3,5] These six facilities recover EO/CO_2 and EO/CFC-12 sterilant gases. Five of these facilities use over 23 Mg/yr (50,000 lb/yr) of EO.[2,3,5] The sixth facility uses just over 6.8 Mg/yr (15,000 lb/yr).[2,3] The chamber sizes range from 5 to 45 m^3 (190 to 1,580 ft^3) at these six facilities.[2,3,5]

The condensation/reclamation systems currently available are designed for the high volumetric flow rates of larger, industrial-sized chambers. The systems are not technically or economically feasible for use with smaller chambers or at facilities that use small amounts of EO.

4.1.1.4 Gas/Solid Reactor. A fourth control technique to control vent emissions is a dry, solid-phase system that chemically converts EO and then binds the product to the solid packing.[1] This system is generally paired with an acid water scrubber. The system operates at room temperature. There are no liquid waste streams produced; the solid waste is returned to the vendor for recycling.[32,33] Although the gas/solid reactor can handle high EO concentrations (i.e., >100,000 ppmv) for brief periods of time, it is designed for low concentrations such as the exhaust from an acid-water scrubber. The manufacturer of this device markets a two-stage control system, which consists of an acid-water scrubber and the gas/solid reactor. (The company also sells the stages separately.) The majority of the EO is removed by the scrubber, which is specifically designed for small sterilizers (<2 m^3 [70 ft^3]). The gas/solid reactor removes the residual EO exiting the scrubber and, because it is designed for low EO concentrations, can also be manifolded to other emission sources (e.g., aeration chambers, sterilizer hood and door, and gas cylinder storage room).

The manufacturer of this system claims greater than 99.9 percent efficiency for the gas/solid reactor.[1] However,

this efficiency is based on a test performed with an inlet EO concentration of 140,000 ppmv, which is much higher than the concentration of the scrubber outlet stream. In another test, no EO was detected (with a lower detection limit of 0.1 ppmv) in the gas/solid reactor outlet stream when the inlet stream (i.e., scrubber outlet stream) was 2 ppmv EO.[32] Because of the inherent problems associated with measuring low EO concentrations, the actual efficiency of the system under normal operating conditions presently cannot be determined. (See Section 4.1.3 for a more detailed discussion of measuring low EO concentrations.) However, the maximum removal efficiency that the gas/solid reactor can achieve on a continuous basis is assumed to be 99.0 percent.

4.1.2 Sterilization Chamber Vacuum Pump Drain Emissions

Ethylene oxide drain emissions result from the use of vacuum pumps that use once-through water as the working fluid. Ethylene oxide is infinitely soluble in water, and, therefore, a portion of the EO evacuated from the chamber enters the drain with the vacuum pump water (see Figure 4-5a). The EO that enters the drain with the vacuum pump water is subsequently released uncontrolled from the air break in the drain line, sewer lines, or the waste water treatment plant.[6-8]

The EO drain emissions can be eliminated by replacing the existing once-through vacuum pump with a closed-loop (recirculating-fluid) vacuum pump. The recirculating fluid (sealant) can be water, oil, or ethylene glycol.[34] In this closed-loop system, the water or liquid from the liquid-gas separator is cooled in a heat exchanger and recirculated through the vacuum pump (see Figure 4-5b). Because ethylene oxide is not soluble in oil or ethylene glycol and will off-gas from water as it is recirculated, nearly all of the EO will be emitted through the liquid-gas separator (chamber) vent. (Techniques for control of chamber vent emissions are discussed above.) In addition, mechanical seals are used to eliminate leakage (and, thus, any EO emissions) from the pump.[35]

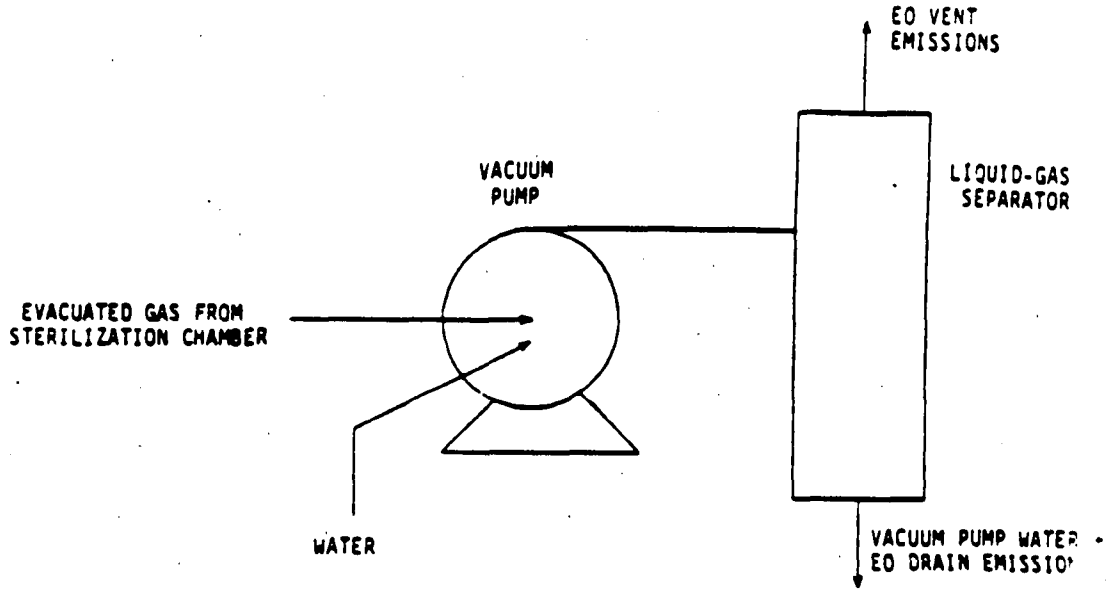

Figure 4-5a. Once-through liquid-ring vacuum pump.

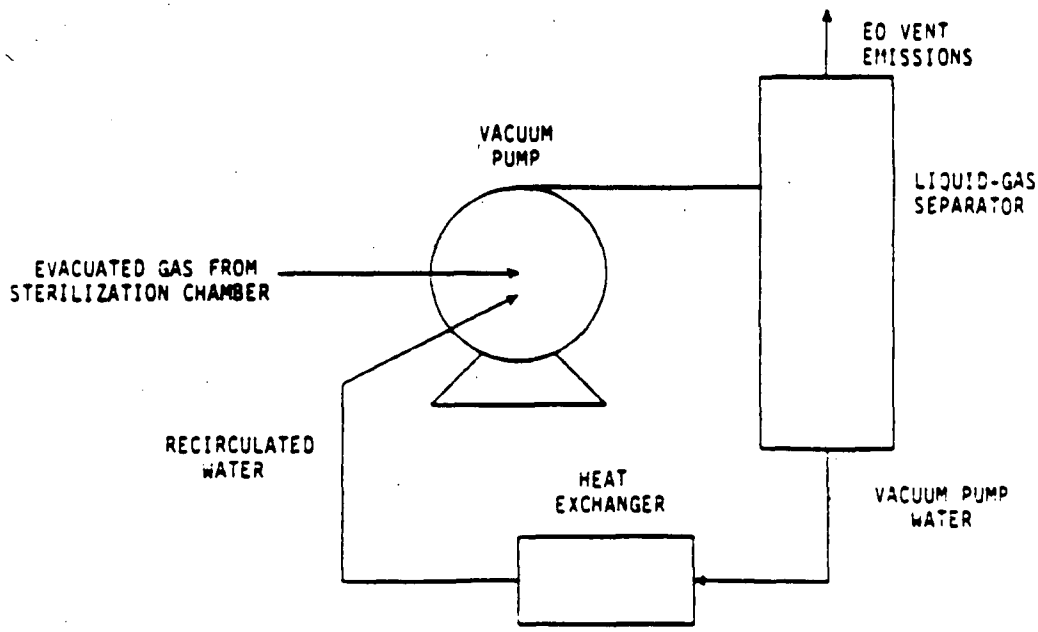

Figure 4-5b. Recirculating liquid-ring vacuum pump.

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Because the sterilization cycle operates under humid conditions, some water will be condensed in the liquid-gas separator and, thus, mix with the liquid sealant in the pump. An overflow collection tank is used to maintain a constant amount of sealant recirculating in the pump.[35] If ethylene glycol is used as the sealant, the contaminated glycol will eventually need to be disposed and replaced with a fresh charge.[35] However, if oil is used as the sealant, the condensed water can be drained off the bottom with minimal oil loss because of the immiscibility of oil and water.[34]

4.1.3 Chamber Exhaust Emissions

Some facilities, in an effort to meet the EO permissible worker exposure level set by the Occupational Safety and Health Administration (OSHA) (see Section 3.5), have installed chamber exhaust vents on sterilizers. The purpose of the exhaust is to quickly dilute EO concentrations in the sterilizer chamber void space and thereby prevent exceedances of exposure limits for workers. Other facilities have installed hoods above the chamber door to reduce worker exposure. At present, there are no data on controlled chamber exhaust emissions in the commercial sterilization data base. As with aeration rooms (see Section 4.1.4.1 for a more detailed discussion), the low-concentration, high-flow-rate exhaust streams of chamber exhausts limit the feasibility and efficiency of add-on controls (particularly thermal oxidation and condensation/reclamation), and the lower detection limit of most analytical methods may make it impossible to determine the efficiency of the control devices at the concentrations typical of the chamber exhaust stream. The same control techniques that are applicable to the control of aeration room emissions (i.e., catalytic oxidation units and gas/solid reactors) may also be applicable to chamber exhaust emissions. In addition, acid/water scrubbers may also be feasible.

The typical chamber exhaust provides a flow rate of 84 m^3/min (3,000 ft^3/min), and the EO concentration in the void volume as the sterilizer door is opened is estimated to be 500 to 15,000 ppmv, depending on sterilizer operating parameters. As

the diluent air enters the chamber, the EO concentration rapidly decreases to below the 1 ppmv OSHA limit. Some EO may evolve from the product during the chamber exhaust cycle, but this amount is negligible when compared to the EO concentration in the void volume.

4.1.3.1 Acid-Water Scrubber. As discussed in Section 4.1.1.1, acid-water scrubbers are commonly used to control sterilizer vent emissions, which have low to moderate flow rates (0.7 to 14 m^3/min [25 to 500 ft^3]) and potentially high EO concentrations (400,000 ppm).[20] Under these conditions, acid-water scrubbers can achieve EO removal efficiencies of 99 percent or greater.[6] While it is technically feasible to control the higher-flow-rate, lower-concentration emissions from the chamber exhaust, the EO removal efficiency of the scrubber may be reduced. The potential decrease in efficiency would be due to decreased residence times of EO in the scrubber and because there would be less EO to react in the scrubbing liquor. Because an acid-water scrubber has never been demonstrated to control chamber exhaust emissions, the control efficiency of the unit under these conditions is unknown.

4.1.3.2 Catalytic Oxidation System. As discussed in Section 4.1.1.2.2, the inlet EO concentration for excess-air catalytic oxidizers is typically reduced to 5,000 ppmv or less, which means that use of this control device could be feasible with chamber exhaust streams. Catalytic oxidation units are also commercially available to handle flow rates from chamber exhausts.[37,38] While no catalytic oxidizers are known to have been installed to control chamber exhaust emissions, units have been installed to control aeration room emissions. As discussed in Section 4.1.4.1, the control efficiency of these units has not been adequately demonstrated.

4.1.3.3 Gas/Solid Reactor. Like the catalytic oxidizers, the gas/solid reactor is designed for low concentration (<100 ppm) inlet streams.[33] As discussed in Section 4.1.4.1, gas/solid reactors are being used for flow rates up to 42 m^3/min (1,500 ft^3/min), and systems can be sized to accommodate larger

flow rates.[39] However, the control efficiency of these units with low EO concentrations has not been adequately determined.

4.1.4 Aeration Room Vent Emissions

4.1.4.1 Aeration Rooms. Most commercial sterilization facilities aerate the sterile products in large, warehouse-type aeration rooms that are typically 280 to 2,800 m^3 (10,000 to 100,000 ft^3) in volume but may be larger than 14,000 m^3 (500,000 ft^3).[4] The ventilation rates are, generally, in the range of 112 to 560 m^3/min (4,000 to 20,000 ft^3/min) but may be as high as 1,680 m^3/min (60,000 ft^3/min).[4] These large flow rates are necessary to maintain a low EO concentration in the room to comply with OSHA standards (see Section 3.5). Data from a cross-sectional survey (44 facilities) of the 188 commercial sterilization facilities represented in EPA's data base indicated an average 8-hour, time-weighted average (TWA) EO concentration of 2.5 to 3 ppmv in aeration rooms.[4]

Two issues of concern regarding the control of aeration room emissions are: (1) most EO emission control devices are impracticable for the low-concentration, high-flow-rate exhaust streams from aeration rooms; and (2) the lower detection limit of most analytical methods may make it impossible to determine the true control efficiency of the low EO concentrations (less than 1 ppmv) found in most aeration rooms. Hydrolysis, thermal oxidation, and condensation/reclamation presently have not been demonstrated to be practicable control techniques for low-concentration, high-flow-rate gas streams. However, catalytic oxidation and the gas/solid reactor system have the potential to control aeration room emissions. Catalytic oxidation units are commercially available to handle flow rates from less than 1 m^3/min (40 ft^3/min) to approximately 340 m^3/min (12,000 ft^3/min).[37,38] The catalytic oxidizers are modular, and systems can be designed to handle higher flow rates; however, the increased size of the system for high flow rates can restrict its practical use. Gas/solid reactors are being used for flow rates up to 42 m^3/min (1,500 ft^3/min), and systems can be designed to

handle any flow rate; however, as with catalytic oxidation, the system size can become impractical.[39]

The manufacturers of catalytic oxidizers and gas/solid reactors claim EO destruction efficiencies greater than 99.9 percent and offer the results of third-party tests to support these claims.[32,40,41] However, test data are not available on the efficiencies of the control units operating under conditions that are typical of aeration room exhaust streams (i.e., low concentrations and high flow rates).

Generally, the control units are tested by sending the control device a stream of EO with a much higher concentration (e.g., 100 to 140,000 ppmv) than that associated with normal operating conditions.[32,40,41] The results of these tests are the efficiencies reported by the manufacturers. However, these test results may be misleading because: (1) it has not been demonstrated whether the control units perform at the same efficiencies under normal operating conditions (i.e., very low inlet concentrations) as during test conditions (i.e., controlled flow, high concentration); (2) EPA has not conducted its own emission test program to verify the efficiency of control devices with aeration room emissions; and (3) EPA has not yet developed or approved a test reference method that is applicable to the evaluation of the efficiencies of these control devices with aeration room emissions.

The lower detection limits of most analytical procedures that are used to measure EO concentrations are approximately 0.5 ppmv to 1 ppmv, which is equal to or greater than the EO concentrations in many aeration rooms. Although one testing laboratory reportedly used a method with a detection limit less than 0.1 ppmv, the test data have not been verified by EPA, and it is unknown whether this method can be applied to high flow rates. (The flow rate tested was 14 m^3/min [500 ft^3/min].)[41] Also, because of the reactivity of EO, the validity of detection limits below 1 ppmv, and particularly below 0.5 ppmv, is questionable.[42] Because the detection limits of the analytical methods (in ppmv) are so close to the room concentrations,

testing under normal operating conditions may yield an efficiency that can only be calculated to be equal to 50 percent or less.

Three possible techniques for reducing EO emissions from aeration rooms are to (1) recirculate the air from the aeration room control device to the aeration room, (2) replace the warehouse-type aeration rooms with smaller, heated aeration chambers, or (3) modify the evacuation and air wash phase of the sterilization cycle. The first two techniques increase the EO concentration in the aeration room and lower the flow rate, which makes both control of the emissions and testing of the control efficiency more practical. The third alternative lowers the EO emissions from the aeration room by decreasing the residual EO in the product prior to aeration. These techniques are discussed in more detail below.

The first alternative refers to routing the aeration room air through an emission control device and back to the aeration room. A small amount of makeup air is added to the control device exit stream to regulate the room temperature. This practice increases the room temperature and, therefore, increases the diffusion rate of EO from the product, producing a higher EO concentration in the room. (Worker exposure and compliance with the OSHA standards will need to be considered if frequent worker access to the room is required.) Catalytic oxidation and the gas/solid reactor are more applicable to gas streams having increased EO concentrations and decreased flow rates associated with this process than to typical aeration room emissions. In addition, increasing the room temperature reduces the energy costs of preheating the inlet stream to the catalytic oxidizer. Hydrolysis, thermal oxidation, and condensation/reclamation are not applicable control techniques because the EO concentrations are too low (<20 ppmv) for these techniques to be practicable. Because the room air is recirculated and not vented to the atmosphere, this technique eliminates practically all aeration room emissions; only a small amount of the emissions from the control device are vented to allow fresh makeup air to enter the room. This practice of recirculating the aeration room air is

used by 2 of the 188 commercial sterilization facilities represented in the EPA data base.[3] The aeration rooms at these two commercial sterilization facilities are each approximately 140 m^3 (5,000 ft^3) in volume.[4] These two facilities manufacture synthetic rubber products, which retain a large amount of residual EO and, therefore, require a longer aeration period than the majority of products that are sterilized with EO. The facilities installed the recirculating system to decrease the aeration time and the residual EO concentrations in the products.[41] A catalytic oxidation system is used to control the EO emissions at these facilities and to provide hot air to heat the room.[43]

Another alternative is to replace the large, warehouse-type aeration rooms with smaller (70 m^3 [2,500 ft^3] or less), heated aeration chambers and control the emissions from the chamber. In this process, instead of storing the sterile products in a warehouse and aerating at normal room temperatures, the products are aerated in heated (>43°C [110°F]), insulated chambers. The emissions from these units can be controlled by catalytic oxidation or the gas/solid reactor system. Emissions from the control device can be recirculated to the aeration chamber or vented to the atmosphere. The aeration chambers can be filled approximately 40 to 75 percent full and still allow sufficient air space for off-gassing.[28,44] The aeration chamber is heated with either supplemental heat or hot air from the control device if catalytic oxidation is used. Several commercial sterilization facilities, particularly contract sterilizers, are aerating at least some of the sterile products in heated, aeration chambers.[4,38] Structures used for aeration include insulated shipping containers, modified walk-in coolers (which are heated instead of cooled), and manufactured units designed specifically for the heated aeration process.[45-47] Most of these facilities have installed these chambers to reduce the aeration time or the residual EO concentration in the products. The heated aeration chambers are similar to the first technique described above (i.e., the practice of recirculating the aeration room air) in

that the EO concentration in the chamber will increase as a result of EO off-gassing from the product due to elevated temperature.

Another strategy for reducing aeration room emissions is to modify the evacuation/air wash phase of the sterilization cycle. Residual EO in the product can be reduced by performing additional sterilization chamber purges. However, this procedure requires that products be held for additional time in the sterilizer and could affect plant operating schedules. The potential reduction in residual EO with evacuation-phase modifications is product dependent. Results from tests performed at one facility that fumigates spices showed an average reduction in residual EO of 26 percent for four different spices following evacuation-phase modifications.[15] Some facilities aerate in the sterilizer, with and without cycle modifications.[4] Aeration emissions from the sterilizer can be sent to the sterilizer control device. However, the removal efficiencies of the hydrolysis techniques have not been determined for the low inlet concentrations associated with aeration emissions. Also, condensation/reclamation would not be practicable for controlling these low concentrations.

An additional system currently used to control EO emissions from aeration rooms is an acid-impregnated carbon adsorption system. When such a system is used, emissions from an aeration room or aeration cabinet (see Chapter 4.1.4.2) are ducted to the carbon adsorption system which typically consists of approximately 20 acid-treated carbon trays. The carbon in these carbon trays has been treated with a strong acid (e.g., sulfuric acid) and is humidified. The EO in the emissions from the aeration room(s)/cabinet(s) is hydrolyzed to ethylene glycol. Because of its increased affinity for EO, the EO removal efficiency of the acid-impregnated carbon greatly exceeds that of plain carbon. However, the actual removal efficiency for this emissions control device have not yet been determined.[48]

4.1.4.2 Aeration Cabinets. Some commercial sterilization facilities use aeration cabinets instead of aeration rooms.

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These cabinets are similar in appearance and size (<1 m^3 [40 ft^3]) to the sterilization chambers used at hospitals. However, the flow rate from the cabinet is much lower than that from aeration rooms. Therefore, catalytic oxidation and the gas/solid reactor are applicable to the control of EO emissions from aeration cabinets. Several small commercial sterilization facilities use catalytic oxidation or the gas/solid reactor system to control aeration cabinet emissions, and at least one commercial sterilization facility uses an acid-water scrubber to control these emissions.[4,37,49] However, as stated in Section 4.1.3.1, the control efficiencies of these techniques have not been determined for the low concentrations from aeration processes.

4.2 OTHER STERILIZATION PROCESSES

There are no demonstrated EO emission control devices for single-item sterilization processes or for portable fumigation units, including beehive fumigators. The problems associated with controlling EO emissions from these sources are discussed below.

4.2.1 Single-Item Sterilization

Single-item sterilization systems do not use a chamber evacuated with a vacuum pump. (See Section 3.2.2 for a description of single-item sterilization.) Instead, the EO is allowed to diffuse from products while they are inside an aeration room or cabinet. The EO from facilities using single-item sterilization systems is, therefore, emitted from one major source, the aeration room/cabinet vent. Because there is no evacuation phase, the EO concentration in the gas stream from single-item sterilization systems is higher than the concentration of EO in aeration rooms. However, the concentration is sufficiently low such that catalytic oxidation or the gas/solid reactor system may be viable control options.

4.2.2 Fumigation with Portable Units

Because of problems with transporting an emission control device, it is not practical to control EO emissions from the portable units operated by State departments of agriculture to

fumigate beehives. However, one State Department of Agriculture is working on the development of an acid-water scrubber for portable fumigation units.[3]

4.3 ALTERNATIVES TO EO STERILIZATION

In some cases, radiation sterilization can replace EO sterilization. Radiation sterilization is used for about half of the products sterilized in the United States.[50] However, not all products can be sterilized with radiation; plastics can become broken, discolored, or rendered malodorous, and Teflon® and acetyl delrin are damaged by radiation.[50,51] According to industry representatives, most of the commonly used plastics have been or are in the process of being reformulated to withstand radiation.[52,53] Therefore, the potential use of this alternative may increase.

There are several chemical alternatives to EO sterilization (e.g., chlorine dioxide, gas plasma, hydrogen peroxide, and ozone). However, these chemicals do not necessarily offer environmental improvements over EO. Other alternatives include X-ray sterilization (a new, developing technology), deep freezing (museum and spice industry), and increased use of disposable medical items in hospitals. However, none of these alternatives can replace the use of EO for all applications, and they may have adverse environmental impacts as well. For example, the increased use of disposables may conflict with a pollution prevention program. Additionally, there may be significant health effects if these alternatives produce less-effective sterilants.[54]

4.4 RETROFIT CONSIDERATIONS

All of the control devices discussed above can be retrofitted to existing EO bulk sterilization chambers. However, the use of flares in urban areas is prohibited because of safety hazards. There are no retrofit problems associated with the replacement of once-through vacuum pumps with closed-loop recirculating vacuum pumps for control of drain emissions.

4.5 IMPACTS OF CFC REGULATION ON EO EMISSION CONTROLS

Federal regulations for stratospheric ozone-depleting chlorofluorocarbons (CFC's) have been developed under EPA's Stratospheric Ozone Protection Program (SOPP). The use of CFC's in sterilant gases is one of the source categories subject to the CFC regulation. The most popular sterilant gas mixture, 12/88, contains 88 percent by weight CFC-12, which is an ozone-depleting CFC. Seventy-five percent of the 188 commercial sterilization facilities represented in the EPA data base use 12/88 at least part of the time.[2,3,5] The requirements of a CFC regulation would not change the ability of a sterilization facility to control EO emissions. The explosion-proof condensation/reclamation system discussed above recovers CFC-12 emissions in addition to EO emissions. However, if this control device is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete. Also, a dedicated CFC-12 condensation/reclamation system that follows the acid-water scrubbing of EO to ethylene glycol would not have to be explosion-proof.[55] Some facilities may switch to sterilant gases that do not contain CFC-12 (such as 10/90 and pure EO), in which case the EO control techniques discussed above would still be applicable.

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5.0 REGULATORY ALTERNATIVES

5.1 INTRODUCTION

The purpose of this chapter is to present the regulatory alternatives developed by EPA. These regulatory alternatives represent the various courses of action that EPA could take in controlling ethylene oxide emissions from commercial sterilization facilities. The environmental, cost, and economic impacts associated with the application of these alternatives to this source category are presented in subsequent chapters. The EPA has developed a facility-specific data base for this source category; the impacts of the regulatory alternatives are based on actual facility data.

Data in the EPA commercial sterilization (CS) data base include facility-specific information from 196 facilities. This information was obtained through a November 1985 Health Industry Manufacturers' Association (HIMA) survey of medical equipment suppliers and a July 1986 Section 114 information collection request submitted to miscellaneous sterilizers and fumigators. Additional information that was used to update the 1986 EPA CS data base was obtained from two subsequent Section 114 information requests (July 1988 and July 1989). Facilities using single-item sterilization (Sterijet®) units and beehive fumigators used by State agriculture departments were not included in the regulatory analyses because there are no demonstrated control technologies for facilities using these sterilization processes (see Section 4.2). Therefore, 188 facilities that operate a total of 404 sterilization chambers are included in the regulatory alternatives analyses. These

facilities are grouped by Standard Industrial Classification (SIC) code into the following categories:

1. Medical equipment suppliers;
2. Pharmaceuticals;
3. Other health-related industries;
4. Spice manufacturers;
5. Contract sterilizers;
6. Libraries, museums, and archives; and
7. Laboratories (research, testing, and animal breeding).

The data base includes information on the number of chambers, chamber size, sterilant gas type, total annual sterilant gas throughput, annual EO use, and levels of emission control.

5.2 REGULATORY ALTERNATIVES

Table 5-1 presents the regulatory alternatives EPA developed to evaluate the environmental and cost impacts of potential emissions controls on commercial sterilization facilities. The regulatory alternatives represent incremental increases in the use of control devices and decreases in the EO use cutoffs that are applicable to the emissions sources. The control devices examined exhibited control efficiencies consistent with those comprising the (MACT) floor. In other words, these devices provide an emission reduction that is at least as stringent as the average emission limitation achieved by the best performing 12 percent of the existing sources. The cutoff levels are based on a facility's total annual EO use. Any facility with an annual EO use rate greater than or equal to the particular cutoff level would be subject to regulation. The analysis of emissions control versus the impacts of control yielded a nonclustered, continuous curve from which clear regulatory cutoffs were not readily determined. However, the trend of the data indicates that lower ethylene oxide annual use rates resulted in higher costs. The cutoff levels presented in Table 5-1 reflect this trend. Sterilization chamber size was also considered as a basis for regulatory alternatives. However, although the sterilization

TABLE 5-1. REGULATORY ALTERNATIVES

Regulatory Alternative	Emission source						Total nationwide emission reduction
	Sterilizer vent		Aeration room		Chamber exhaust		
	Cutoff, kg/yr (lb/yr)	Control device efficiency, percent	Cutoff, kg/yr (lb/yr)	Efficiency of control device, percent	Cutoff, kg Mg/yr (lb/yr)	Efficiency of control device, percent	
A	11 (25)	99	11 (25)	99	11 (25)	98	99
B	270 (600)	99	18,160 (40,000)	99	270 (600)	98	97
C	270 (600)	99	18,160 (40,000)	99	Status quo[a]	N/A[b]	94
D	270 (600)	99	No controls	N/A[b]	Status quo[a]	N/A[b]	91
E	900 (2,000)	99	No controls	N/A[b]	Status quo[a]	N/A[b]	90

[a]Status quo means that baseline chamber exhaust emissions are not exceeded.
[b]N/A = Not applicable.

chamber size is related to the quantity of EO used, actual EO use is a more direct measure of emissions.

Regarding the 900 kilograms per year (kg/yr) (2,000 pounds per year [lb/yr]) EO use cutoff for sterilizer vent and chamber exhaust emissions controls, no plants in the CS data base using less than 900 kg/yr (2,000 lb/yr) of EO have controlled emissions from sterilizer vents or chamber exhausts. Regarding the 18,160 kg/yr (40,000 lb/yr) EO use cutoff for aeration room emissions control, none of the existing sources presently control emissions from facilities using less than 18,160 kg/yr (40,000 lb/yr) of EO. Additionally, risk modeling data indicated that emissions from sources above these cutoffs would pose a more significant threat to human health and the environment. Also, cost estimates show that the cost impacts would be unreasonably high for sources below these cutoffs.

Estimates for emission rates and the cost of regulatory compliance are based on the following control technologies: EO emissions from the sterilizer vent would be controlled by an acid-water scrubber, and vacuum-pump drain emissions would be controlled by replacing the once-through, water-sealed, vacuum pump with a vacuum pump that has a closed-loop recirculation system. All EO entering the vacuum pump would be routed to the control device through the sterilizer vent rather than being split between the vent and drain, thus eliminating EO emissions from the drain. Aeration room emissions would be controlled by either a catalytic oxidizer or solid-bed reactor. The same controls as the aeration room would apply to chamber exhaust emissions.

The alternatives are presented in decreasing order of stringency. Regulatory Alternative A represents the maximum nationwide level of control. At this level, an estimated 99 percent of ethylene oxide emissions from commercial sterilization operations would be captured and controlled. All facilities in the data base would be subject to the control requirements because there are no facilities in the EPA data base that use less than 11 kg (25 lb) of EO per year. Regulatory

Alternative B has less stringent maximum EO use cutoffs. Under Regulatory Alternative C, a cap on chamber exhaust emissions limiting emissions to baseline emission levels would be required; additional controls are assumed necessary to maintain the baseline level. Under Regulatory Alternatives D and E, the only emission source to be controlled is the main sterilizer vent. Regulatory Alternative E represents the MACT floor for existing sources; at least 12 percent of the best performing existing sources already apply a 99-percent efficient control device to control sterilizer vent emissions.

It is important to note that while the efficiency of acid-water scrubbers (at least 99-percent) is widely accepted, the efficiencies assumed for the controls for aeration rooms and chamber exhaust vents are not well supported. For purposes of the analyses in this document, 99 and 98 percent were selected for the aeration room and chamber exhaust vent control device efficiencies, respectively. However, actual control efficiencies may be lower given the high-flow, low concentration emissions streams that are typical of these emissions sources.

6.0 ENVIRONMENTAL IMPACTS

This chapter presents estimated primary and secondary impacts on air, water, solid waste, and energy for each of the regulatory alternatives discussed in Chapter 5. Both beneficial and adverse impacts, as well as potential emission reductions, are assessed for the 188 facilities represented in EPA's 1989 commercial sterilization (CS) data base. Because no significant growth is expected for this industry, the 5-year impacts are the same as current impacts, and, therefore, only current impacts are presented in this section.[1,2]

6.1 AIR POLLUTION IMPACTS

6.1.1 Baseline Emissions and Emission Reduction

Based on facility-specific data in the EPA 1989 CS data base, baseline EO emissions and potential emission reductions were calculated for each of the regulatory alternatives described in Section 5.2. The control devices (and their efficiencies) at each emission point considered were respectively: (1) acid-water scrubber for sterilizer vent (99 percent); (2) recirculating-fluid vacuum pump for sterilizer vent drain (100 percent); (3) acid-water scrubber for chamber exhaust (assumed to be 98 percent), and (4) a gas/solid reactor for aeration room vent (99 percent).

The total nationwide estimated potential emission reductions and residual emissions for each of the five regulatory alternatives are presented in Table 6-1.

6.1.2 Secondary Impacts

Secondary air pollutants are those emissions that are not usually associated with an uncontrolled facility but result from the use of pollution control equipment (i.e., the control of one

TABLE 6-1. NATIONWIDE AIR IMPACTS

Regulatory Alternative	Nationwide emission reduction, %	EO emission reduction, Mg/yr (tons/yr)	EO residual emissions, Mg/yr (tons/yr)
A	99	1,061 (1,170)	11 (12)
B	97	1,042 (1,148)	30 (33)
C	94	1,004 (1,107)	68 (75)
D	90	963 (1,062)	109 (120)
E	89	952 (1,049)	120 (132)

Source: U. S. EPA Ethylene Oxide Commercial Sterilization Data Base, 1986, 1988.

pollutant results in the production of another pollutant). Secondary air pollutants are not associated with the use of acid-water scrubbers, recirculating-fluid vacuum pumps, or gas/solid reactors.

6.2 WATER QUALITY IMPACTS

If an acid-water scrubber is used to control EO emissions, there may be water quality impacts, depending on how the spent scrubber solution (predominately ethylene glycol) is disposed. Ethylene glycol is generated when the EO exhaust stream contacts and then reacts with the acid-water solution in the scrubber. When this solution is spent, the scrubber tank must be emptied and a fresh acid-water solution added. Each tank initially holds about 220 gallons (833 liters) of a 10 percent (by volume) aqueous sulfuric acid (H_2SO_4) solution, which is neutralized with 50 percent (by weight) caustic (NaOH) before the tank is drained.[3] (See Appendix E Section E.2 [sample calculations for acid-water scrubbers, assumption 3] for a sample calculation of the amount of ethylene glycol solution produced per pound of EO entering the scrubber.) The amount of ethylene glycol solution produced was calculated based on the assumption that the scrubber would be drained after 907 kilograms (kg) (2,000 pounds [lb]) of EO were treated, resulting in a 64 percent (by weight) aqueous solution of ethylene glycol.

Several methods for the final disposal of the ethylene glycol were examined. The ethylene glycol produced by the scrubber can be removed by a waste disposal company, sent to a municipal wastewater treatment plant, or shipped to a recovery plant. Removal of the ethylene glycol by a waste disposal company may not be economically practical for all of the facilities; this disposal method could account for a high percentage of the annual operating costs.[3] Sending the ethylene glycol solution to a municipal wastewater treatment plant also would not be feasible for all sterilization facilities. Some municipal treatment facilities restrict the concentration level and amount of ethylene glycol allowed in the discharge to the wastewater treatment plant.[3]

The final disposal method examined was shipping the ethylene glycol solution to a recovery company. At least three companies accept the ethylene glycol solutions for recovery on a no-credit, no-cost (except for shipping) basis.[4-6] Shipment of the ethylene glycol solution to a recovery company is a disposal method that would be applicable to all EO users and would not result in any wastewater impacts. Therefore, the nationwide wastewater impacts calculated for this control device shown in Table 6-2 represent the maximum potential wastewater impacts. Because of ethylene glycol recycling, the actual impacts are expected to be lower.

6.3 SOLID WASTE IMPACTS

Solid waste impacts could occur if the owners or operators of EO sterilization facilities choose to landfill spent reactant from the gas/solid reactor used to control aeration room emissions. However, the reactant replacement costs were developed based on spent reactant being returned to the vendor for recycling because this alternative was more cost-effective. Therefore, the nationwide solid waste impacts calculated for this control device shown in Table 6-2 represent the maximum potential solid waste impacts. Because of spent reactant recycling, the actual impacts are expected to be lower.

Additionally, if an owner or operator of an EO sterilization facility chooses to control emissions with a catalytic oxidizer, solid waste impacts may occur if the spent catalyst is landfilled.

6.4 ENERGY IMPACTS

The energy requirements for acid-water scrubbers are considerably less than those of the gas/solid reactor fan. Energy requirements for each of the regulatory alternatives are also presented in Table 6-2. If a catalytic oxidizer is used at a facility to control emissions, energy impacts will be considerably higher.

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TABLE 6-2. POTENTIAL NATIONWIDE WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS

Regulatory Alternative	Total annual wastewater production, m^3 (gal)[a b]	Total annual solid waste production, Mg/(tons)[c d]	Total annual electricity consumption, Kw/hr (000's)
A	2,150 (569,000)	190 (209)	4,600
B	2,140 (566,000)	137 (151)	2,700
C	2,140 (566,000)	137 (151)	2,700
D	2,140 (566,000)	0	0
E	2,120 (561,000)	0	0

[a]Actual impacts anticipated to be zero because of recycling of ethylene glycol.
[b]Approximately 60 percent (by volume) of wastewater is composed of ethylene glycol.
[c]Actual impacts anticipated to be zero because of recycling of reactant.
[d]Based on the use of gas/solid reactor.

Source: U. S. EPA Ethylene Oxide Commercial Sterlization Data Base, 1986, 1988.

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6.5 OTHER ENVIRONMENTAL CONCERNS

6.5.1 Irreversible and Irretrievable Commitment of Resources

Regulatory compliance would not preclude the development of future control options nor would such compliance curtail any beneficial use of the environment. No long-term environmental losses would result from regulatory compliance by commercial sterilization facilities.

6.5.2 Environmental Impact of Delayed Standards

Delaying the standards would result in possible solid waste impact reductions, but the reductions would be minimal compared with the air quality benefits attributable to promulgation of the standards. There do not appear to be any emerging emission control technologies that achieve greater emissions reductions or have significantly lower costs than the control devices considered here. Consequently, there are no benefits or advantages to delaying the proposed standards.

6.6 REFERENCES FOR CHAPTER 6

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5. Telecon. Srebro, S., MRI, with K. Dalton. High Valley Chemicals. March 16, 1989. Discussion about recovery of ethylene glycol from ethylene oxide scrubbing liquor.

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7.0 EMISSION CONTROL COSTS

This chapter presents a summary of the methodology used to develop emission control cost estimates for 188 of the 196 facilities (8 State department of agriculture mobile beehive fumigation units were not included in this cost analysis) in the 1989 EPA commercial sterilization (CS) data base. These 188 CS facilities operate a total of 404 sterilization chambers. A method for estimating EO emission control costs for sterilizer vents at CS facilities is presented in Section 7.1. Cost information for chamber exhaust and aeration room controls is discussed in Sections 7.2 and 7.3, respectively. The results of the cost analyses are presented in Section 7.4, and Section 7.5 presents other cost considerations.

Costs are further explained in Appendix E. Appendix E includes: (1) costs for acid-water scrubbers (Section E.1); (2) sample calculations of the equations used to develop capital and annual costs for acid-water scrubbers (Section E.2); (3) aeration room cost analysis (Section E.3); (4) capital and annual control costs for the sterilizer chamber, chamber exhaust, and aeration room vent(s) at an example facility (Section E.4); (5) a breakdown of manifolding costs for these three vents (Section E.5); and (6) the cost indices and conversion factors used to convert costs to fourth quarter 1987 dollars (Section E.6).

Costs presented in this chapter are in fourth quarter 1987 dollars and are for existing facilities only. No new facilities are anticipated.

7.1 STERILIZER VENT CONTROL COSTS

This section describes a method for estimating emission control costs for sterilizer vent(s) and vacuum pump drains at commercial sterilization facilities. Acid hydrolysis (i.e., acid-water scrubbing) was chosen as the basis for the costing procedure because this control technique currently is known to be used at 28 commercial sterilization facilities, representing a variety of industries and a wide range of sterilizer chamber sizes (7 to 274 cubic meters [m^3] [264 to 9,800 cubic feet {ft^3}]).[1,2] This control technique is also the most cost effective of the technologies in use.[3] A detailed review of the available test data indicated that 99.0 percent is the maximum EO removal efficiency that acid hydrolysis techniques can achieve on a continuous basis.[4] Therefore, 99.0 percent was used to calculate the emission reductions.

The costing procedure presented in this section has been used to develop emission control costs for the 188 commercial sterilization facilities represented in the 1989 EPA CS data base.[5] (See Chapter 3 for a description of how the data base was developed.) Detailed example calculations for a typical commercial sterilization facility are given in Appendix E, Section E.4. Because these costs depend on sterilizer volume, the number of sterilizers, and annual EO use, example cost calculations for the sterilizer vent and chamber exhaust controls were provided for only one facility. However, the methodology for determining example costs for sterilizer vent and chamber exhaust emission controls was applied to all plants represented in the CS database. Therefore, the example costs provided in Appendix E, Section E.4, apply to all commercial sterilization facilities. However, because the methodology used to develop control costs for the aeration room is more complex, facility-specific costs are included in Appendix E, Section E.3, to supplement Tables E-12 and E-13 in Section E.4.

7.1.1 Description of Components Costed

The following components were costed: (1) an acid-water scrubber, (2) water-sealed vacuum pump(s) with closed-loop recirculation, (3) piping for manifolding the chambers to the existing control device or to a scrubber, (4) operating materials (i.e., chemicals and chlorine filters), (5) scrubber effluent disposal, and (6) labor.

Scrubber prices (freight-on-board [F.O.B.]) are listed in Table E-1. The capital costs associated with the scrubber and the piping system (for manifolding) are presented in Appendix E, Sections E.2 and E.5, respectively. The costs of operating materials, as well as the shipping charges used for computing disposal costs for the spent scrubber solution, are also presented in Appendix E, Section E.2.

7.1.2 General Assumptions

Scrubbers were not costed for facilities that had existing sterilizer vent control devices with efficiencies greater than or equal to 98-percent. Because of the chemical/physical characteristics of ethylene oxide as explained in Section 3.4.1, control devices operating at 98-percent efficiency (e.g., flares) may be assumed to operate at 99-percent efficiency. If a facility had a control device with an efficiency below 98 percent, a scrubber to remove 99.0 percent of the remaining emissions was costed. If a facility had an existing control but had uncontrolled chambers, it was assumed that the uncontrolled chambers were manifolded to the control device and that the existing control device had the capacity to control the additional emissions from the uncontrolled chambers.

Chamber volume was used as the basis for scrubber sizing. The relationship of chamber volume to a typical scrubber size is presented in Table E-1.

If a facility had three or more sterilization chambers, the scrubber costed was chosen based on the sum of the volumes of the two largest chambers at that facility. This methodology simulates the cost of controlling emissions from a facility if two chambers at that facility were to be evacuated

simultaneously. If a facility had two chambers, the scrubber was selected based on the volume of the larger chamber. For facilities with only two chambers, it was assumed that the sterilization cycles could be staggered so that the chambers would not be evacuated simultaneously.[5]

Costs were developed for recirculating-fluid vacuum pumps to control drain emissions normally associated with once-through, water-sealed vacuum pumps. Each sterilization chamber at a facility was costed for a recirculating-fluid vacuum pump unless the chamber had a control device that utilized a recirculating-fluid vacuum pump or a recirculating-fluid vacuum pump was already in place.

Piping costs for existing low-efficiency control devices were calculated based on the assumption that all sterilizers at a facility could be manifolded to the existing control device. An acid-water scrubber could then be manifolded to the existing control device to handle the remaining emissions. For facilities that had existing high-efficiency control devices, piping was costed to manifold any uncontrolled chambers to the existing control device. Otherwise, piping was costed to manifold all sterilizer chambers to an acid-water scrubber.

The disposal cost for the aqueous ethylene glycol solution produced by the acid-water scrubbers was computed as the cost to ship the solution, either in 55-gallon drums or in a tank truck, depending on quantity, to a recovery facility. Three recovery facilities that will accept the ethylene glycol on a no cost/no payment agreement were identified.[6-8] Transportation costs were calculated by assuming that most CS facilities (except those in Puerto Rico) are located within 1,000 miles of one of the three known recovery facilities.[5] This method of disposal was chosen because an earlier investigation of alternative disposal methods indicated that (1) discharging ethylene glycol to municipal wastewater treatment plants is a disposal method that may not be available to all sterilization facilities and (2) hauling by a waste disposal company would be costly for most sterilization facilities.

7.2 CHAMBER EXHAUST CONTROL COSTS

This section describes a method for estimating control costs for chamber exhausts. Although three types of control devices (i.e., catalytic oxidizers, gas/solid reactors, and acid-water scrubbers) are theoretically applicable to chamber exhaust emissions, none are currently in operation controlling chamber exhaust emissions. The costs of all three control devices were estimated. However, only the costs of the least expensive option, acid-water scrubbers, are presented here. Normally, an efficiency of 99.0 percent is used for an acid-water scrubber controlling sterilizer vent emissions. However, due to the differences in emission stream characteristics between the sterilizer vent and the chamber exhaust, an efficiency of 98 percent was used as a best-case estimate for an acid-water scrubber controlling the chamber exhaust.

Because both the sterilizer chamber and chamber exhaust vent use acid-water scrubbers to control EO emissions, the calculations used to determine annual operating costs (in Appendix E, Section E.2) for chamber exhaust controls are similar to those for the sterilizer vent. The main difference is that the acid-water scrubber for the chamber exhaust controls only 2 percent of the total facility EO use at an efficiency of 98 percent, whereas the sterilizer vent scrubber controls 95 percent of the total facility EO use at an efficiency of 99 percent. Capital costs for the chamber exhaust are based on a scrubber sized to control a flow rate of either 84 or 168 m^3/min (3,000 or 6,000 ft^3/min) (shown in Table E-1), ductwork for manifolding the chamber exhaust(s) to a common control (Table E-15), and associated installation costs. A breakdown of control costs for the chamber exhaust is included in Table E-11.

7.2.1 Description of Components Costed

The following components were costed: (1) an acid-water scrubber, (2) ductwork for manifolding vents, (3) operating materials, (4) scrubber effluent disposal, and (5) labor. Because of the extreme differences in ethylene oxide concentrations and the flow rates emitted from the emission

vents, manifolding was only costed between multiple emissions sources of the same type (e.g., manifolding multiple sterilizer vents or chamber exhaust vents or aeration room vents).

7.2.2 General Assumptions

In November 1989, the Health Industry Manufacturer's Association (HIMA) conducted a survey of 14 companies (23 facilities) to determine the prevalence of chamber exhaust use. Although these facilities represent only 12 percent of the facilities in the EPA CS data base, they represent 40 percent of the annual EO use. Of the 156 chambers these companies operate, 35 chambers (22 percent) do not have chamber exhausts.[9] Typically, these chambers are small in size, i.e., less than 7 m^3 (250 ft^3). Therefore, based on this HIMA survey, sterilizer chambers that were smaller than 7 m^3 (250 ft^3) were not assumed to have chamber exhaust and were not costed for control devices. It was assumed that these facilities can perform more air washes to reduce worker exposure to EO, which is the purpose of the chamber exhaust.

A flow rate of 84 m^3/min (3,000 ft^3/min) was assumed for chamber exhaust emissions and served as the basis for sizing an acid-water scrubber to control chamber exhausts. For this cost analysis, if a facility has more than two sterilizers, the total emission flow rate to the control is assumed to be 168 m^3/min (6,000 ft^3/min). This methodology simulates the control cost if two sterilizers were to vent to the chamber exhaust simultaneously. If a facility has one or two sterilizers, the emission flow rate is assumed to be 84 m^3/min (3,000 ft^3/min). This methodology is based on the assumption that a facility with only two sterilizers will rarely need to vent the chamber exhausts simultaneously and is consistent with the methodology used to develop sterilizer vent costs.[5]

The scrubber effluent disposal costs for the chamber exhaust scrubber are the same as those for the sterilizer vent control.

7.3 AERATION ROOM CONTROL COSTS

This section describes a method for estimating emission control costs for aeration rooms at CS facilities.

Initially, costs were developed for gas/solid reactors and catalytic oxidizers to control aeration room emissions. Because the gas/solid reactor was the most cost-effective of the controls considered, it was selected as the basis for the cost estimating procedure. However, catalytic oxidizers are equally viable and effective control devices; therefore, cost estimating tables for catalytic oxidizers, similar to those developed for gas/solid reactors, are included in Appendix E (Tables E-9 and E-13). For both of these control devices, facilities and test reports reported a 99-percent efficiency; therefore, 99 percent was used as a best-case estimate of control device efficiency.

A gas/solid reactor was costed for 185 of the 188 CS facilities. Three facilities already controlled aeration room emissions with catalytic oxidizers and were, therefore, not included in the cost analysis. A breakdown of the costs of controlling aeration emissions with gas/solid reactors is included in Table E-8. A breakdown of the manifolding costs is shown in Table E-16.

7.3.1 Description of Components Costed

The following components were costed: (1) gas/solid reactor(s), (2) insulated shipping containers (aeration chambers) to take the place of aeration rooms, (3) ductwork to manifold the aeration chambers to a common control device, (4) operating materials (including utilities), and (5) labor.

7.3.2 General Assumptions

Aeration chambers were costed to replace existing aeration rooms because emission flow rates from aeration rooms are typically high (greater than 280 m^3/min [10,000 ft^3/min]) with very low (less than 2 parts per million [ppm]) EO concentrations. By reducing the aeration room size, the emissions can be more easily controlled because the flow rate is decreased, and the EO concentration is increased. Therefore, it was assumed that aeration chambers could be used to replace all existing aeration processes. The aeration chambers were assumed to be unheated and, consequently, at ambient temperature. No decrease in aeration time was attributed to temperature for this cost analysis.

A regression analysis was performed on aeration room data received from 35 facilities.[10] This analysis was used to correlate the number of model aeration chambers (necessary to replace existing aeration processes) to a facility's EO use so that aeration chambers could be assigned to facilities to replace existing aeration rooms.

The result of the correlation is that facilities that use 2.27 Mg/yr (5,000 lb/yr) or less of EO were assigned one aeration chamber; however, no cost was attributed to this unit because facilities that use this amount of EO typically have aeration rooms smaller than the aeration chamber. Facilities that use 2.27 to 4.54 Mg/yr (5,000 to 10,000 lb/yr) EO were costed for one aeration chamber. Facilities that use between 4.54 and 36.3 Mg/yr (10,000 and 80,000 lb/yr) EO were costed for aeration chambers based on the equation $Y = 1.35 \times (10^{-4})X$. Facilities that use more than 36.3 Mg/yr (80,000 lb/yr) were costed for aeration chambers based on the equation $Y = 2.9\ (10^{-5})X + 8.6$ (where Y = number of aeration chambers and X = annual EO use, lb/yr, for both equations).

Cost estimates for a 28 m^3/min (1,000 ft^3/min) gas/solid reactor were obtained from a vendor. This gas/solid reactor is capable of handling EO emission concentrations up to 100 ppm.[11] Costs were extrapolated using an equation provided by the vendor to determine the cost of an 84 m^3/min (3,000 ft^3/min) gas/solid reactor. It was assumed that a maximum of 12 aeration chambers (2 parallel sets of 6 in series) could be vented to a control unit. The emission flow rate from each of these aeration chambers was assumed to be 7 m^3/min (250 ft^3/min), and the number of control units was selected so as to minimize capital costs.[11]

Disposal costs for the spent gas/solid reactant were calculated for a transportation distance of 1,500 miles. This cost was based on the assumption that the reactant could be returned to the vendor for recycling on a no-charge, no-credit basis. A distance of 1,500 miles was used because most facilities (except those in Puerto Rico) are located within 1,500 miles of the manufacturer of the reactant.[11]

7.4 RESULTS OF COST ANALYSIS

The nationwide cost impacts associated with each of the regulatory alternatives are shown in Table 7-1. Table 7-2, shows the cost impacts on three representative facilities. A "facility" in this case includes the sterilization vent, chamber exhaust vent, and aeration room vent emissions. These facilities were selected to represent the median facility (with regard to annual EO use and cumulative sterilizer chamber volume) in each of the following annual EO use ranges: <272, 272 to 18,150, and >18,150 kg/yr (<600, 600 to 40,000, and >40,000 lb/yr). A representative facility was not selected for facilities that use less than 11 kg/yr (25 lb/yr) EO because such a facility does not exist. The facilities that were selected represent small, medium, and large facilities that use 228, 3,963, and 67,604 kg/yr (504, 8,736, and 149,000 lb/yr) of EO; and have cumulative sterilizer volumes of 5.7, 28, and 112 m^3 (204, 1,000, and 4,002 ft^3), respectively.

7.5 OTHER COST CONSIDERATIONS

In addition to the costs described above, costs to comply with other Federal rules or regulations may be incurred by commercial sterilization facilities. These costs are described in the following section.

At CS facilities where workers handle or are near product during the sterilization process, measures must be taken to reduce EO worker exposure to less than 1 ppm per 8-hour time-weighted average concentration. In most facilities with cumulative sterilizer volumes less than 7 m^3 (250 ft^3) worker exposure is minimized using the chamber exhaust, which evacuates EO-laden air from the chamber while workers are loading/unloading the sterilizer chamber. Two of the regulatory alternatives require add-on controls for the chamber exhaust. If a facility were to elect to disable the chamber exhaust in lieu of the add-on control there would be additional costs to ensure continued OSHA compliance.

TABLE 7-1. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS

Regulatory Alternative	Emission reduction, %	EO use cutoff			Total annual costs, $/MM	Emission reduction, Mg/yr (tons/yr)	Cost effectiveness $/Mg ($/ton)	Incremental cost effectiveness, $/Mg ($/ton)
		Sterilizer vent, kg/yr (lb/yr)	Aeration room, kg/yr (lb/yr)	Chamber exhaust				
A	99	11 (25)	11 (25)	Add-on controls[a]	12	1,061 (1,170)	11,300 (10,300)	47,000 (133,000)
B	97	272 (600)	18,144 (40,000)	Add-on controls[a]	9.2	1,042 (1,149)	8,800 (8,000)	74,000 (67,000)
C	94	272 (600)	18,144 (40,000)	Status quo[b]	6.4	1,004 (1,107)	6,400 (5,800)	51,000 (46,000)
D	90	272 (600)	N/A	Status quo[b]	4.3	963 (1,062)	4,500 (4,050)	45,000 (41,000)
E	89	907 (2,000)	N/A	Status quo[b]	3.8	952 (1,049)	4,000 (3,600)	4,000 (3,600)

[a]Ethylene oxide use cutoff same as for sterilizer vent.
[b]Status quo means that baseline chambers exhaust emissions are not exceeded.

TABLE 7-2. REPRESENTATIVE FACILITY COST IMPACTS

Regulatory Alternative	Facility EO use, kg/yr (lb/yr)	Sterilizer control costs, $1,000		Chamber exhaust control costs, $1,000		Aeration room control costs, $1,000		Total emission reduction Mg (ton)	Total cost effectiveness, $/Mg ($/ton)
		Capital	Annual	Capital	Annual	Capital	Annual		
A	228 (504)	82.4	22.1	a	a	27.5	9.3	0.226 (0.249)	139,000
	3,963 (8,736)	175	43.7	66.8	18.8	45.9	13	3.92 (4.32)	(126,000)
	67,604 (149,000)	309	103	118	30.6	274	73.4	66.9 (73.7)	19,300 (17,500)
									3,090 (2,810)
B	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	66.8	18.8	N/A	N/A	3.8 (4.19)	16,500 (14,900)
	67,604 (149,000)	309	103	118	30.6	274	73.4	66.9 (73.7)	3,090 (2,810)
C	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	274	73.4	65.6 (72.3)	2,690 (2,440)
D	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	N/A	N/A	63.6 (70.1)	1,620 (1,470)
E	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	N/A	N/A	63.6 (70.1)	1,620 (1,470)

7.6 REFERENCES FOR CHAPTER 7

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9. Letter and confidential attachments from Jorkasky J., Health Industry Manufacturers' Association, to S. Srebro, MRI. December 1989. Information on use of rear chamber exhaust at medical equipment suppliers.

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8.0 THE ECONOMIC IMPACTS OF THE CANDIDATE NESHAP CONTROLS

8.1 INTRODUCTION

Companies performing ethylene oxide (EO) sterilization fall into two general groups: in-house sterilizers and contract sterilizers. In-house sterilizers are companies that produce the goods needing sterilization. As part of their production process, they also sterilize the products. Also included in this group are laboratories, museums, and libraries. These in-house sterilizers do not produce goods needing sterilization, but, like the other in-house sterilizers, sterilization is a small but necessary part of their operations. Museums, for example, specialize in preserving and displaying artworks or artifacts. To be preserved, some of these artifacts must be sterilized or fumigated. Sterilization is only a very small part of the activities carried on by museums; some of them choose to perform it onsite, while others send their artifacts offsite to a contract sterilizer.

Contract sterilizers are companies that specialize in sterilization/fumigation, so sterilization is a major part of their business. They do not, in general, produce any of the goods being sterilized; rather, they offer the service of sterilization to other producers.

This chapter identifies the industries affected by this regulation and evaluates the economic impacts of three possible control options. First, the industries that perform EO sterilization are described; then the industries producing

products requiring sterilization are profiled. Finally, the effects of the control options on these industries are assessed.

8.2 ETHYLENE OXIDE STERILIZATION

8.2.1 Process Inputs

The major capital equipment requirement for sterilization is the sterilization chamber. The 188 facilities covered in this profile operate 404 chambers, an average of 2.2 chambers per facility. The number of chambers per facility ranges from one to nine. Chamber sizes range from 0.01 cubic meters (m^3) (0.35 cubic feet [ft^3]) to 177 m^3 (6,250 ft^3) and average about 16 m^3 (565 ft^3).[1] A typical chamber has a useful life of approximately 10 years; at the end of that time, the salvage value of the chamber is less than 1 percent of the initial capital investment.[2]

Certain design characteristics of the sterilization chamber are determined by the gas to be used for sterilization. These design characteristics limit the possibility of switching gases in the short run. When pure EO is used, the chamber instrumentation and room must be explosion-proof.[3] Pure EO chambers must also operate with a deep vacuum to rid the chamber of oxygen. Chambers that use an EO/CO_2 mixture, which requires a substantially higher operating pressure than other gases, have to meet higher standards of construction to withstand the pressure.[4]

The various chamber specifications are not mutually exclusive. For example, a chamber designed to withstand the high operating pressure associated with the EO/CO_2 mixture can also accommodate the lower pressures required by other sterilant gases. Therefore, some facilities can have chambers with the characteristics necessary for use with more than one type of sterilant gas. Consequently, these facilities can alternate between gases to achieve optimal combinations of product and sterilant gas for each sterilization cycle. Facilities involved in testing and research and those that sterilize a wide variety of products are more likely to operate chambers in this manner.

Other equipment required for the sterilization process includes:

1. A pump to create a vacuum in the chamber; and
2. A pump to force sterilant gas or air into the chamber.

Some facilities also have a separate room for the aeration step of the process, although aeration at some facilities can be accomplished in the sterilization chamber so that products do not have to be moved.

Labor requirements for EO sterilization are usually higher than for other types of sterilization (e.g., thermal or radiation). Each sterilization cycle must be closely monitored because several critical process variables require careful attention.[5] In addition, sterilization with pure EO requires strict safety precautions and extensive monitoring by facility personnel because pure EO is flammable.

8.3 SUBSTITUTION POSSIBILITIES AND THE PRICE ELASTICITY OF DEMAND

The extent of substitution between the EO-based gases is limited by the characteristics of the sterilization chamber and the compatibility of the sterilizing medium with the products being sterilized. As noted earlier, both pure EO and the EO/CO_2 mixtures may require specially designed sterilization chambers. Chambers may be modified to use pure EO, but industry standards prohibit modifying chambers for use with the EO/CO_2 mixture. However, the different pressures under which sterilization is performed for each sterilant gas can damage some products or packaging. Consequently, substituting with sterilant gases that require extremely high or low operating pressures is limited by the characteristics of the products being sterilized.

Gamma radiation sterilization can substitute for EO sterilization for many products. Unlike EO, radiation can sterilize liquids and products in vapor-tight packages; however, it discolors plastics and damages Teflon and acetyl delrin.[4,5] Gamma radiation cannot be used to sterilize pharmaceuticals because the radiation may alter the chemical structure of the drugs. Gamma radiation is expected to make some additional inroads into the EO market for sterilization.[2] Although gamma radiation is a likely substitute for EO sterilization, safety

concerns regarding transportation and disposal of the radiation source and the cost of the radioactive cobalt used as a radiation source will probably limit any increase in the percentage of the products sterilized by radiation. [Several other chemical substitutes for EO exist, but their use is more limited than gamma radiation; the substitution possibilities for these chemicals are discussed in later sections in conjunction with the appropriate end products.]

The importance of the sterilization procedure in the overall production process of many products presumably has a profound effect on its demand elasticity (i.e., the responsiveness of quantity demanded to a change in the price of sterilization services). Four main issues influence the elasticity of demand for a factor within an industry.[6] Specifically, the elasticity of demand should vary directly with the elasticity of demand for the final product, the factor's share of the costs of production, the elasticity of supply of other factors, and the elasticity of substitution between the factors.

These influences suggest that the demand for sterilization within the relevant industries is relatively inelastic. This conclusion is based in part on the low ratio between the cost of sterilization and the total cost of production.[7] Additionally, the elasticity of substitution between factors of production within the industries is relatively low; precautions taken to minimize contamination during production do not necessarily lessen the need for sterilization but enhance the effectiveness of the process. Generalizations regarding the elasticity of demand for the final product and the elasticity of supply of other factors are not possible due to variations from industry to industry.

8.4 SUPPLY OF EO STERILIZATION SERVICES

This section profiles the facilities that sterilize/fumigate medical devices and other miscellaneous products with EO, excluding sterilization activities in hospitals. For simplicity, we refer to this process simply as sterilization. For a variety of reasons discussed later in this section,

sterilization does not form a cohesive industry but is instead a part of the production process in several industries. Therefore, this profile will be limited in the scope of its analysis. The most important limiting factor is the lack of data on sterilization as a separate step in the production process. Consequently, commercial sterilizers are grouped here by industry; sterilization is then analyzed within the context of that industry.

8.4.1 National Summary of Ethylene Oxide Sterilization

The economic analysis presented in this chapter covers 188 sterilization facilities for which data are available. About half of the 188 facilities are suppliers of medical devices or other health-related items; the other facilities engage in several miscellaneous sterilization and fumigation operations (discussed later).

In 1988, approximately 1,913 megagrams (Mg) (4.22 million pounds [lb]) of EO was used for sterilization purposes by the 188 facilities covered in this analysis. [The EPA commercial sterilization database contains 1988 data for 32 facilities, the remainder are 1985 or 1986 values; for simplicity, 1988 will be referred to as the base year.] Table 8-1 presents some summary statistics on the use of the sterilant gases at the 188 facilities, separated into two categories--EO use and total gas use. The tremendously wide range in the use of sterilant gas per facility is noteworthy.

As mentioned above, several characteristics of the sterilization process make it difficult to profile the process as a discrete industry. The most important characteristic stems from the role of sterilization in the overall production process. Except for contract sterilizers, the sterilization process is an intermediate step in the production process. Therefore, separating sterilization from the production of the sterilized products is difficult. Another difficulty is the absence of a Standard Industrial Classification (SIC) code listing for sterilization either separately or within the classifications for the industries that employ this process. Furthermore, EO

TABLE 8-1. SUMMARY STATISTICS ON THE USE OF STERILANT GAS AT 188 COMMERCIAL STERILIZATION FACILITIES, 1988

		Ethylene oxide	Total gas
Total use	Mg/yr (tons/yr)	1,913 (1,883)	6,560 (6,456)
Use per facility			
Average	kg/yr (lb/yr)	10,179 (22,441)	34,897 (76,935)
Range	kg/yr (lb/yr)	1-129,090 (2-284,594)	6-359,400 (13-792,341)
Use per chamber			
Average	kg/yr (lb/yr)	4,737 (10,443)	16,239 (35,801)
Range	kg/yr (lb/yr)	0.1-62,045 (0.2-136,786)	0.1-168,000 (0.2-370,382)

sterilization accounts for only 50 to 60 percent of all sterilization activities.[4] Finally, the diversity and specialization of the industries that sterilize products limit the amount of data available for this profile.

8.4.2 Industry Groups Supplying EO Sterilization Services

Several main categories of facilities sterilize some portion of their output:

1. Medical device suppliers;
2. Other health-related suppliers;
3. Pharmaceutical manufacturers and other drug-related manufacturers;
4. Spice manufacturers and other food-related manufacturers;
5. Museums and libraries;
6. Laboratories (research, testing, and animal breeding); and
7. Contract sterilizers.

Table 8-2 summarizes the specific SIC codes associated with these industry categories and the number of facilities in each. As might be expected from the large number of SIC codes, the 188 sterilization facilities sterilize a wide variety of products. These products include surgical gloves and hypodermic needles sterilized by medical device suppliers, books fumigated by libraries and museums, and spices fumigated by spice manufacturers.

The sterilization processes used by the above industries have several similarities. However, a distinction can be made between in-house sterilization and contract sterilization. A majority of the facilities covered in this profile operate a sterilization chamber at the same location as the remainder of the production process. The exception to this rule is the subset of commercial sterilizers that sterilize products for other companies on a contract basis. Not only do contract sterilizers accept a variety of products for sterilization, but they may also supervise the final distribution of the products. It should be noted that the distinction between these two types of

TABLE 8-2. STANDARD INDUSTRIAL CLASSIFICATION CODES FOR 188 COMMERCIAL STERILIZATION FACILITIES, 1988

SIC Code	No. of facilities	Description of category
Medical device suppliers = 62		
3841	44	Surgical and medical instruments and apparatus
3842	18	Orthopedic, prosthetic, and surgical appliances and supplies
Other health-related suppliers = 24		
3079	7	Miscellaneous plastic products
3693	5	Radiographic X-ray, fluoroscopic X-ray, therapeutic X-ray, and other X-ray apparatus and tubes; electrochemical and electrotherapeutic apparatus
5086	4	Professional equipment and supplies
2211	1	Broad woven fabric mills, cotton
2821	2	Plastics materials, synthetic resins, and nonvulcanizable elastomers
2879	1	Pesticides and agricultural chemicals, NEC
3069	1	General industrial machinery and equipment NEC
3569	1	Electronic coils, transformers, and other inductors
3677	1	Electronic coils, transformers and other inductors
3999	1	Manufacturing industries, NEC
Pharmaceutical manufacturers = 39		
2834	34	Pharmaceutical preparations
5122	2	Drugs, drug proprietaries, and druggist's sundries
2831	2	Biological products
2833	1	Medicinal chemicals and botanical products
Spice manufacturers = 23		
2099	17	Food preparations, NEC
5149	3	Groceries and related products, NEC
2034	1	Dried and dehydrated fruits, vegetables, and soup mixes
2035	1	Pickled fruits and vegetables, vegetable sauces and seasonings, and salad dressings
2046	1	Wet corn milling
Museums and libraries = 13		
8411	11	Museums and art galleries
8231	2	Libraries and information centers
Laboratories = 10		
2790	4	Animal specialties, NEC
7391	2	Research and development labs
8071	1	Medical labs
8922	2	Noncommercial educational, scientific, and research organizations
7397	1	Commercial testing labs
Contract sterilizers = 17		
7399	14	Business services, NEC
7218	1	Industrial launderers
8091	2	Health and allied services, NEC

NEC = Not elsewhere classified.

sterilization is not always well defined. Some facilities, especially those within the medical device suppliers and pharmaceutical industries, sterilize their own products in-house and also accept products on a contract basis from other firms.[8]

8.4.2.1 Medical Device Suppliers. Sterilizers of medical devices (SIC 3841 and 3842) represent the largest single segment of commercial sterilizers covered in this analysis, including 62 of the 188 facilities. The total annual output of medical devices sterilized in the United States is estimated as 15 to 20 billion products, with at least 50 percent of these products sterilized with EO.[1]

Some medical devices must be sterilized to be marketed. Ethylene oxide, especially the 12/88 mixture, is used for medical device sterilization because of its wide range of effectiveness. The FDA has set strict guidelines for medical device sterilizers to ensure that necessary levels of sterility are achieved. These guidelines, called Good Manufacturing Practices (GMP), include requirements for such things as preliminary testing, procedural supervision, quality assurance, and final labeling.[5]

The U.S. medical device supply industry has been changing rapidly because of cost containment measures, increased competition, and changes in the health care system. A trend toward consolidation among both buyers and sellers of medical devices has been evident. Many hospitals have formed buyers' groups or corporate buying arrangements for purchasing supplies. Consolidation has allowed suppliers to increase their efficiency and broaden their product and distribution bases. Declining hospital occupancy and shorter visits have decreased the demand for medical devices from hospitals. At the same time, demand for medical devices from outpatient facilities has experienced strong growth. The number of surgical procedures being performed has been growing, but a larger share of these procedures is being done on an outpatient basis.

Product quality is becoming a major issue in the medical device industry. Under pressure from the FDA and increasing competition, suppliers are striving to improve their

manufacturing processes and products. The surgical and medical instruments industry (SIC 3841) is expected to grow about 7 percent per year (in 1982 dollars) between 1989 and 1993. The surgical appliances and supplies industry (SIC 3842) is projected to grow at an annual rate of 8.5 percent during this time. According to the Census of Manufactures, there were 2,600 establishments in the surgical and medical instruments and surgical appliances and supplies industries (SIC 3841 and 3842) in 1987. Table 8-3 summarizes various statistics for these industries. Product data were collected for all products classified in either SIC 3841 or 3842 that are produced by all industries; industry data represent all facilities classified in either SIC 3841 or 3842, including their output of nonmedical products.[9,10]

The data presented in Table 8-3 reveal several trends within the industry. The total value of shipments for medical device suppliers is given in current dollars and in 1982 dollars. Throughout the 1980's, the industry has shown strong, steady growth. Total employment has risen steadily since 1972, while the proportion of production workers has fallen slightly. In 1988, production workers made up 63 percent of the total work force, as compared with 69 percent in 1972. Growth in foreign markets, along with a lower value of the U.S. dollar relative to other currencies, has allowed U.S. manufacturers to increase exports of medical devices. Manufacturers of surgical and medical instruments (SIC 3841) increased exports by 17 percent between 1987 and 1988. Imports of these products also increased but at a slower rate (13.8 percent), allowing the trade surplus to grow by 29 percent. Exports of surgical appliances and supplies (SIC 3842) grew 25 percent during this time, while imports grew only 5.7 percent. Exports of medical devices are expected to remain high if the U.S. dollar does not appreciate substantially. Although the U.S. has consistently had an overall trade surplus in the medical device industry, it continues to have trade deficits with West Germany and Japan.[9]

TABLE 8-3. RECENT PERFORMANCE AND FORECAST DATA FOR MEDICAL DEVICE SUPPLIERS (SIC 3841 AND 3842)[a-c]

		1972	1975	1980	1985	1986	1987	1988	1989[d]
Product data[e]									
Value of shipments	(10^6 \$)	2,126	3,302	6,185	11,863	12,447	13,383	14,858	NA
Value of shipments	(10^6 1982 \$)	4,435	5,243	6,892	10,828	11,077	12,165	13,213	14,402
Industry data[f]									
Total employment	(10^3 people)	78.4	94.4	113.1	137.7	140.3	139.4	147	NA
Production workers	(10^3 people)	54.1	64.1	75.8	88.5	88	86.5	92.7	NA
Capital expenditures	(10^6 \$)	89.5	157.6	281.0	551.2[h]	471.7[h]	552.7[h]	NA	NA
Value added	(10 \$)[9]	1,559.0[g]	2,240.9[g]	4,077.3[g]	8,503.2[h]	8,954.8[h]	10,619.8[h]	NA	NA
Trade data									
Value of imports[i]	(10^6 \$)	44.2	106.4	268.4	581	785	959	1,069	1,160
Value of exports[i]	(10^6 \$)	217.6	432.0	698.0	1,124	1,275	1,486	1,790	2,060

NA = not available.
[a]Numbers represent the sum of the values of the two industry groups.
[b]Source: Years 1972, 1975, and 1985 are Reference 11 unless otherwise noted.
[c]Source: Years 1985 through 1989 are Reference 12 unless otherwise noted.
[d]Forecast.
[e]Represents products classified in SIC codes 3841 and 3842 produced by all industries.
[f]Represents all facilities classified as SIC 3841 and 3842.
[g]Source: 13.
[h]Source: 10.
[i]Developed by International Trade Administration.

Although a wide range of products is included under the broad category of medical devices, generalizing about the importance of the products is still possible. Medical equipment is a basic part of health care service, which is a necessary service. Therefore, the elasticity of demand for medical devices should be highly inelastic. However, the trends mentioned above (increased price competition among health care facilities and increased use of alternatives to hospitals) may indicate that the demand for medical devices is becoming more elastic. The availability of imports may also increase the elasticity of demand for domestically produced medical devices.

Table 8-4 shows some summary statistics on the sterilization chambers and sterilant gases used by the 62 medical device suppliers included in this study. These 62 facilities operated a total of 145 EO sterilization chambers in 1988, an average of 2.3 per facility. The number of chambers per facility varied from one to eight. Average chamber volume per facility was 40.1 m^3 (1,416.0 ft^3) but covered a wide range from 0.03 m^3 (1.06 ft^3) to 232 m^3 (8,193 ft^3). In 1988, these 62 facilities used 665 Mg (654 tons) of EO, slightly under 11 Mg (10 tons) per facility. Like chamber volume per facility, EO use varied widely from 0.01 Mg (0.01 tons) to 109 Mg (107 tons). Total gas use, which averaged 42 Mg (41 tons) per facility, also covered a wide range; the smallest user reported 0.05 Mg (0.06 tons) and the largest reported 511 Mg (503 tons).[1]

By subtracting EO use from the total gas use, and then dividing by EO use, an inert-gas ratio is obtained. This ratio indicates the extent of reliance on pure EO versus mixed sterilant gases. In particular, a ratio near zero would suggest extensive reliance on pure EO (because EO use and total gas use would be almost identical), but a much higher ratio would indicate greater use of sterilant mixtures, such as 12/88. During 1988, the inert-gas ratio for the 62 medical device suppliers was 2.88.

8.4.2.2 <u>Other Health-Related Suppliers</u>. Twenty-four facilities were included in this study that produce some type of

TABLE 8-4. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 62 MEDICAL DEVICE SUPPLIERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 145			
Number per facility	2.3	1.6	1 - 7
Chamber volume per facility, m^3 (ft^3)	40.1 (1,416.1)	37.9 (1,338.4)	0.03 - 232 (1.06 - 8,193)
Ethylene oxide use = 665.6, Mg/yr (655.1 tons)			
Use per facility, Mg/yr (tons)	10.7 (10.5)	6.9 (6.8)	<0.05 - 109.1 (<0.05 - 107.3)
Total gas use = 2,576.7 Mg/yr (2,536.0 tons)			
Use per facility, Mg/yr (tons)	41.6 (40.9)	76.2 (75.0)	0.05 - 511.2 (0.5 - 503)

health-related supplies but are classified under a more general SIC code (see Table 8-2). For example, five facilities have a primary SIC code that involves the manufacturing of X-ray equipment and nine facilities manufacture various plastic products. The large number of SIC codes illustrates the diversity of industries that sterilize health-related equipment with EO. For this reason, the value of shipments in Table 8-3 was presented on a product basis rather than on an industry basis. No other data specific to the relevant SIC codes will be presented.

Table 8-5 provides some summary statistics on the sterilization chambers and sterilant gas used by the 24 other health-related suppliers included in this study. These 24 facilities operated a total of 53 sterilization chambers in 1988, an average of 2.2 per facility. This is slightly lower than the medical device suppliers group, which averaged 2.3 chambers per facility.

The other health-related suppliers used 276 Mg (271 tons) of EO in 1988. They averaged 11.5 Mg (11.3 tons) of EO per facility, covering a range of 0.002 Mg (0.0022 tons) to 129.0 Mg (127.0 tons). Overall, these facilities used less EO than did the medical device suppliers. However, their EO use per facility and their total gas use per facility are slightly higher than those of medical device suppliers. The inert gas ratio for other health-related suppliers was 2.46.

8.4.2.3 Pharmaceutical Manufacturers. The broad category of pharmaceutical manufacturers includes those facilities whose SIC code was 2831, 2832, 2834, or 5122. These facilities are all connected with pharmaceutical preparations or other medicinal or biological products as manufacturers or, in some cases, as wholesalers. However, a vast majority of the facilities are classified as SIC 2834. Therefore, the profile of pharmaceutical manufacturers is focused on that industry group. Sterilization has a variety of uses in this industry, but it is as closely tied to the ultimate safety and effectiveness of the products as is the medical device industry.

TABLE 8-5. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 24 OTHER HEALTH-RELATED SUPPLIERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 53			
Number per facility	2.2	1.5	1 - 6
Chamber volume per facility, m^3 (ft^3)	41.3 (1,458.5)	58.4 (2,062.4)	0.4 - 207.2 (14.1 - 7,317.2)
Ethylene oxide use = 275.5 Mg/yr (271.2 tons)			
Use per facility, Mg/yr (tons)	11.5 (11.3)	7.07 (6.96)	<0.05 - 129.1 (<0.05 - 127.1)
Total gas use = 952.5 Mg/yr, (937.5 tons)			
Use per facility, Mg/yr (tons))	39.7 (39.1)	51.1 (50.3)	0.05 - 152.2 (0.05-149.8)

The pharmaceutical industry shows several interesting trends. Pharmaceutical companies continue to spend increasing amounts on research and development: they spent $5.4 billion in 1987 and a record $6 billion in 1988. Experts expect that the high cost of research and development will lead to consolidation, especially among small specialty manufacturers. Patent piracy remains a problem for this industry. Manufacturers lost an estimated $2 billion to patent pirates in 1988. Sales of generic drugs will continue to grow as patents on existing drugs expire. Generic drugs currently make up about 12 percent of the prescription market and will probably account for 30 percent by 1993. The pharmaceutical industry also expects strong growth in the market for over-the-counter drugs as more drugs are made available for purchase without a prescription.[9]

The value of pharmaceutical product shipments rose an estimated 2.7 percent (in constant dollars) between 1987 and 1988. The U.S. Department of Commerce predicts that the industry will grow between 2 and 3 percent a year between 1989 and 1993. Factors contributing to this growth will include an increasing demand for drugs by an aging population, greater exports to developing countries, and improved productivity through computerization.[9]

According to the Census Bureau, a total of 718 facilities were classified under SIC code 2834 in 1987. Only 34 have been identified as commercial sterilizers.[10] The pharmaceuticals group, as defined in this chapter, includes five additional facilities from SIC codes 5122, 2831, and 2833. Table 9-6 reports recent performance and forecast data for all pharmaceutical manufacturers classified under SIC code 2834. The data are presented in much the same manner as in Table 8-3, with a distinction between industry and product data.

As shown in Table 8-6, the value of pharmaceutical shipments has increased steadily through the 1980's in both nominal and real terms. Industry employment, after falling in the early 1980's, has shown an upward trend since 1985. Capital expenditures decreased somewhat between 1985 and 1986 but

TABLE 8-6. RECENT PERFORMANCE AND FORECAST DATA FOR PHARMACEUTICAL MANUFACTURERS (SIC 2834)[12]

	1972	1975	1980	1985	1986	1987	1988	1989
Product data								
Value of shipments (10^6 \$)	6,295	8,247	13,012	22,318	24,280	26,898	29,820	NA
Value of shipments (10^6 1982 \$)	12,422	14,202	15,974	17,283	18,836	19,213	19,735	20,290
Industry data								
Total employment (10^3 people)	112.0	123.0	135.0	123.0	124.0	128.0	128.0	129.0
Production workers (10^3 people)	57.0	60.2	68.4	58.4	58.7	59.4	60.7	61.3
Capital expenditures (10^6 \$)	167.0	321.0	675.0	1,171.1[a]	1,057.8[a]	1,470.4[a]	NA	NA
Value added (10^6 \$)	5,640[b]	6,923[b]	11,048[b]	19,095[a]	20,598[a]	23,868[a]	NA	NA
Trade data								
Value of imports[c] (10^6 \$)	14.5	33.9	61.6	216	157	164	202	245
Value of exports[c] (10^6 \$)	182.0	270.0	421.0	691	648	675	840	1,050

NA = Not available.
[a]Source: 10.
[b]Source: 13.
[c]Developed by International Trade Administration.

increased in 1987. In recent years, both imports and exports of pharmaceuticals have been increasing.

Table 8-7 contains some summary statistics on the sterilization chambers and sterilant gas used by the 39 pharmaceutical manufacturers included in this study.[1] These 39 facilities operated a total of 82 sterilization chambers in 1988, averaging 2.1 per facility. The average chamber volume per facility for pharmaceutical manufacturers is 29.2 m^3 (1,031.2 ft^3), with chamber volume ranging from 0.1 m^3 to 147 m^3 (3.5 ft^3 to 5,191 ft^3. Although the number of chambers per facility in the pharmaceuticals group roughly equals the number for the medical device suppliers group, the average chamber volume per facility for pharmaceutical manufacturers is about 70 percent of the average for medical device suppliers.

The pharmaceutical manufacturers used 416 Mg (409 tons) of EO in 1986, averaging 10.7 Mg (10.5 tons) per facility and varying from 0.01 Mg (0.01 tons) per facility to 84 Mg (82.7 tons) per facility. They also used 830 Mg (818.9 tons) of total gas, with an average of 21.3 Mg (21.0 tons) per facility and a range of 0.06 Mg to 92 Mg (0.06 to 90.5 tons) per facility. The ranges of both EO use and total gas use are much narrower for pharmaceutical manufacturers than they are for medical device suppliers. Finally, the inert-gas ratio for pharmaceuticals is 1.00, compared to a 2.88 ratio for the medical device suppliers.

8.4.2.4 Spice Manufacturers. Twenty-three of the 188 facilities in this study have been categorized as spice manufacturers. These firms fall into five SIC codes: 2099, 5149, 2034, 2035, and 2046. However, as shown in Table 8-2, about two-thirds of these firms are in SIC code 2099. Consequently, the discussion below focuses on this industry group.

About one-quarter of all spices manufactured in the United States are treated with EO to control fungi, molds, bacteria, and insect eggs.[14] Ethylene oxide pasteurization increases shelf life and decreases health risks.[14] An industry magazine reports that "since the spice processor cannot preclude or remove

TABLE 8-7. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 39 PHARMACEUTICAL MANUFACTURERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 82			
Number per facility	2.1	1.4	1 - 6
Chamber volume per facility, m^3 (ft^3)	29.2 (1,031.2)	20.0 (706.3)	0.1 - 147.3 (3.5-5,201.9)
Ethylene oxide use = 416.1 Mg/yr (409.6 tons)			
Use per facility, Mg/yr (tons)	10.7 (10.5)	3.12 (3.07)	<0.05 -129.1 (<0.05-127.1)
Total gas use = 830.4 Mg/yr (817.3 tons)			
Use per facility, Mg/yr (tons)	21.3 (21.0)	28.1 (27.7)	0.06 - 92.2 (0.06 - 90.7)

microorganisms from spices, the only means to control microorganisms are: (1) to maintain low moisture content to hinder growth and activity and (2) to treat spices with EO."[15]

Several substitutes within the spice industry are available for EO, each of which has disadvantages. Heat sterilization is useful on only a small number of spices, because it lightens or darkens spice color and can cause a 15-percent loss in spice strength by volatizing spice oils. Neither ionizing radiation nor ethylene imine are approved by the FDA, and their effectiveness is not known. The use of propylene oxide is restricted by the FDA to starches, gums, processed spices, cocoa, and processed nut meats.[14] However, propylene oxide must be heated to be as effective as EO. Using heat restricts its use to a small number of spices because heat volatizes oils in spices, affecting their quality. Without heat, propylene oxide has one-tenth the microbial killing activity of EO. Finally, propylene oxide requires 16 to 48 hours of exposure time, compared to 6 to 8 hours for EO.

According to an industry source, radiation treatment is a promising alternative to EO fumigation, having several advantages over EO.[16] First, although EO kills a high percentage of bacteria, radiation kills all bacteria. Second, EO requires high humidity and a vacuum, while radiation treatment can be done under ambient conditions. Third, EO leaves a residue in all foods that have been treated, but radiation leaves no residues of any kind.

According to the Census Bureau, SIC 2099 had 1,976 firms in 1982.[17] As shown in Table 8-8, the value of shipments for SIC 2099 increased steadily from $3.6 billion in 1972 to $11.0 billion in 1982, a nominal growth of 201 percent over the 10-year period. Value added also increased steadily over the same period rising from $1.8 billion in 1972 to $5.7 billion in 1982. Employment experienced two low periods, one in the mid-1970's and another in the early 1980's. The number of production workers declined in 1975 and again in 1979 and 1980, while total employment declined in 1979 and 1981. Both employment measures

TABLE 8-8. RECENT PERFORMANCE DATA FOR SPICE MANUFACTURERS (SIC 2099)

		1972	1975	1977	1978	1979	1980	1981	1982
Product data									
Value of shipments	(10^6 $)	3,647.9	5,583.8	6,531.0	7,360.6	7,568.9	8,536.5	9,598.9	10,979.3
Industry data									
Total employment	(10^3 people)	66.2	64.3	71.5	76.8	71.8	73.4	72.8	81.4
Production workers	(10^3 people)	44.7	44.2	50.9	55.8	52.3	51.7	52.3	57.9
Capital expenditures	(10^6 $)	91.8	171.3	166.2	199.6	236.0	285.0	208.0	295.4
Value added	10^6 $)	1,805.2	2,431.3	3,028.1	3,487.8	3,493.8	4,038.0	4,569.6	5,663.3

increased from 1981 to 1982. Capital expenditures increased from $91.8 million in 1972 to $295.4 million in 1982 with declining years in 1977 and 1981.

In 1987, the industry definition of SIC 2099 changed. Although spice manufacturers are still included under the new definition, industry figures for 1987 cannot be compared with previous years. Table 8-9 presents the 1987 data for SIC 2099.

The spice and seasoning industry relies heavily on foreign trade. According to one estimate, two-thirds of the spices consumed in the United States are imported.[18] This estimate includes some dehydrated vegetables that are used as seasonings but are not included in the FDA definition of spices.

The 23 firms in the spice manufacturers group that use EO sterilization are distributed evenly across the country, except for a large concentration of seven firms in California.[10,13] Table 8-10 shows some summary statistics on the sterilization chambers and sterilant gas used by these manufacturers.[1] The 23 facilities operated a total of 27 sterilization chambers in 1986, an average of only 1.2 per facility. The number of chambers per facility ranged from one to four. Average chamber volume per facility was 33.1 m^3 (1,168.9 ft^3), which is considerably lower than the average for medical device suppliers of 40.1 m^3 (1,416.1 ft^3). In addition, the range of chamber volumes per facility, 0.1 m^3 to 177 m^3 (3.5 ft^3 to 6,250 ft^3), was narrower for the spice manufacturers. Both average chamber volume per facility and the range of chamber volumes per facility for the spices group were roughly equal to the average range for the pharmaceuticals group. Table 8-10 presents the 1987 data for SIC 2099.

The spice manufacturers used 124 Mg (122 tons) of EO and 287 Mg (282 tons) of total gas during 1986. Annual EO use per facility averaged 5.4 Mg (5.3 tons), while total gas use per facility averaged 12.5 Mg (12.3 tons). Average total gas use per facility is roughly equal to average total gas use for the pharmaceuticals group, but average EO use per facility is about half the average for pharmaceutical manufacturers. The inert-gas

TABLE 8-9. 1987 PERFORMANCE DATA FOR SPICE MANUFACTURES (SIC 2099)

Product data	1987
Value of shipments (10^6 $)	9,815.8
Industry data	
Total employment (10^3 people)	58.1
Production workers (10^3 people)	40.9
Capital expenditures (10^6 $)	248.0
Value added (10^6 $)	5,201.1

TABLE 8-10. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 23 SPICE MANUFACTURERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 27			
Number per facility	1.2	0.6	1 - 4
Chamber volume per facility, m^3 (ft^3)	33.1 (1,168.9)	14.3 (499.4)	0.1 - 177.0 (3.5 - 6,250.7)
Ethylene oxide use = 124.0 Mg/yr (122.0 tons)			
Use per facility, Mg/yr (tons)	5.4 (5.3)	11.2 (11.0)	<0.05 - 40.0 (<0.05-39.4)
Total gas use = 286.6 Mg/yr (282.1 tons)			
Use per facility, Mg/yr (tons)	12.5 (12.0)	14.0 (13.8)	<0.05 - 56.3 (<0.05 - 55.4)

ratio for the spice manufacturers is 1.31, which is comparable to the 2.88 ratio for the medical device suppliers.

8.4.2.5 Museums and Libraries. According to the 1982 Census of Services, the United States has 1,909 non-commercial museums and art galleries (SIC 8411).[17] In addition, the country had 31,524 public and private libraries in 1987. The sterilization data base contains data for 11 museums and 2 libraries. Interestingly, 4 of the 13 are in Massachusetts and none are in the Southeast or Northwest.

Museums and libraries fumigate books, documents, and other artifacts with EO chiefly to control insect pests and mold. Museum experts report that EO is "especially valuable for treatment of books and archival documents, furs, textiles, and furniture."[19] However, EO has one significant drawback as an artifact fumigant: it settles in rubber, leather, wood, and other organic materials, making it necessary for EO-fumigated artifacts to be aerated for up to a month before they are safe to handle.[19,20]

It is recommended that all organic materials be fumigated before they are introduced into a museum or library collection.[19] However, telephone conversations with museum and library conservators who use EO revealed a range of fumigation criteria. Some conservators fumigate all new articles, while others fumigate only those articles that fail a visual inspection or that have suspect backgrounds, such as books that were kept in a damp basement.[21,22]

Ethylene oxide has several substitutes as a fumigant in museum and library use. One possible substitute is sulfuryl fluoride, marketed under the trademark Vikane™. Sulfuryl fluoride is not absorbed by organic materials and dissipates more quickly than EO.[20] Furthermore, the cost of sulfuryl fluoride has generally been comparable to the cost of 12/88, based on retail prices and the recommended doses of each sterilant.[19] Sulfuryl fluoride, however, is toxic at high concentrations. It is also corrosive to metals, making it an unacceptable

alternative for artifacts that contain metal. In particular, it could damage books with staple bindings.[23]

Conversion from EO to sulfuryl fluoride would entail some startup costs. Some EO fumigation chambers would require modifications to use sulfuryl fluoride. Because sulfuryl fluoride is corrosive to metals, the vent pipes from the chamber must be stainless steel; installing these new vent pipes would represent a startup capital cost for museums/libraries converting to sulfuryl fluoride use.[23]

Sulfuryl fluoride is registered with the U.S. Department of Agriculture as a "restricted" pesticide and, therefore, can only be applied by a certified applicator. Certified applicators must pass a test administered by the U.S. Department of Agriculture. Ethylene oxide is not registered as a restricted pesticide and can, therefore, be applied by anyone.[24] The time and effort involved in passing the certified applicator test would represent another startup cost for museums/libraries converting to sulfuryl fluoride. Finally, sulfuryl fluoride is registered for use in fumigation chambers, and presently no regulations control sulfuryl fluoride emissions.[24]

Other alternatives to EO fumigation include deep freezing, CO_2 fumigation, and vacuum treatment. Several European institutions have tested the freezing method and reported that maintaining -18°C (-0.4°F) for 48 hours kills 100 percent of insect life in all stages of the life cycle. Freezers ranging from 0.9 to 1.1 m^3 (31.8 to 40 ft^3) in size are most commonly used.[19] The necessary freezing apparatus costs approximately $3,000 to $4,000.[22] Placing artifacts in a vacuum or fumigating them with carbon dioxide also kills insect life.[21,25] These three methods, however, do not kill mold and fungi; therefore, they are only partial substitutes for EO.

Table 8-11 provides some summary statistics on the sterilization chambers and sterilant gas used by the 11 museums and two libraries included in this study.[1] Each of these 13 facilities operated one sterilization chamber in 1988. These chambers averaged 2.60 m^3 (91.82 ft^3) in volume and ranged from

TABLE 8-11. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 13 MUSEUMS AND LIBRARIES, 1988

	Average	Standard deviation	Range
Sterilization chambers = 13			
Number per facility	1.0	0.0	1 - 1
Chamber volume per facility, m^3 (ft^3)	2.6 (91.8)	3.7 (130.7)	0.5 - 13.7 (17.7 - 483.8)
Ethylene oxide use = 0.20 Mg/yr (0.20 tons/yr)			
Use per facility, Mg/yr (tons))	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 - 0.05 (<0.05 - 0.05)
Total gas use = 1.68 Mg/yr (1.65 tons/yr)			
Use per facility, Mg/yr (tons/yr)	0.1 (0.1)	0.1 (0.1)	<0.05 - 0.4 (<0.05-0.4)

0.5 m^3 to 13.8 m^3 (17.7 ft^3 to 487.3 ft^3). The average chamber volume per facility for this group is roughly one-twentieth the average chamber volume per facility for the medical device suppliers. Additionally, all of the gas use figures are much lower than are the figures for medical device suppliers.[1]

During 1988, the museums and libraries group used a total of 0.20 Mg (0.20 tons) of EO and 1.67 Mg (1.64 tons) of total gas. Medical devices suppliers used over 3,000 times as much EO and over 1,500 times as much total gas as did the museums and libraries group. In addition, gas use per cubic meter of chamber volume was much lower for this group than for any other group. Medical device suppliers used 14 times as much total gas and 22 times as much EO per cubic meter of chamber volume as did the museums and libraries group. Furthermore, this latter group used substantially less EO per cubic meter of chamber volume than any other industry group in this study--12.6 $kg/m^3/yr$ (0.78 $lb/ft^3/yr$), while all other industry groups each used over 200 $kg/m^3/yr$ (12.5 $lb/ft^3/yr$). The inert-gas ratio for the museums and libraries group was 7.40, which suggests that facilities in this group used 12/88 exclusively.

8.4.2.6 Laboratories. Four of the firms being considered for regulation are commercial laboratory rat and mice breeders, which are classified as SIC Code 2790. Animal breeders use EO to sterilize heat-sensitive plastics, heat- and water-sensitive electronic lab equipment, and prepackaged articles required for breeding. These articles include books, phones, optical equipment, meters, microscopes, and face masks.[14]

Some alternatives to EO sterilization for laboratory animal breeding do exist, although each has disadvantages. Pressurized steam damages plastics, electronic equipment, and other heat-/water-sensitive materials. In addition, steam does not permeate prepackaged materials as effectively as EO. Dry heat degrades those heat-sensitive materials that cannot withstand temperatures of 160° to 165°C (320° to 329°F). Another alternative, peracetic acid, is not registered as a pesticide and is considered to be carcinogenic. It is also corrosive to most metals and plastics

and has poor penetrating properties. Glutaraldehyde requires at least 10 hours immersion and cannot be used with prepackaged materials. It poses a recontamination danger from hand manipulations and air and cannot be used for materials that would be damaged by water.[14]

Two noncommercial research organizations, SIC Code 8922, have also been identified as operators of sterilization chambers. These firms use EO in the same manner as the lab animal breeders mentioned above but on a somewhat more limited scale. Ethylene oxide alternatives and disadvantages mentioned for animal breeders also apply here.[14]

The remaining facilities classified as laboratories are two research and development labs (SIC Code 7391), one medical lab (SIC Code 8071), and one commercial testing lab (SIC Code 7397). These firms are considered together because their sterilization practices are similar. In particular, these facilities investigate whether medical devices can be effectively sterilized and yet still function within the human body. Alternatives to EO for these facilities are limited; EO must be used for heat- and moisture-sensitive medical devices and drugs.[14]

Table 8-12 reports some summary statistics on the sterilization chambers and sterilant gas used by the 10 laboratories included in this study.[1] These facilities operated 22 EO sterilization chambers during 1988, an average of 2.2 per facility. The number of chambers per facility ranged from one to five. Average chamber volume per facility was 4.15 m^3 (146.56 ft^3) but varied from 0.05 m^3 to 16.1 m^3 (1.77 ft^3 to 568.57 ft^3) per facility. The laboratories group averaged about the same number of chambers per facility as the medical device suppliers group; however, the laboratories group had a lower average chamber volume per facility than did all other groups (except the museums and libraries group). This comparison suggests that the laboratory group operated smaller chambers than did the other groups (except the museums and libraries group).

The laboratory group used 9.55 Mg (9.40 tons) of EO and 78.1 Mg (76.9 tons) of total gas during 1988. The group average

TABLE 8-12. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 10 LABORATORIES, 1988

	Average	Standard deviation	Range
Sterilization chambers = 22			
Number per facility	2.2	1.6	1 - 5
Chamber volume per facility, m^3 (ft^3)	4.15 (146.56)	4.81 (169.86)	0.5 - 16.1 (17.66-568.57)
Ethylene oxide use = 0.20 Mg/yr (0.20 tons)			
Use per facility, Mg/yr (tons/yr)	0.96 (0.91)	2.57 (2.53)	<0.05 - 8.68 (<0.05 - 8.54)
Total gas use = 1.68 Mg/yr (1.658 tons/yr)			
Use per facility, Mg/yr (tons/yr)	7.8 (7.7)	21.5 (21.2)	<0.05 - 72.3 (<0.05 - 71.2)

of 0.96 Mg (0.94 tons) of EO per facility is roughly equal to the spice manufacturer's use per facility but less than all other groups, excluding museums and libraries. The laboratories also used less total gas per facility, 7.8 Mg/yr (7.7 tons/yr), than did all other groups excluding museums and libraries. The inert gas ratio for laboratories was 7.17.

8.4.2.7 Contract Sterilizers. As mentioned earlier, a subset of sterilization facilities sterilize products on a contract basis. These contract facilities are normally classified under SIC Code 7399 (business services, not elsewhere classified). However, depending on the main type of product sterilized, the facility may fall under another related category. For example, one contract sterilizer works with surgical garments and is classified under SIC Code 7218 (industrial launderers). In addition to the facilities whose primary function is contract sterilization, several facilities that sometimes accept contract work are classified under a different category. These are especially prevalent within the medical device industry.

Reports vary as to the number of contract sterilizers in the United States. One official at the FDA estimated that there are 100 to 125 contract sterilizers of all types (i.e., EO, steam, radiation, etc.). Of these, approximately 60 are EO sterilizers.[26] Another source at the FDA estimated that there are 65 contract sterilizers of medical devices, 18 of which do contract work only.[27] Only 17 of the 188 facilities in this study have been identified as contract sterilizers exclusively; however, an undetermined number of the other facilities also accept contract work.

The price for contract sterilization varies with the type of sterilization performed. The prices for EO contract sterilization are calculated based on the time the product remains in the chambers (length of cycle) and the amount of gas used. The pressure chambers contain a limited amount of space, and the cost to the sterilization firm is the same whether the chamber is completely full or not. Thus, the price per cubic

foot of product sterilized also varies depending on how full the chamber is.

Some contract sterilizers said in telephone conversations that the articles they processed tended to be of awkward shapes and sizes, limiting the number of articles in the sterilization chambers. Other firms processed smaller and denser loads. The prices quoted were those for full chambers and averaged about $0.04 per-cubic meter ($1.30 per-cubic foot).[28]

Typically, sterilizing with 12/88 is more expensive than sterilizing with pure EO. The difference in price between sterilizing with pure EO and with 12/88 is due to the increased amount of gas necessary to sterilize with 12/88.[2] In spite of the higher cost, facilities have used the 12/88 formulation because some products or packaging cannot withstand sterilization with pure EO, as was noted previously. In addition, pure EO is explosive, making worker safety a concern. (Note: However, during the early 1990's many facilities are switching to pure EO because of chlorofluorocarbon (CFC) phase-out regulations.)

One expert on sterilization predicted 30 percent growth in the late 1980's and early 1990's for contract sterilizers.[2] Growth would then continue at a rate of 4 to 5 percent annually. Implicit in this projection is the assumption of no additional Federal regulations in the future. Any new regulations would probably augment the positive growth of contract sterilization, because smaller facilities might cease in-house sterilization operations and begin sending products offsite. [See Section 8.2.1 for further discussion of the possible substitution of contract sterilization for in-house sterilization due to the candidate NESHAP controls on EO emissions.] Indeed, this is already occurring because of CFC regulations.

Table 8-13 contains some summary statistics on the sterilization chambers and sterilant gas used by the 17 contract sterilizers included in this study.[1] These 17 facilities operated 62 EO sterilization chambers in 1988--an average of 3.6 per facility, which is more than any other group in the study. The contract sterilizers also had more chamber volume than any

TABLE 8-13. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 17 CONTRACT STERILIZERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 62			
Number per facility	3.6	2.8	1 - 10
Chamber volume per facility, m^3 (ft^3)	87.1 (3,075.9)	72.6 (2,563.8)	13.8 - 277.5 (487.3 - 9,799.8)
Ethylene oxide use = 336.9 Mg/yr (331.6 tons)			
Use per facility, Mg/yr (tons)	19.8 (19.5)	13.0 (12.8)	1.5 - 97.7 (1.5 - 96.2)
Total gas use = 1,567.6 Mg/yr (1,542.9 tons/yr)			
Use per facility, Mg/yr (tons/yr)	92.2 (90.7)	95.8 (94.3)	10.6 - 359.4 (10.4 - 353.7)

other group, averaging 87.1 m^3 (3,083.0 ft^3) per facility. During 1986, the contract sterilizers used 337 Mg (332 tons) of EO and 1,568 Mg (1,543 tons) of total gas--somewhat more than half the amounts used by the medical device suppliers. However, the contract sterilizers used much more EO and total gas than any other group on a per-facility basis. The inert-gas ratio for contract sterilizers was 3.65, indicating that contract sterilizers fall in the middle of the industry groups regarding their reliance on pure EO. This is not surprising because contract sterilizers service diverse industries with varying sterilization requirements.

8.5 DEMAND FOR ETHYLENE OXIDE STERILIZATION SERVICES

The demanders of EO sterilization services are the facilities that produce (or, in the case of museums and libraries, acquire) the goods that require sterilization. The demand for sterilization arises because sterilization is necessary to ensure the ultimate safety and effectiveness of the object sterilized. Specifically, many products cannot be marketed unless they meet FDA sterilization standards. Medical device suppliers sterilize their products because inadequately sterilized products could cause harmful health effects for users of the devices. Similarly, spice manufacturers sterilize their products because they may otherwise be damaged or contaminated by insects, molds, or bacteria.

The demanders can be separated into two groups. One group demands sterilization of the products they produce and also satisfies their own demand by sterilizing the products in-house. These are the facilities profiled in Sections 8.4.2.1 through 8.4.2.6. The other group of facilities demanding EO sterilization satisfies their demand by using the services of contract sterilizers. We assume that these demanders are facilities in the same industry groups as the facilities that perform in-house EO sterilization. Rather than sterilize their own goods in-house, however, they demand the services of a contract sterilizer.

The market for sterilization services may be viewed as being in equilibrium in the absence of an air emission standard. Demanders of sterilization compare the costs of sterilizing products in-house with the costs of sending their products offsite to a contract sterilizer. Likewise, they compare the costs of the various types of sterilization that can be employed with their products. They select the sterilization technique that minimizes the cost of producing their good or service, including the cost of sterilization. Imposing an air emission standard on EO sterilizers will increase the cost of this type of sterilization relative to other types. It will also increase the cost of producing goods requiring sterilization. The following section analyzes the impact of this relative increase in costs.

8.6 ECONOMIC EFFECTS OF CANDIDATE NESHAP CONTROLS UNDER THREE CONTROL OPTIONS

This section analyzes the economic effects that the candidate NESHAP controls will have on sterilization facilities under three control options.[29] As discussed above, EO has been designated a probable human carcinogen, so EPA has developed three possible control options representing increasing levels of stringency. Imposing controls on EO sterilization will increase the cost of performing this type of sterilization. This increase in sterilization costs will, in turn, increase the cost of producing goods and services in the industry groups that demand sterilization.

In the following sections, the provisions of the three control options are summarized. Then, the theoretical framework for analyzing economic impacts that increase production costs are described. Next, the analytical procedure used to evaluate the impacts of the control options is described, and the empirical results of the analysis are presented.

8.6.1 The Three Control Options

The three control options assessed in this analysis represent increasing levels of stringency of control:

1. Option 1 controls only emissions from the chamber vent and the vacuum pump drain;

2. Option 2 controls these two sources of emissions, plus emissions from the aeration room; and

3. Option 3 controls emissions from the main chamber vent, the vacuum pump drain, the aeration room, and the rear chamber exhaust.

8.6.2 Theoretical Framework for Economic Impact Analysis

The ideal procedures for estimating the economic effects of the proposed NESHAP controls use a framework based on the supply and demand for goods or services in the regulated market. [For a detailed description of this framework, see Chapter 2 in Reference 29.] A market demand curve describes the maximum quantity (per period) of a commodity, Q, that individuals or firms are willing to purchase at various prices, ceterus paribus (all else equal). As shown in Figure 8-1, demand curves slope downward, indicating that consumers are willing to buy more of Q at lower prices than at higher prices. This assumes that all other factors that might influence demand--for example, income, prices of related goods, and tastes or preferences--do not change.

If the market process establishes a price of P_1, consumers will purchase Q_1 of the commodity for a total expenditure equal to OP_1BQ_1. Because a demand curve measures maximum willingness to pay for each unit of a commodity, the total willingness to pay for Q_1 is the entire area $OABQ_1$--total expenditures plus the triangle P_1AB. This triangle, which is the difference between what consumers actually pay and the amount they are willing to pay, is known as consumer surplus. It is a good empirical approximation of the dollar value of the well-being consumers receive from consuming a commodity, over and above what they pay for the commodity.

The other principal construct in our conceptual framework is a market supply curve. A supply curve shows the maximum output (per time period) of a commodity that firms are willing to supply at various prices, ceterus paribus. The upward slope of supply curves (as shown in Figure 8-2) indicates that firms are willing to produce more at higher prices than at lower prices, assuming

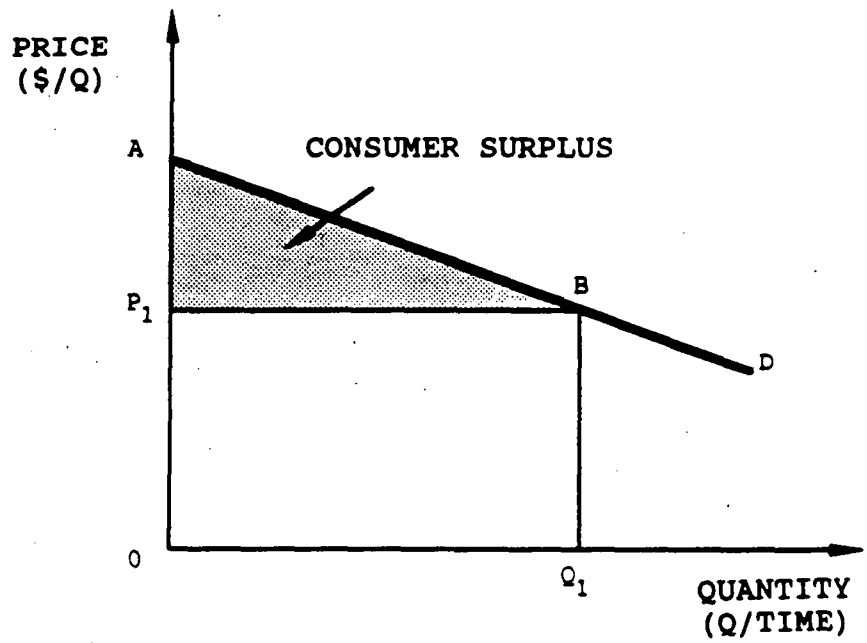

Figure 8-1. Demand curve for Commodity Q.

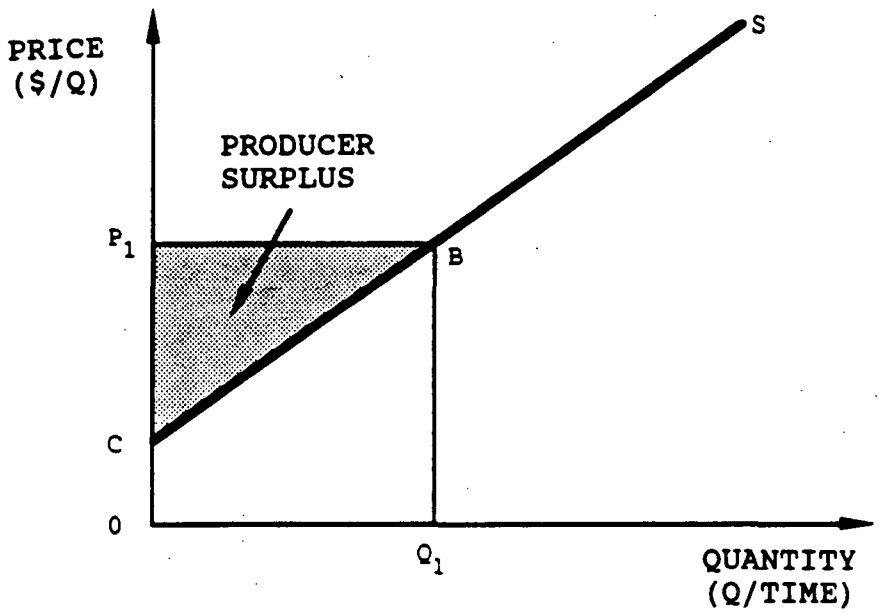

Figure 8-2. Supply curve for Commodity Q.

that other factors influencing the supply curve--prices of inputs (such as labor, energy, and machinery) and production technology--do not change.

If the market process establishes a price of P_1, then suppliers will produce Q_1 units of the commodity, receiving OP_1BQ_1 in total revenues. However, the cost of producing these Q_1 units is represented by the area $OCBQ_1$. The triangle CP_1B, which is known as producer surplus, is the difference between the minimum amount firms would accept for the Q_1 units and the actual amount they receive for these units. Producer surplus is a good empirical approximation of the dollar value of the returns that firms experience from producing a commodity, over and above the costs of production.

Installing and operating controls on EO emissions from sterilization chambers will increase the cost of sterilization. In a demand-supply framework, this additional cost is represented by an upward shift in the supply curve (from S_1 to S_2 in Figure 8-3). This upward shift in the supply curve leads to a higher market price (P_2) and a smaller quantity demanded (Q_2). The changes in price (from P_1 to P_2) and quantity (from Q_1 to Q_2) are market adjustments attributable to the emissions controls.

The cost of this change in market-clearing price and quantity due to the emissions controls is represented by the area CDEB--the area between the two supply curves S_1 and S_2 and under the demand curve. This area, which constitutes the cost that society experiences because of the emissions controls, equals the sum of the additional cost of producing Q_2 units of the commodity (area CDEF) plus the foregone consumer and producer surplus ($Q1 - Q_2$) on the units of the commodity that are no longer produced or consumed (area EFB). Equivalently, the social cost of emissions controls can be determined by aggregating the impact of the controls on the well-being of consumers and producers of affected commodities. In other words, social cost equals the sum of the change in consumer and producer surplus as a result of the price and quantity adjustments.

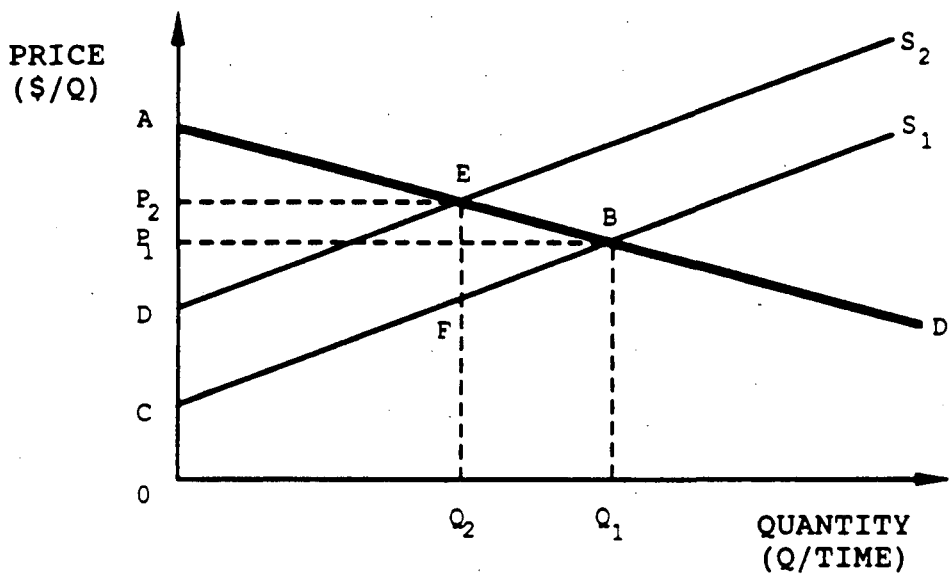

Figure 8-3. Market equilibrium with and without an upward shift in the supply curve due to ethylene oxide emissions controls.

S_1 shows market supply witout EO emissions controls.
S_2 shows market supply with emissions controls.

The simple model in Figure 8-3 ignores two potentially important aspects of the economic impact of the candidate NESHAP control under the three control options. First, the controls will apply both to existing and new plants (when they are constructed) that produce sterilized products. Thus, two supply curves are relevant: a supply curve from existing plants and a supply curve from new plants. The candidate NESHAP controls will shift both of these supply curves upward, although the magnitude of these shifts will probably differ. The potential effects of the candidate NESHAP controls on new facilities are addressed in Section 8.8.2.

Second, this discussion implies that all EO sterilization is offered in a market. In fact, much EO sterilization is performed in-house. In this case, the facility's demand for sterilization services is met by its own supply of sterilization services. These facilities do not generally offer to sterilize products for others on a contract basis, so their services are not part of market supply and have no market price. Only the EO sterilization performed on a contract basis is actually marketed. Therefore, employing the supply and demand framework to analyze the impacts of the regulation is not possible. Rather, because most sterilization takes place in the context of producing some other good or service, the impact of the regulation on the production of those goods and services has been analyzed.

As noted above, imposing air emission controls on EO sterilization increases the cost of sterilization, which in turn increases the cost of producing goods requiring sterilization. The candidate NESHAP controls will probably cause some firms to substitute contract sterilization for in-house sterilization. If the candidate NESHAP controls are promulgated, facilities currently sterilizing in-house using EO will face four possible alternatives:

1. Adopt the candidate controls;
2. Switch to another sterilization process;
3. Discontinue in-house sterilization, switching to contract sterilization; or

4. Discontinue sterilizing or producing the sterilized product.

Undoubtedly, substituting contract sterilization for in-house sterilization (Alternative 3) will be the least-cost alternative for some facilities. Others may choose to switch to another method of sterilization. Finally, some facilities may decide to discontinue sterilization or to stop producing products that require sterilization. Because of a lack of necessary data, no attempts are made to decide which facilities will respond in which way to the candidate NESHAP. [For a detailed explanation of the substitution effect, see Section 8.7.4.]

Contract sterilizers' costs will also be increased by imposing the control options. Their choices of possible responses are limited to three alternatives:

1. Adopt the candidate controls;
2. Switch to another sterilization process; or
3. Discontinue sterilization.

8.6.3 Analytical Procedure

The theoretical framework for analyzing economic impacts involves estimating changes in the market price and quantity sold of a product or service. As noted above, however, in-house sterilization is not marketed. Consequently, using the supply and demand framework to analyze the economic effects of the candidate commercial sterilization NESHAP is not possible. As an alternative, EO sterilization is analyzed within the context of the production of the goods and services requiring sterilization and a more qualitative approach is used that approximates the ideal approach.

This approach has four parts. First, dividing commercial sterilizers into seven industry groups imposes some homogeneity on the facilities. Second, each facility's chamber volume and annual EO use is used as proxies for the quantity of sterilized goods produced. By dividing these proxies into the annual compliance cost under the three control options, rough estimates are obtained of the *per-unit* production cost increase caused by the candidate NESHAP. Third, for each control option, dividing

each facility's annual compliance cost by its total baseline cost of sterilization produces an *upper-bound* for the *percentage* increase in production cost caused by the NESHAP under each control option. Finally, dividing each facility's annual compliance cost under each control option by its total sales produces a *lower-bound* estimate of the percentage production cost increase. Each facility's actual percentage production cost increase attributable to the candidate NESHAP under each control option lies somewhere between its upper- and lower-bound estimates.

8.6.3.1 Industry Grouping. The 188 affected facilities were divided into seven industry groups based on their SIC Code: medical device suppliers, other health-related manufacturers, pharmaceuticals manufacturers, spice manufacturers, museums and libraries, laboratories, and contract sterilizers. The firms within each of these subgroups produce a more homogeneous mix of goods than does the aggregate group. Nevertheless, the product mix is still quite diverse within the industry groups, as is demonstrated in Section 8.1.

8.6.3.2 Chamber Volume as an Output Measure. The sum of the volumes of all sterilization chambers at a facility is one measure of the facility's sterilization capacity. If sterilization cycles for all sizes and types of chambers are of equal duration, then a facility with twice the chamber volume of another facility also have twice the sterilization capacity. If this assumption is not true, then the direct relationship will not hold. For example, if larger chambers undergo longer cycles, then chamber volume will overstate sterilization capacity for large chambers and understate capacity for small chambers. If small chambers undergo longer cycles, then the reverse will hold.

Chamber volume can be used not only as a measure of capacity but also as a measure of output under the following two additional assumptions.

1. All facilities within an industry group perform about the same number of sterilization cycles per year; and

2. The sterilization chambers are always filled with products to approximately the same level.

Under these assumptions, chamber volume would be highly correlated with the volume of goods sterilized.

How valid are these two assumptions? Data from the EPA commercial sterilization data base indicates that facilities do not perform equal numbers of sterilization cycles per chamber, even within industry groups.[1] These data indicate that the first assumption is not true. Therefore, chamber volume may be a poor output measure.

8.6.3.3 <u>EO Use as a Measure of Output.</u> Ethylene oxide use is the second surrogate output measure. The EPA commercial sterilization data base provides data on the amount of EO used per facility during 1986 (1988 or 1985 for some facilities).[1] Ethylene oxide use is a better output measure than chamber volume because EO use varies directly with the volume of goods sterilized, even if firms do not run a consistent number of sterilization cycles per chamber. However, using EO as a measure of the volume of products sterilized requires making the following two assumptions:

1. The concentration of EO per unit of chamber volume is roughly the same for all chambers; and

2. Sterilization chambers are filled with products to roughly the same level for each cycle.

Again, the assumptions necessary for EO use to be a valid measure of output are probably not met. First, the concentration of EO per unit of chamber volume varies depending on the type of gas mixture used. Sterilization with pure EO requires a lower concentration of EO than does sterilization using 12/88. Also, although we have no supporting data, we can speculate that sterilization chambers may not always be filled with products to the same level. Probably facilities running frequent sterilization cycles would always fill their chambers to capacity to minimize costs. However, facilities that sterilize infrequently may run some cycles at less than capacity because they face sporadic orders for sterilized goods and shipment

deadlines. To the extent that this occurs, EO use may overstate the volume of goods sterilized by small-volume sterilizers. If so, this overstatement of facilities' output would make the industry supply curve appear flatter (i.e., more price-elastic) than it actually is.

To this point, a potentially important problem with the output measures has been ignored. As mentioned above, many types of products are sterilized with EO. Chamber volume and EO use are measures of the physical volume of products sterilized, but with such a diverse group of products, volume is not an appropriate measure of output. For example, one facility may sterilize pacemakers while another sterilizes scalpels. Output (in physical or monetary units) per cubic meter of chamber volume will likely differ substantially between pacemakers and scalpels. A similar conclusion seems reasonable regarding EO use as an output measure. In summary, the diversity of products sterilized in the seven industry groups undermines the usefulness of chamber volume and EO use as proxies for facility output.

In addition to measures of total annualized compliance cost (TAC) per unit of output, approximated by the measures described above, two measures are computed that approximate TAC as a percentage of the total baseline cost of producing sterilized products. Ideally, TAC would be reported as a percentage of the total cost of producing sterilized products. However, no data on such costs at the affected facilities are available. Therefore, TAC is reported as a percentage of the total annualized baseline cost of sterilization at a facility (TAC/C) and TAC as a percentage of total facility sales (TAC/S). Because the total cost of producing sterilized products (hereafter referred to as total production cost) equals or exceeds the sterilization cost for any facility, TAC/C is an upper bound for TAC/total production cost. Conversely, total production cost is generally less than or equal to facility sales, particularly because most affected facilities produce a mix of sterilized and unsterilized products. Therefore, TAC/S is a lower bound for TAC/total production cost. The denominators of these two measures,

baseline sterilization costs and facility sales, are described in the following two sections.

8.6.3.4 Baseline Cost of Sterilization. The total annual costs of sterilization for each facility were calculated using a model chamber approach. Specifically, the capital cost and operating cost per cycle are calculated for representative size chambers in the following chamber categories: 12/88, pure EO, nonflammable EO/CO_2, and flammable EO/CO_2. Four representative chamber sizes for the 12/88 gas type were chosen, four for pure EO, three for flammable EO/CO_2, and two for nonflammable EO/CO_2. Representative chamber sizes were selected by first minimizing the total variance between the representative chamber sizes and the sizes of chambers currently in use, as reported in the EPA commercial sterilization data base. Then the selection of representative chamber sizes was finalized by reviewing scatter plots of actual chamber sizes and talking with a vendor of sterilization chambers.

A sterilization chamber vendor provided estimates of capital and operating costs for each model chamber. Capital costs include the cost of the sterilization chamber, the cost of installing the chamber, and the cost of explosion protection equipment for use with flammable sterilant gases. Chamber operating costs include labor, electricity, and sterilant gas costs.

After determining the capital and operating costs for the model chambers, the chambers were divided at the affected facilities into the four gas types outlined above. The operating cost per cycle and capital cost for each chamber were determined by interpolating between the model chambers based on chamber size. Multiplying the operating cost per cycle by the annual number of cycles for the chamber, as reported in the EPA commercial sterilization data base, produced the annual operating cost of the chamber. The capital cost was annualized using a useful life of 10 years and an interest rate of 10 percent, and the annualized capital cost and the annual operating cost were added to obtain the annual sterilization cost for the chamber.

Next, determining the annual baseline cost of sterilization at the facility involved aggregating the annual sterilization costs for individual chambers at each facility. Then, for facilities with controls in place at baseline, the annualized cost of these controls was added. Finally, because the compliance costs are given in last quarter 1987 dollars, the Producers' Price Indices were used for all commodities for 1986 and 1987 to adjust the baseline facility costs from 1986 dollars to 1987 dollars. The costs, therefore, represent 1986 data in 1987 prices.[17]

8.6.3.5 Facility Sales. Total facility sales provide an upper-bound estimate of the total costs of producing sterilized goods for several reasons. First, total sales for a facility include sales of sterilized and unsterilized products. For facilities that sterilize only a small portion of output, total sales may substantially exceed sales of sterilized products. Second, sales reflect the price of final products multiplied by the output of these products. They do not directly measure production costs. In general, sales equal production costs plus producer surplus. Producer surplus is only zero when the supply curve is horizontal or the firm is the marginal firm in its industry; therefore, using sales to measure production costs implies one of these two conditions. If producer surplus is not zero, then total sales will overstate total production costs.

As noted, sales are reported on a facility-specific basis. When a facility did not report its own sales and the parent company sales were available, the amount of sales per employee for the parent company was multiplied by the number of employees at the facility. This calculation assumes that the amount of sales per employee at the parent company and the facility are the same, which would not be true, for example, if the facility were more capital-intensive than the parent company. No information regarding the validity of this assumption is available.

Where neither sales nor employment information was available, estimating facility sales was accomplished by using an ordinary least-squares regression of facility sales on facility EO use. Dummy variables were included to represent the seven

industry groups, and a log-log functional form was used. As with baseline annual sterilization costs, facility sales were adjusted from 1986 dollars to 1987 dollars, using the Producers' Price Indices for all commodities for 1986 and 1987.[17]

8.6.4 Results

As explained in the previous section, the economic analysis was based on the annual cost of complying with the candidate NESHAP controls under each of three control options. The three control options represent increasing levels of stringency of control, as described in Section 8.6.1. The control costs under each control option are evaluated relative to chamber volume, EO use, total baseline sterilization costs, and total facility sales. The summary statistics on these values are presented in this section.

8.6.4.1 Total Annualized Cost (TAC). Total annualized cost measures the annual engineering cost of compliance with the candidate NESHAP controls under each of the three control options, as described in Chapter 7 of the Background Information Document. Total annualized cost under Option 1 equals the capital cost of an acid water scrubber and other necessary hardware annualized over a 10-year period at an interest rate of 10 percent, plus annual operating costs for the scrubber, including labor, materials, and ethylene glycol disposal costs. Electric and water costs for scrubber operation were assumed to be insignificant and are not included. Emissions from the vacuum pump drain were assumed to be controlled using a water-sealed vacuum pump(s) with closed-loop recirculation and a liquid-gas separator. Costs for these were estimated, as were costs for the piping for manifolding the chambers at a facility to the existing control device or to a scrubber.[30]

The total annualized compliance costs under Option 2 include the costs described under Option 1 plus the additional costs of controlling the emissions from the chamber in which the product is aerated. For the cost analysis, it was assumed that a facility could use insulated shipping containers as modular aeration units, replacing all existing aeration processes

conducted in aeration rooms over 84 cubic meters. For these facilities, the number of modular units needed was estimated as were the costs for purchasing and installing these units. Costs were assessed for both catalytic oxidation units and gas/solid reactant systems that might be used to control the emissions, for any manifolding required, and for materials, labor, and other operating costs. The least costly approach, a gas/solid reactant system, was selected for the impact analysis.[31]

Finally, the total annualized compliance cost under Option 3 includes the compliance costs under Option 2 plus, for those facilities with rear chamber exhausts on some or all of their chambers, the costs of controlling the emissions from that source. Facilities with total sterilizer volumes less than 7 m^3 probably do not have rear chamber exhausts and therefore were not included in this cost analysis.[32] Several control methods were considered for rear chamber exhaust emissions, including installing dedicated scrubbers and manifolding the rear chamber exhaust emissions to the aeration room control. This impact analysis used the least costly method, the dedicated add-on scrubbers.

Table 8-14 reports the median and range of TAC per facility for each of the seven industry groups under each control option and includes only facilities incurring positive total annual compliance costs. As shown in Table 8-15, under Option 1, 29 facilities do not incur compliance costs. Under Option 2, only two facilities escape compliance costs, and under Option 3, all facilities but one incur at least some compliance cost.

Under Option 1, the median TAC's range from $8,400 to $44,000. The highest median TAC, $44,000, is incurred by contract sterilizers. Spice manufacturers experience the second highest median TAC, $35,000. Other industries with relatively high TAC's are other health-related manufacturers (median TAC of $31,900) and medical device suppliers (median TAC of $28,000).

A medical device supplier incurs the maximum TAC of any facility--$128,000. Other industry groups having individual

TABLE 8-14. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS[a] [b]

Industry group	Option 1		Option 2		Option 3	
	Median, $\$10^3$	Range, $\$10^3$	Median, $\$10^3$	Range, $\$10^3$	Median, $\$10^3$	Range, $\$10^3$
Miscellaneous/laboratories	13.5	8.3 - 38.2	22.8	17.6 - 61.5	22.8	17.6 - 90.4
Spice manufacturers	35.0	8.3 - 71.6	47.1	17.6 - 90.7	65.8	17.6 - 109.6
Pharmaceuticals manufacturers	23.8	2.5 - 106.0	35.2	9.3 - 180.4	52.6	17.6 - 211.1
Other health-related	31.9	8.3 - 75.6	47.1	17.6 - 206.6	65.5	17.6 - 238.4
Medical equipment suppliers	28.0	0.6 - 128.0	38.6	9.3 - 240.0	55.4	17.6 - 271.7
Contract sterilizers	44.0	26.4 - 104.0	63.1	39.4 - 210.0	89.5	58.8 - 240.8
Museums and libraries	8.4	8.3 - 29.5	17.7	17.6 - 38.8	17.7	17.6 - 57.5

[a]Total annual compliance cost is "cumulative" in the sense that the TAC under Option 2 equals the TAC under Option 1 plus the incremental annualized compliance costs associated with Option 2, and the TAC under Option 3 equals the TAC under Option 2 plus the incremental annualized compliance costs associated with Option 3.

[b]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. See Table 9-15 for the total number of facilities in each industry group and the number incurring no compliance costs as a result of each control option.

TABLE 8-15. COUNT OF FACILITIES HAVING POSITIVE AND ZERO CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS[a]

Industry group	Option 1		Option 2		Option 3	
	TAC=0	TAC > 0	TAC = 0	TAC > 0	TAC = 0	TAC > 0
Miscellaneous/laboratories	0	10	0	10	0	10
Spice manufacturers	4	19	0	23	0	23
Pharmaceuticals manufacturers	3	36	1	38	1	38
Other health-related	3	21	1	23	0	24
Medical equipment suppliers	13	49	0	62	0	62
Contract sterilizers	6	11	0	17	0	17
Museums and libraries	0	13	0	13	0	13

[a]Total annual compliance cost is "cumulative" in the sense that the TAC under Option 2 equals the TAC under Option 1 plus the incremental annualized compliance costs associated with Option 2, and the TAC under Option 3 equals the TAC under Option 2 plus the incremental annualized compliance costs associated with Option 3.

facilities that experience high TAC's include pharmaceutical manufacturers, with a maximum TAC of $106,000, and contract sterilizers, with a maximum TAC of $104,000.

At the same time, facilities in six of the seven industry groups do not incur compliance costs under Option 1 (see Table 8-15). These are facilities that already have the required controls in place. Under Option 1, the lowest positive TAC for an affected facility is a medical device supplier, with a TAC of $600. The lowest TAC for an affected contract sterilizer, on the other hand, is a relatively high $26,400.

Under Option 2, the median TAC ranges from $17,700 for museums and libraries to $63,100 for contract sterilizers. Also experiencing relatively high median TAC under Option 2 are spice manufacturers and other health-related manufacturers, each with a median TAC of $47,100. Under this control option, the highest TAC facility is again a medical device supplier, with a TAC of $240,000. Contract sterilizers and other health-related manufacturers also have facilities with TAC's over $200,000. The lowest cost-controlled facilities, each with a TAC of $9,300 under Option 2, are found in the pharmaceuticals manufacturers and medical device suppliers groups.

Finally, under Option 3, facilities with a chamber fitted with rear chamber exhausts incur incremental control costs, compared to Option 2. The highest median TAC, again for contract sterilizers, rises to $89,500. Spice manufacturers and other health-related manufacturers incur a median TAC under Option 3 of $65,800 and $65,500, respectively. Museums and libraries, on the other hand, incur a median TAC of only $17,700 under Option 3. The maximum value for a TAC is incurred by a medical device supplier: $271,700. Pharmaceuticals manufacturers, other health-related manufacturers, and contract sterilizers also contain facilities that incur a TAC over $200,000 under Option 3. The highest TAC experienced by a museum or library, on the other hand, is only $57,500 even under Option 3.

8.6.4.2 <u>TAC Relative to Chamber Volume.</u> Table 8-16 reports the median and range of total annualized costs per cubic meter of

TABLE 8-16. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER CUBIC METER OF FACILITY CHAMBER VOLUME, FOR AFFECTED INDUSTRY GROUPS[a]

Industry group	Option 1		Option 2		Option 3	
	Median, $\$10^3/M^3$ ($\$10^3/ft^3$)	Range, $10^3/M^3$ ($\$10^3/ft^3$)	Median, $\$10^3/M^3$ ($\$10^3/ft^3$)	Range, $\$103/M^3$ ($\$10^3/ft^3$)	Median, $\$10^3/M^3$ ($\$10^3/ft^3$)	Range, $\$10^3/M^3$ ($\$10^3/ft^3$)
Miscellaneous/laboratories	6.4 (226.0)	2.4 - 293.8 (84.8 - 10,375.5)	10.4 (367.3)	3.8 - 622.2 (134.2 - 21,972.8)	10.4 (367.3)	5.6 - 622.2 (197.8 - 21,972.8)
Spice manufacturers	2.0 (70.6)	0.4 - 97.9 (14.1 - 3,457.3)	2.7 (95.3)	0.2 - 207.4 (7.1 - 7324.2)	3.8 (134.2)	0.5 - 207.4 (17.7 - 7,324.2)
Pharmaceuticals manufacturers	3.0 (105.9)	0.0 - 59.2 (0.0 - 2,090.6)	4.0 (141.3)	0.4 - 124.9 (14.1 - 4,410.8)	5.6 (197.8)	0.7 - 124.9 (24.7 - 4,410.8)
Other health-related	1.8 (63.6)	0.6 - 21.0 (21.2 - 741.6)	2.3 (81.2)	0.2 - 44.4 (7.1 - 1,568.0)	3.0 (105.9)	0.3 - 44.4 (10.5 - 1,568.0)
Medical device suppliers	2.3 (81.2)	0.0 - 297.7 (0.0 - 10,513.2)	2.6 (91.8)	0.1 - 626.1 (3.5 - 22,110.5)	4.1 (144.8)	0.3 - 626.1 (10.5 - 22,100.5)
Contract sterilizers	1.5 (53.0)	0.7 - 2.3 (24.7 - 81.2)	1.6 (56.5)	0.2 - 3.5 (7.1 -123.6)	1.8 (63.6)	0.3 - 4.3 (10.5 - 151.9)
Museums and libraries	8.2 (289.6)	2.1 - 16.4 (74.2 - 579.2)	17.4 (614.5)	2.8 - 34.7 (98.9 - 1,225.4)	17.4 (614.4)	4.2 - 34.7 (148.3 - 1,225.4

[a]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have positive TAC, but the TAC/CV is less than 0.05 percent.

chamber volume per facility (TAC/CV) under each of the control options. Under all three control options, the highest medians are experienced by the museums and libraries group of facilities, while the laboratories industry group contains the highest single value of TAC/CV. These two industries incur relatively low compliance costs, but they also have extremely low chamber volume. Thus, their TAC/CV is high. Under Option 1, museums and libraries have a median TAC/CV of \$8,200/m^3 (\$289,581/ft^3), while laboratory facilities incur a median TAC/CV of \$6,400/m^3 (\$2,260,142/ft^3). Four of the other five industry groups experience median values for TAC/CV of \$2,200/m^3 (\$77,692/ft^3) or less. The maximum TAC/CV under Option 1 is experienced by a medical device supplier: \$297,700/m^3 (\$10,513,194/ft^3).

Under Options 2 and 3, the median TAC/CV for the museums and libraries group increases to \$17,400/m^3 (\$614,476/ft^3), while the median TAC/CV experienced by the laboratories group is \$10,400/m^3 (\$367,273/ft^3). The highest single TAC/CV is again experienced by a medical device supplier: \$626,100/m^3 (\$22,107,018/ft^3). Finally, under Option 3, the museums and libraries group again experiences a median of \$17,400 (\$614,476/ft^3) and the maximum again is \$626,100 (\$22,110,549/ft^3), experienced by a medical device supplier.

8.6.4.3 <u>TAC Relative to EO Use.</u> Table 8-17 shows summary statistics for total annualized compliance cost per metric ton of facility EO use (TAC/EO) under each of the three control options. As with TAC/CV, the museums and libraries and the laboratories incur the largest impacts, when measured by TAC/EO. As with TAC/CV, these facilities' relatively low compliance costs combine with extremely low EO use to yield high TAC/EO values. Under Option 1, the median TAC/EO incurred by the museum and library facilities is \$1,216,100/Mg (\$1,196,894/ton). The median experienced by the laboratories group of facilities is \$163,100/Mg (\$160,524/ton). The other five industry groups experience much lower median TAC/EO, ranging from \$8,100/Mg (\$7,972/ton) for contract sterilizers to \$31,100/Mg (\$30,609/ton) for spice manufacturers. The maximum TAC/EO experienced by any

TABLE 8-17. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER METRIC TON OF ETHYLENE OXIDE USED BY FACILITY, FOR AFFECTED INDUSTRY GROUPS[3,a]

Industry group	Option 1		Option 2		Option 3	
	Median, $\$10^3$/Mg ($\$10^3/ft^3$)	Range, 10^3/Mg ($\$10^3/ft^3$)	Median, $\$10^3$/Mg ($\$10^3/ft^3$)	Range, $\$10^3$/Mg ($\$10^3/ft^3$)	Median, $\$10^3$/Mg ($\$10^3/ft^3$)	Range, $\$10^3$/Mg ($\$10^3/ft^3$)
Miscellaneous/laboratories	163.1 (160.5)	4.4 - 3,050.7 (4.3 - 3,002.5)	240.0 (236.2)	7.1 - 6,460.7 (7.0 - 6,358.7)	292.7 (288.1)	10.4 - 6,460.7 (10.2 - 6,358.7)
Spice manufacturers	31.1 (30.6)	7.0 - 2,033.8 (6.9 - 2,001.7)	28.3 (27.9)	1.8 - 4,307.1 (1.8 - 4,239.0)	37.6 (37.0)	2.4 - 4,307.1 (2.4 - 4,239.1)
Pharmaceuticals manufacturers	18.3 (18.0)	0.0 - 1,076.7 (0.0 - 1,059.7)	19.8 (19.5)	1.1 - 2,280.2 (1.1 - 2,244.2)	26.9 (26.5)	1.7 - 2,280.2 (1.7 - 2,244.2)
Other health-related	11.0 (10.8)	0.6 - 3,660.8 (.59 - 3,603.0)	14.3 (14.1)	1.6 - 7,752.8 (1.6 - 7,630.4)	16.8 (16.5)	1.8 - 7,752.8 (1.8 - 7,630.4)
Medical device suppliers	12.4 (8.0)	0.0 - 1,525.3 (0.0 - 1,501.2)	13.2 (13.0)	1.2 - 3,230.3 (1.2 - 3,179.3)	19.5 (19.2)	2.0 - 3,230.3 (2.0 - 3,179.3)
Contract sterilizers	8.1 (8.0)	1.1 - 20.9 (1.1 - 20.6)	6.1 (6.0)	2.0 - 39.1 (2.0 - 38.5)	7.3 (7.2)	2.5 - 54.4 (2.5 - 53.5)
Museums and libraries	1,216.1 (1,196.9)	183.0 - 9,152 (180.1 - 9,007.5)	2,352.8 (2,315.6)	385.5 - 19,382 (379.4 - 19,076.0)	2,352.8 (2,315.6)	38.5 - 19,382 (37.9 - 19,076)

[a]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/EO is less than 0.05 percent.

facility under Option 1 is $9,152,000/Mg ($9,007,458/ton), experienced by a museum and library facility. Other industry groups reveal maximum TAC/EO values ranging from $20,900/Mg ($20,576/ton) for contract sterilizers to $3,660,800/Mg (3,604,048/ton) for other health-related manufacturing. The minimum TAC/EO is $0 for six of the seven industry groups under Option 1 but is $183,000/Mg ($180,110/ton) for the museums and libraries group.

Under Options 2 and 3, the same basic pattern is evident. The highest median TAC/EO is experienced by the museums and libraries industry, $2,352,800/Mg ($2,315,641/ton) under both control options. The second highest median TAC/EO under Options 2 and 3 is experienced by the laboratories industry group: $240,000/Mg ($236,210/ton) under Option 2 and $292,700/Mg ($288,077/ton) under Option 3. The maximum TAC/EO value for any facility is experienced by a museum and library facility, $19,382,000/Mg ($19,075,890/ton) under both control options. Maximum TAC/EO values for other industry groups range from $39,100/Mg ($35,530/ton) for contract sterilizers to $7,752,800/Mg ($7,630.356/ton) for other health-related manufacturing groups under Option 2 and from $54,400/Mg ($53,541/ton) for contract sterilizers to $7,752,800/Mg ($7,630,356/ton) for other health-related manufacturing groups under Option 3.

8.6.4.4 <u>TAC Relative to Baseline Annual Sterilization Cost</u>. Table 8-18 reports the medians and ranges of total annualized compliance cost as a percentage of baseline annual sterilization costs (TAC/C) under the three control options. As mentioned above, TAC/C represents an upper-bound estimate of TAC relative to total production cost, the desired impact measure.

Under Option 1, the median values for TAC/C range from 16.0 percent for medical device suppliers to 48.3 percent for museums and libraries. The second highest median TAC/C for Option 1 is 44.7 percent, experienced by spice manufacturers. The laboratories industry group has a median TAC/C of 27.6 percent, while contract sterilizers have a median TAC/C of

TABLE 8-18. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF BASELINE ANNUAL STERILIZATION COSTS, FOR AFFECTED INDUSTRY GROUPS[a] [b]

Industry group	Option 1		Option 2		Option 3	
	Median, %	Range, %	Median, %	Range, %	Median, %	Range, %
Miscellaneous/laboratories	27.6	3.2 - 67.4	46.0	5.2 - 101.4	56.0	7.6 - 142.3
Spice manufacturers	44.7	18.8 - 118.1	52.3	1.9 - 144.9	68.4	4.0 - 198.8
Pharmaceuticals manufacturers	20.2	0.4 - 117.2	31.6	2.5 - 166.7	40.1	7.9 - 182.0
Other health related	20.4	1.0 - 45.0	19.1	1.3 - 95.3	25.5	1.1 - 95.3
Medical device suppliers	16.0	0.1 - 83.3	16.6	1.3 - 118.6	24.4	2.0 - 177.8
Contract sterilizers	16.3	4.5 - 78.6	10.9	1.2 - 63.4	13.8	2.0 - 91.8
Museums and libraries	48.3	11.4 - 115.8	100.4	24.1 - 152.4	100.4	24.1 - 225.8

[a]Baseline annual sterilization costs include annual operating costs, annualized capital costs, and annualized costs of any emissions controls present at baseline. Baseline costs represent 1986 data adjusted from 1986 dollars to 1987 dollars using the Producers' Price Indices for all commodities for 1986 and 1987.

[b]Including only facilities with positive compliance costs. This includes 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/C is less than 0.05 percent.

20.2 percent under Option 1. Other health-related manufacturers have a median TAC/C of 20.4 percent, while contract sterilizers have a median TAC/C of 16.3 percent. Although some facilities in six of the seven industry groups experience no compliance cost under Option 1, other facilities experience TAC/C as high as 118.1 percent. This maximum TAC/C is incurred by a spice manufacturing facility. Other facilities with TAC/C over 100 percent are found in the pharmaceuticals manufacturing industry (maximum TAC/C of 117.2 percent) and museums and libraries (maximum TAC/C of 115.8 percent).

Under Options 2 and 3, the median facility in the museums and libraries industry experiences sterilization costs doubled by the controls (TAC/C of 100.4 percent). The median TAC/C for the other six industry groups ranges from 10.9 percent for contract sterilizers to 52.3 percent for spice manufacturers under Option 2, and from 13.8 percent for contract sterilizers to 68.4 percent for spice manufacturers under Option 3.

The highest TAC/C for any facility under Option 2 is 166.7 percent, experienced by a pharmaceuticals manufacturer. Other high TAC/C facilities are found in the museums and libraries group (152.4 percent) and the spice manufacturing group (144.9 percent). Even in the contract sterilizer industry, one facility experiences a TAC/C of 63.4 percent. Under Option 3, the maximum impacts range from 91.8 percent for contract sterilizers to 225.8 percent for museums and libraries, and four of the seven industry groups have facilities that experience 177 percent TAC/C values, or higher. The lowest TAC/C facilities in six of the seven industry groups incur TAC/C less than 8 percent under Options 2 and 3, but the lowest TAC/C facility in the museums and libraries group has a value of 24.1 percent under both Options 2 and 3.

The relatively low TAC/CV, TAC/EO, and TAC/C for the contract sterilizers under all three control options support the hypothesis that the contract sterilizers may experience economies of scale in controlling EO emissions. In other words, the candidate NESHAP controls may cause lower per-unit increases in

production costs for contract sterilizers than for facilities in the other groups.

8.6.4.5 TAC Relative to Total Facility Sales. Table 8-19 reports the total annualized compliance cost as a percentage of total annual facility sales (TAC/S) under the three control options. As described above, this measure represents the lower-bound estimate of total annualized compliance cost as a percentage of total annual baseline production cost.

Under Option 1, the median TAC/S values range from less than 0.1 percent (for museums and libraries and pharmaceuticals manufacturers) to 2.0 percent for contract sterilizers. The highest TAC/S under Option 1 is experienced by a contract sterilizer: 12.8 percent. Medical equipment suppliers have the next highest maximum TAC/S under Option 1. One medical device supplier experiences a TAC/S of 5.5 percent. The maximum TAC/S for the other industry groups ranges from 1.6 percent, for the other-health-related-and-miscellaneous-and-libraries groups, to 4.2 percent for museums and libraries.

Under Option 2, the contract sterilizers have a median TAC/S of 3.9 percent, while all other industry groups experience median TAC/S values between 0.0 percent and 0.5 percent. The maximum TAC/S incurred under Option 2 is again a contract sterilizer. For this facility, TAC represents 25.9 percent of annual sales under Option 2. The maximum TAC/S values experienced by other industry groups range from 2.3 percent, for other health-related manufacturers, to 8.8 percent, for museums and libraries.

Under Option 3, the median TAC/S for contract sterilizers rises to 4.6 percent. Again, all the other industry groups have median TAC/S values less than one percent. The highest maximum value is again a contract sterilizer, which incurs TAC/S of 29.7 percent. Industry maximums for TAC/S for the other six industry groups range from 3.0 percent to 9.6 percent.

8.7 EFFECTS OF THE REGULATION ON SMALL BUSINESSES

8.7.1 Requirements of the Regulatory Flexibility Act

The Regulatory Flexibility Act requires the awareness and consideration of small entities as regulations are being

TABLE 8-19. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF ANNUAL FACILITY SALES, FOR AFFECTED INDUSTRY GROUPS[a b d]

Industry group	Option 1		Option 2		Option 3	
	Median, %	Range, %	Median, %	Range, %	Median, %	Range, %
Miscellaneous/laboratories	0.1	0.0 - 1.6	0.2	0.0 - 2.6	0.2	0.0 - 3.8
Spice manufacturers	0.4	0.0 - 2.7	0.5	0.0 - 6.2	0.7	0.0 - 8.0
Pharmaceuticals manufacturers	0.0	0.0 - 3.2	0.1	0.0 - 4.6	0.1	0.0 - 4.6
Other health related	0.2	0.0 - 1.6	0.3	0.0 - 2.3	0.4	0.0 - 3.0
Medical device suppliers	0.1	0.0 - 5.5	0.1	0.0 - 6.9	0.2	0.0 - 9.6
Contract sterilizers	2.0	0.3 - 12.8	3.9	0.3 - 25.9	4.6	0.5 - 29.7
Museums and libraries[c]	0.0	0.0 - 4.2	0.0	0.0 - 8.8	0.0	0.0 - 8.8

[a]Facility sales amounts represent 1986 data adjusted from 1986 dollars to 1987 dollars using the Producers' Price Indices for all commodities for the years 1986 and 1987.
[b]Some facility sales figures were unavailable and were estimated using parent company sales or a regression of facility sales on EO use.
[c]Rather than facility sale, operating budgets were estimated for each facility in this group.
[d]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/S is less than 0.05 percent.

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developed. The RFA requires a determination of whether there is a "significant economic impact" on a "substantial number" of small entities. The EPA has issued RFA guidelines containing the following criteria for use in determining what is a significant economic impact:

1. Annualized compliance costs increase total cost of production by more than 5 percent;

2. Compliance costs as a percentage of sales for small plants are at least 10 percentage points higher than for large plants;

3. Capital costs of compliance represent a significant portion of capital available to small entities; and

4. The requirements of the regulation are likely to result in closures of small entities.

Normally, a substantial number of small entities are said to incur significant impacts, if at least 20 percent of the small entities experiencing increased costs as a result of the regulation meet the above criteria. However, even if 20 percent of affected small entities meet the above criteria, if that 20 percent represents only a very small absolute number of affected entities, a substantial number of affected small entities do <u>not</u> incur significant impacts.

8.7.2 <u>Small Businesses Performing Ethylene Oxide Sterilization</u>

Because EO sterilization is the major line of business for contract sterilizers, these firms will probably incur relatively large impacts. In the other industry groups, EO sterilization is only one of many operations performed in the course of producing another good or service. For most of these firms, EO sterilization represents a small share of their total production costs. Therefore, firms in these sectors are not expected to incur significant economic impacts. In addition, in many of the other sectors, firms performing EO sterilization are larger than those in the contract sterilizer sector. For these reasons, the contract sterilizer sector's impacts and firm sizes were first examined in detail. Then, small business impacts were considered in the other industry groups.

8.7.3 Small Businesses in the Contract Sterilizer Industry Group

Firms in the contract sterilizer sector are considered small if they have annual sales of less than $3.5 million. Nine of the 17 facilities included in the contract sterilizer industry group were contacted to obtain information on facility sales and credit availability and cost, to characterize the contract sterilizers' clients, and to investigate the possibility of substituting other sterilization techniques for EO sterilization. Of the nine, eight responded, with one of the eight indicating that it no longer used EO. Additional information about firm sales was obtained from Dun and Bradstreet's "Dun's Market Identifiers."

As expected, many of the contract sterilizers are small. Based on sales information obtained from the facilities or from Dun and Bradstreet where available, and on our sales estimates when no data are available from the other sources, 12 of the remaining 16 facilities in the contract sterilizer sector still performing EO sterilization are small. To estimate the increase in total production costs for these small businesses, baseline sterilization costs were used as a proxy for total production cost. This yields a conservative estimate of the total production cost increase. Under control Option 1, eight of the 12 small businesses are expected to incur compliance costs exceeding 5 percent of baseline sterilization costs. Under control Option 2 and 3, 11 of 12 are expected to incur compliance costs exceeding five percent of baseline sterilization costs.

Initially, therefore, a substantial number of small entities may be significantly affected by the regulation. In talking to the facilities, however, several things were discovered that will mitigate the severity of the impacts. First, some of the facilities contacted indicated that EO sterilization is only a part of their business. Several mentioned that they also offer other types of sterilization and that they are encouraging their customers to substitute these other types for EO wherever possible. Thus, even if the facilities stopped offering EO sterilization, they might not close. Secondly, and potentially more importantly, six of the eight facilities contacted indicated

that if their client industries were also regulated, they expected demand for their services to increase. Their estimates for the increases in their business ranged from 20 percent to 200 percent.

Because of the relatively lower per-unit compliance costs incurred by contract sterilizers, some facilities currently sterilizing in-house will probably choose, as a result of the regulation, to stop sterilizing in-house and substitute contract sterilization. If such a substitution occurs, then both the revenues and the costs of contract sterilizers may increase as a result of the regulation, and revenues may increase by more than costs. The following section discusses substituting contract for in-house sterilization in more detail.

8.7.4 Substitution of Contract Sterilization for In-House Sterilization

As discussed above, EO sterilization is performed in-house by facilities that specialize in producing other goods or services, of which sterilization is a small but necessary part, and by contract sterilizers who specialize in sterilizing goods for other producers. In this analysis, in-house sterilization is performed by medical device suppliers, spice manufacturers, pharmaceuticals manufacturers, other health-related manufacturers, laboratories, and museums and libraries.

The cost of using contract sterilization includes some additional costs not experienced in in-house sterilization. These additional costs include the cost of transporting the products to and from the contract sterilizer, the inventory cost of products while in transit, the reliability and negotiation costs of dealing with an outside supplier, and the cost of products damaged or not properly sterilized. These are referred to as transactions costs. The per-unit cost of actually performing the sterilization is expected to be lower for contract sterilizers because their higher volume enables them to take advantage of economies of scale.

Figure 8-4 shows the market for contract sterilization prior to the regulation. Because in-house sterilization is demanded by

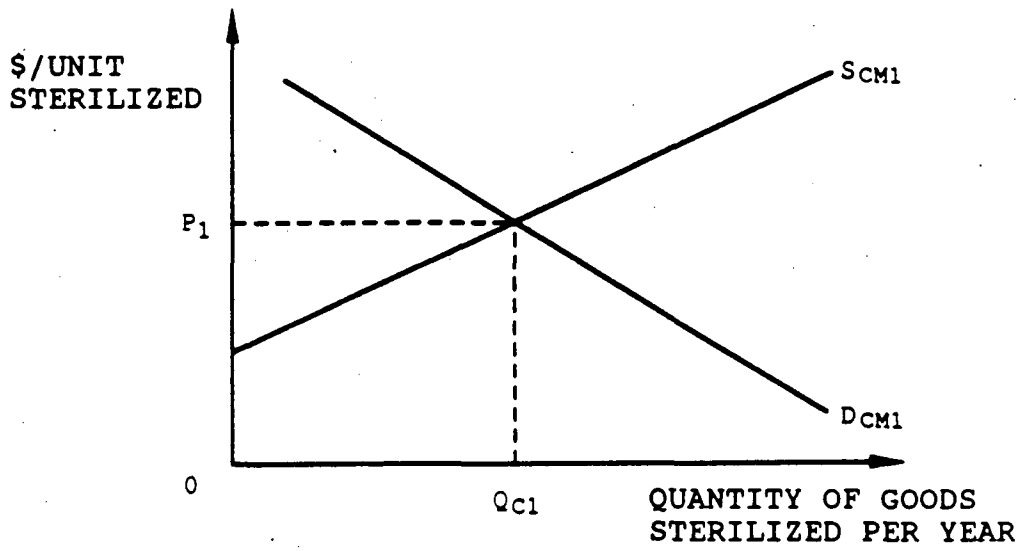

Figure 8-4. The market for contract sterilization without the air emission standard in place.

the same facility that performs it, in-house sterilization services are not marketed, so in-house services have no market price. Facilities that produce goods that need sterilization compare the cost of sterilizing them in-house with the cost of using a contract sterilizer, including the transactions costs described above. Without the air emissions standard in place, the market for contract sterilization services is in equilibrium at a price P_1. At this price, producers of Q_{C1} goods requiring sterilization have found that the cost of sterilizing them in-house exceeds the cost of using a contract sterilizer, including the transactions costs, and have chosen to substitute contract sterilization for in-house sterilization.

Imposing emissions controls on EO sterilizers will increase the marginal costs of both in-house and contract sterilization. Figure 8-5 shows the effect of the regulation on the sterilization supply curves of a typical contract sterilizer and a typical in-house sterilizer. These supply curves show the relationship between the marginal cost of sterilization and the number of goods sterilized per unit of time. The upward slope indicates that, as more goods are sterilized per unit of time, the cost of sterilizing each additional good (the marginal cost) increases.

Marginal cost curve MC_{C1} shows the contract sterilizer's marginal cost of sterilizing each quantity of goods without the air emission standard in place, while MC_{C2} shows the marginal cost of sterilizing each quantity of goods with the air emission standard in place. The vertical distance between the two curves is the total annual compliance cost per unit sterilized (TAC/unit) for each quantity sterilized. For example, suppose the contract sterilizer sterilizes Q_C quantity of goods. (This quantity is arbitrarily chosen; without information about the market price of contract sterilization, it is not known what quantity of goods the facility sterilizes.) If this sterilizer processes Q_C quantity of goods, the marginal cost of sterilization without the regulation in effect is OA. The marginal cost of sterilization at output level Q_C with the

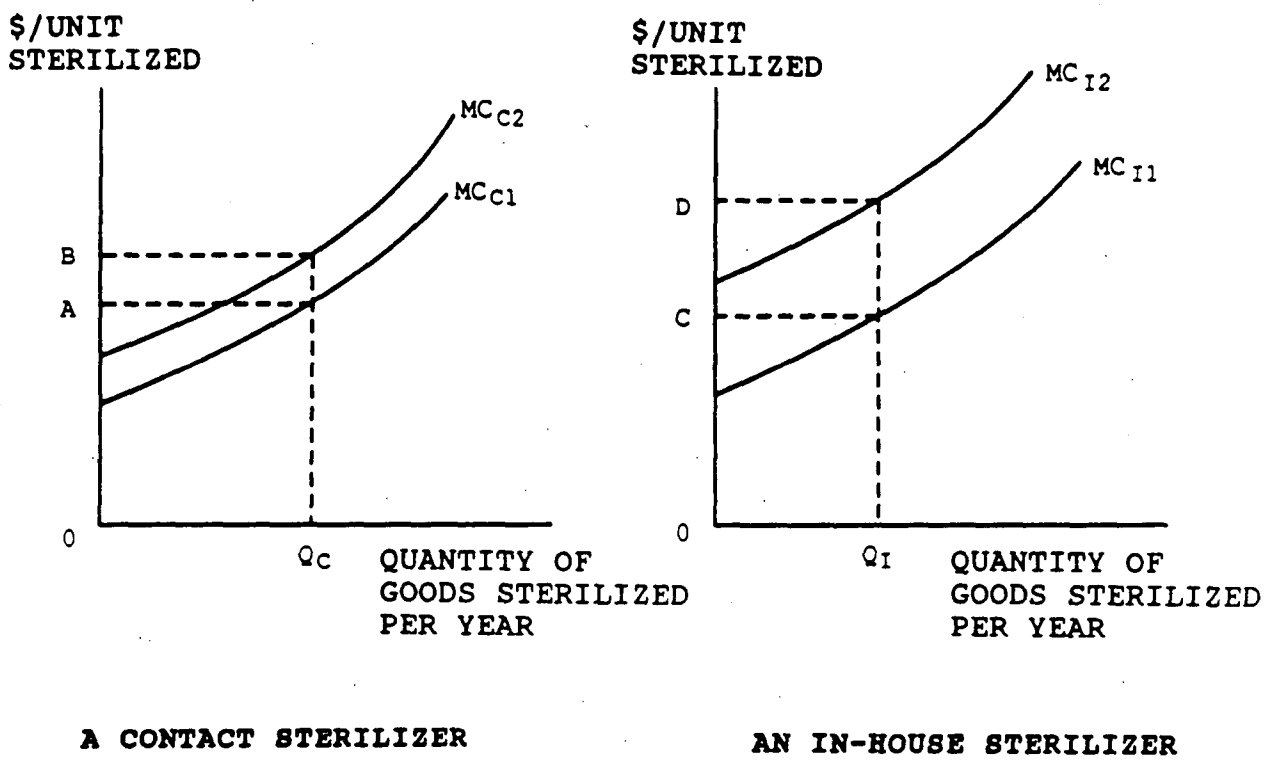

Figure 8-5. Marginal cost curves for a contract sterilizer and an in-house sterilizer, with and without the air emission standard in effect.

regulation in effect is OB. The distance BA measures the TAC/unit for that quantity sterilized. Similarly, if the in-house sterilizer sterilizes Q_I quantity of goods (again, an arbitrarily selected quantity), OC measures the marginal cost of sterilization without the regulation in effect, OD measures the marginal cost of sterilization at output level Q_I with the regulation in place, and DC measures the TAC/unit for that quantity sterilized.

The compliance cost per Mg of EO used should be lower for the contract sterilizers, on average, than for in-house sterilizers. Because of economies of scale in controlling the emissions, larger emitters, such as the contract sterilizers, will incur lower TAC per unit of product sterilized. This expectation is embodied in the relatively larger upward shift in the supply curve for the in-house sterilizer (DC is greater than AB). The economies of scale in compliance are reflected in our estimated costs of compliance. As shown in Tables 8-17 and 8-18, contract sterilizers have the lowest median TAC per Mg of EO used and the lowest median TAC per dollar of annual sterilization cost.

If nothing else changes, the air emission standard results in a higher equilibrium price and a smaller total quantity of contract sterilization performed. However, the demand for contract sterilization is expected to change. Because of their higher per-unit TAC, some of the in-house sterilizers will find that their cost of sterilizing in-house, with the compliance costs imposed, now exceeds the cost of using a contract sterilizer. This condition will increase the market demand for contract sterilization. At baseline, 16 contract sterilizers use approximately 335 Mg (330 tons) of EO per year, and approximately 170 in-house sterilizers use about 1,482 Mg (1,459 tons) of EO per year. If the quantity of EO used is closely related to quantity of goods sterilized, then in-house sterilization accounts for approximately 81 percent of the total quantity of goods sterilized annually. Depending on the cost functions and compliance costs of the individual in-house sterilizers, many of

them may choose to substitute contract for in-house sterilization, resulting in a substantial increase in the market demand for contract sterilization.

Figure 8-6 shows a new equilibrium in the contract sterilization market, with the market supply curve, S_{CM2}, shifted upward by the per-unit TAC of the regulation. The market demand curve, D_{CM2}, is shifted outward as a result of former in-house sterilizers who have decided to substitute contract sterilization for in-house sterilization. In this figure, both the price and quantity of contract sterilization have increased.

This absolute increase in contract sterilization may or may not occur, depending on the actual positions and shapes of the supply and demand curves. Contract sterilization's share of total sterilization will definitely increase, however, because their lower average TAC per unit sterilized will cause some in-house sterilizers to decide to switch to contract sterilization. In this example, contract sterilizers' revenues increase by more than their compliance costs as a result of the regulation. Revenues without the regulation in place are shown by the rectangle OP_1AQ_{C1}, and revenues with the regulation in effect are shown by OP_2CQ_{C2}. The change in revenues is shown by the difference in these two rectangles, shaded in on the graph. The TAC/unit is the vertical distance between the two market supply curves, CB, so the compliance costs as a result of the regulation are shown in the rectangle, DP_2CB. The change in revenues in this case exceeds the compliance costs for the contract sterilization sector.

In summary, adopting the emissions controls on EO sterilization will increase the unit cost of sterilization for both in-house sterilizers and contract sterilizers. Because of economies of scale in controlling emissions, the TAC per unit sterilized will be higher for the in-house sterilizers than for the contract sterilizers. In the new market equilibrium, some in-house sterilizers will probably decide to substitute contract sterilization for their in-house sterilization. The share of contract sterilization in the sterilization market will increase

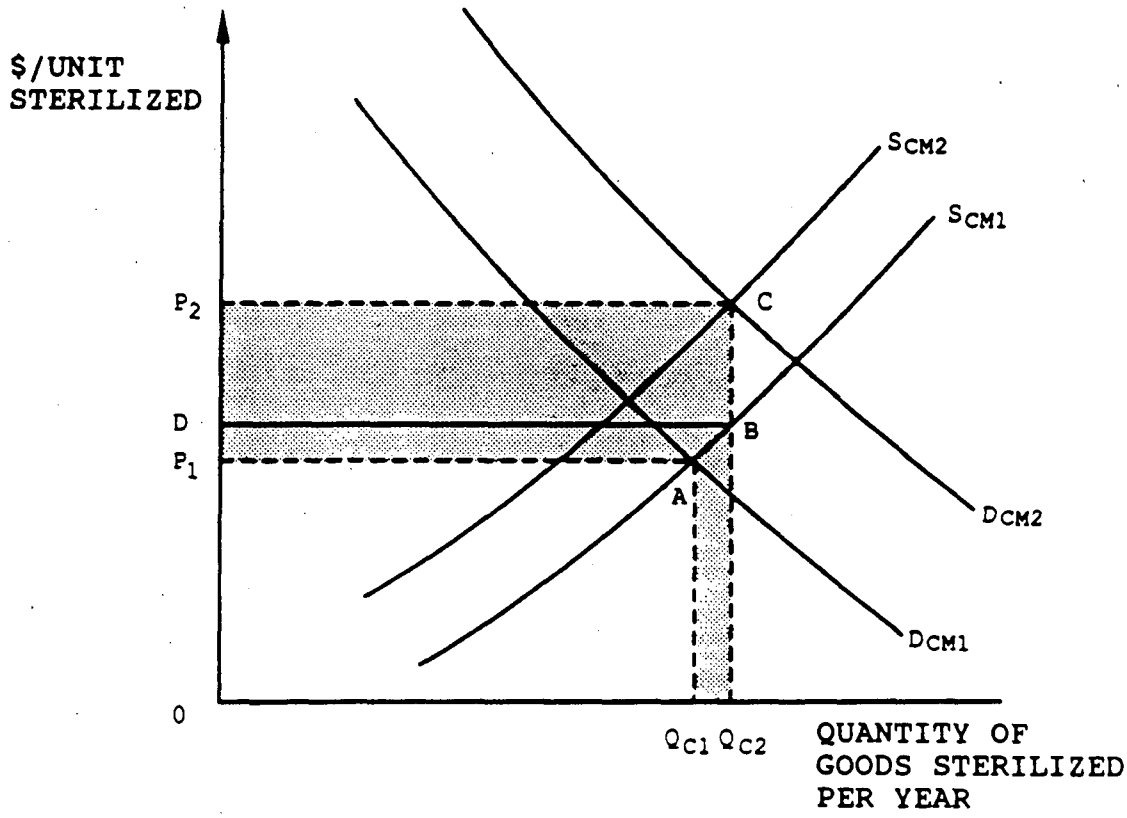

Figure 8-6. The market for contract sterilization with the air emission standard in effect.

as a result of the regulation, and the absolute quantity sterilized may actually increase. In fact, the market price may increase by more than the TAC per unit sterilized for contract sterilizers so that their revenues will increase by more than their costs as a result of the regulation. For these reasons, a regulatory flexibility analysis for contract sterilizers, a more detailed examination of small entity impacts, is not required.

8.7.5 Small Business Impacts in Other Industry Groups

Many of the other industry groups in our analysis include SIC codes for which the actual size definitions in the Federal Register, 13 CFR Part 121, specify numbers of employees, rather than sales. Unfortunately, no employee data for any of the firms are in the data base. Therefore, the sales criterion used for the contract sterilizers was applied. The results are shown in Table 8-20.

Of the approximately 170 facilities in the other industry groups, only 22 are defined as small, based on their estimated sales revenues. Using facility sales as a proxy for total production costs, the number of these facilities that would experience an increase in total production costs of more than 5 percent was estimated. Given this criteria for a significant impact, 1 of the 22 experiences significant impacts under Option 1, 6 of the 22 under Option 2, and 8 of the 22 under Option 3. Another factor to consider when examining the impacts of these small facilities is whether a facility is a major or an area source. If a facility is an area source, it is possible that the facility will be required to adopt less stringent controls than major sources or may even be exempt from the regulation. For this regulation, an area source is a facility that emits less than 10 tons of EO per year. Given this definition, 20 of the 22 small businesses are classified as an area source. As a result of the information presented above and because only a small absolute number of small entities in each industry experience significant impacts as a result of the regulation, it is concluded that a regulatory flexibility analysis is not required.

TABLE 8-20. SMALL BUSINESSES IN THE INDUSTRY GROUPS PERFORMING IN-HOUSE STERILIZATION

Industry group	No. of small entities	No. of significant impacts		
		Option 1	Option 2	Option 3
Laboratories	2	0	1	1
Spice manufacturers	3	0	1	1
Pharmaceuticals manufacturers	2	0	1	1
Other health-related	5	0	0	0
Med. device suppliers	6	1	2	3
Museums and libraries	4	0	1	2

8.7.6 Summary

The majority of contract sterilizers are small businesses, and most of the small businesses in the contract sector will experience compliance costs exceeding 5 percent of baseline sterilization costs. Because contract sterilizers, on average, sterilize larger quantities than in-house sterilizers, they will, on average, experience economies of scale in controlling their emissions. This condition will result in lower total annual compliance costs per unit sterilized for contract sterilizers than for in-house sterilizers, which in turn will result in contract sterilizers having a larger share of the sterilization market with the regulation in effect than they have at baseline. Depending on the extent to which supply and demand for contract sterilization change in response to the regulation, and the characteristics of the supply and demand relationships, contract sterilizers may find that their revenues increase by more than their costs as a result of the regulation. Finally, depending on the positions and shapes of the supply and demand curves, the absolute quantity of contract sterilization performed may actually increase as a result of the regulation. In the other industry groups, only a small absolute number of small firms is significantly affected by the regulation. For these reasons, it is concluded that a regulatory flexibility analysis is not required.

8.8 CONCLUSIONS

In this section conclusions are summarized regarding the economic effects of the candidate NESHAP controls, under each control option, on existing and new facilities.

8.8.1 Effects on Existing Facilities

This study suggests that the candidate NESHAP controls will increase the cost of performing EO sterilization at affected facilities. The incremental costs involved in moving from one control option to the next appear to be substantial, on average. As described at the beginning of this section, the increased cost of sterilization (resulting in shifting the supply curve for sterilized products upward) will probably result in reductions in

the quantities produced of products sterilized using EO and an increase in their prices. Because the data required to estimate the elasticities of supply and demand for the products sterilized using EO are not available, it is not possible to make quantitative estimates of these quantity and price changes.

Faced with the increased costs of sterilization with EO, facilities may choose one of the following four alternatives:

1. Pay the increased costs, implement the controls, and continue to sterilize using EO;

2. Switch from EO sterilization to another onsite sterilization process;

3. Discontinue onsite sterilization and switch to contract sterilization; or

4. Discontinue producing the sterilized product.

Without quantitative estimates of the changes in price and quantity for sterilized products, and without adequate data about the relative costs of the alternatives facing the facility, it is not possible to determine which alternative facilities will choose. However, some facilities will probably decide to discontinue EO sterilization as a result of the candidate NESHAP controls.

Based on the median values reported in Section 8.6.4, the candidate NESHAP is likely to significantly affect three industry groups: museums and libraries, spice manufacturers, and contract sterilizers. The candidate NESHAP will have a substantial effect on all facilities in the museums and libraries group. These facilities have very small chambers and use a very small quantity of EO. Consequently, the TAC/CV and TAC/EO values for museums and libraries are relatively high under all three control options. The TAC/C values indicate that the candidate NESHAP controls will increase sterilization costs by more than 50 percent for many facilities under Option 1 and will more than double sterilization costs for many museums and libraries under Options 2 and 3. Furthermore, the TAC/S values indicate that the costs of the candidate NESHAP controls represent a significant percentage of the operating budget for many of the

museums and libraries. To the extent that museums and libraries do not have ready access to capital markets, they may also have difficulty getting the capital needed to acquire the relevant control devices.

Museums and libraries do, however, have possible substitutes for EO. As discussed in Section 8.1, sulfuryl fluoride, marketed under the trade name Vikane™, may be an acceptable substitute for EO in sterilizing nonmetallic objects. Converting to Vikane as a sterilant involves some costs, including those of chamber modification and training the operators to be certified to apply Vikane™, a registered pesticide. Other possible substitutes include deep freezing, CO_2 fumigation, and vacuum treatment. Converting from EO to any of these would entail some conversion costs. Conversion costs must be compared with the costs of implementing the candidate NESHAP controls and the costs of switching from onsite sterilization to using a contract sterilizer. Depending on the relative costs, some facilities may choose to continue onsite sterilization, others may switch to Vikane, and still others may use a contract sterilizer. Alternatively, some museums and libraries may decide to use the services of a contract sterilizer or discontinue fumigation altogether, because of a lack of the capital needed either to implement the candidate NESHAP controls or to switch to Vikane™. Also, some facilities may conclude that the value they receive from fumigation does not justify the additional cost of implementing controls, employing a contract sterilizer, or converting to Vikane™.

The TAC/CV and TAC/EO are also fairly large for the facilities in the laboratories group, because of the below-average size of their sterilization chambers and relatively small quantity of EO they use. Nevertheless, the TAC/S and TAC/C values for this group are low, suggesting that sterilization costs are a very small part of total production costs at these facilities. Without knowing the precise figure, an animal-breeding laboratory indicated that sterilization costs are "surely less than 1 percent of total production cost."[33]

The TAC/C median values for the medical device suppliers, other health-related suppliers, and pharmaceutical manufacturers range from 16.0 percent to 20.4 percent under Option 1, from 16.6 percent to 31.6 percent under Option 2, and from 24.4 percent to 40.1 percent under Option 3. Thus, the candidate NESHAP controls will substantially increase sterilization costs in the industry groups. However, sterilization costs are generally very small relative to the total cost of producing sterilized products in these industries. For example, a pharmaceutical manufacturer estimated that sterilization costs represent only about 3 percent of total production costs.[8] Consequently, the candidate NESHAP controls probably will not significantly increase production costs for most medical device suppliers, other health-related manufacturers, or pharmaceutical manufacturers. The very low TAC/S values for these industry groups support this expectation. Although median values do not indicate significant impacts, individual facilities in each of these industries might incur significant adverse impacts.

Spice manufacturers incur relatively low unit compliance costs, as shown by TAC/CV and TAC/EO. At the same time, they incur some significant increases in sterilization costs, as measured by TAC/C. Their median TAC/C is the second highest, almost 45 percent under Option 1, 52 percent under Option 2, and 68 percent under Option 3. Also, the most severely affected facilities in this sector incur compliance costs greater than their baseline costs under Option 1, nearly 1.5 times their baseline costs under Option 2, and nearly twice their baseline costs under Option 3. Fortunately, sterilization represents a small proportion of total production costs in this industry (TAC/S is less than one percent, even under Option 3). Also, a good substitute exists for EO fumigation in the spice manufacturing industry: radiation. As described in Section 8.1, an industry source stated that radiation has several advantages over EO fumigation.[16] These advantages include killing all bacteria, rather than only a large percentage of bacteria. Second, radiation can be done under ambient conditions. Third,

radiation leaves no residue and requires no aeration. It does, however, entail the costs of purchasing the equipment needed to irradiate the product and training employees to use the new equipment. No information is available about the relative costs of radiation and EO as sterilization techniques. The candidate NESHAP will probably significantly affect many contract sterilizers. For the other industry groups in this study, sterilization is one of many steps in the production process. In contrast, sterilization is nearly the entire "product" for contract sterilizers. (As discussed in Section 8.1, many contract sterilizers may also perform some packaging, testing, and distribution services that are linked to their sterilization operations.) Thus, the candidate NESHAP will probably cause a more pronounced increase in contract sterilizers' production costs, which is reflected in the relatively high median TAC/S (2 percent under Option 1, 3.9 percent under Option 2, and 4.6 percent under Option 3) for contract sterilizers. [As noted earlier, one of the shortcomings of total sales is that it includes sales of sterilized and nonsterilized products; because virtually all sales from contract sterilizers involve sterilized products, this shortcoming would tend to result in higher TAC/S for these facilities than for facilities in the other industry groups.]

In addition to significantly increasing their sterilization costs, the candidate NESHAP may result in increased demand for contract sterilization services. Because contract sterilizers on average have larger chambers than the other industry groups and run more EO through them, the per-unit cost of the candidate NESHAP is less for contract sterilizers than for the other groups. This conclusion is supported by the data in Tables 8-14 through 8-19, which indicate that contract sterilizers have the lowest median TAC/CV, TAC/EO, and TAC/C of the seven industry groups under all three control options. As explained in Section 8.7, the contract sterilizers' lower per-unit control costs may actually cause them to gain additional business if

firms switch from in-house sterilization to contract sterilization.

Aside from the effects of the candidate NESHAP controls on the museums and libraries group, the contract sterilizers group, and perhaps the spice manufacturers group, significant effects may occur at some individual facilities in the other five industry groups. In general, these are the facilities with the highest TAC/S values in the groups. These facilities may choose to incur the relatively high control costs, to switch to another sterilization process, to switch from in-house to contract sterilization, or to discontinue their production of sterilized products. Without further information on these facilities, there is no way to predict which response will be chosen in each case.

8.8.2 Effects on New Facilities

Up to this point the analysis has focused on the economic effects of the candidate NESHAP controls on existing facilities. Without data on possible control costs for new (not-yet-constructed) facilities in each industry group, making any quantitative estimates of the potential effects of the candidate NESHAP, under each control option, on these facilities was not possible. Nevertheless, some general conclusions may be reached on this matter based on the information presented earlier in this chapter.

The supply curve for products sterilized using EO will shift upward as a result of the candidate NESHAP controls. If the demand curves for these products are at all elastic, the quantity of the products sold will decrease. This decrease will delay investment in new facilities that would use EO.

The effect on investment by contract sterilizers is more difficult to predict. Because some facilities in the other six industry groups may decide to switch from in-house sterilization to contract sterilization, the demand curve for contract sterilization may shift out as a result of the candidate NESHAP controls. The market share of contract sterilization will increase, and the absolute quantity of contract sterilization may increase. Depending on the change in the profitability of

contract sterilizers resulting from the candidate NESHAP controls, some additional investment by contract sterilizers might occur.

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25. Telecon. Colglazier, D. L., Old Sturbridge Village Conservation Lab, with A. S. Ross, Research Triangle Institute, July 17, 1987. Fumigation in museums.

26. Telecon. Lowery, A., U.S. Food and Drug Administration, with C. Beal, Midwest Research Institute, October 11, 1985.

27. Rice, L. L. Memo to D. Markwordt, U.S. Environmental Protection Agency, including a list of contract sterilizers. April 18, 1986.

28. Telecons with six contract sterilizers who each requested that their information be treated as confidential.

29. Dunford, R. W., et al. Economic Analysis of Candidate hazardous Organics NESHAP Controls: Draft Report. Research Triangle Institute, Research Triangle Park, NC. November 1986.

30. Midwest Research Institute. Cost Effectiveness of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. Draft Memo to D. Markwordt, March 1990.

31. Midwest Research Institute. Costing Methodology for the Control of Aeration Room Emissions, Commercial Sterilization NESHAP. Draft Memo to D. Markwordt, April 1990.

32. Midwest Research Institute. Costing of Control Alternatives for the Rear Chamber Exhaust, Commercial Sterilization NESHAP. Draft Memo to D. Markwordt, April 1990.

33. Telecon. Morin, R., Plant Manager, Charles River Laboratories, Raleigh, NC. with A. S. Ross, Research Triangle Institute, December 17, 1987. Cost of sterilization relative to total production cost.

APPENDIX A.

EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT

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TABLE A-1. EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT

Date	Event
October 2, 1985	The EPA announces intent to list ethylene oxide (EO) as a hazardous air pollutant under Section 112 of the Clean Air Act (Act) (50 FR 40286).
October 1985	Collection of background information begun by Midwest Research Institute.
January 8, 1986	Site visit to Sterilization Services of Tennessee to observe sterilization and gas reclamation facilities.
January 13, 1986	Site visit to North Carolina Archives and Records to observe EO fumigation chamber and obtain data on EO use.
January 16, 1986	Site visit to McCormick and Company, Inc., to observe EO fumigation chambers and Deoxx™ control system.
April 2, 1986	Meeting with Johnson and Johnson (J&J) International and Damas Corporation to discuss the EO scrubber manufactured by Damas and used by J&J.
April 1986	Data received from a Health Industry Manufacturers' Association (HIMA) survey performed in November of 1985 are compiled in the Commercial Sterilization data base.
July 1986	Questionnaires sent to miscellaneous sterilization and fumigation facilities. Responses were received from 113 of these facilities.
August 1987	Mail out Chapters 3-5 of the background information document (BID) for review.
August 27, 1987	Work Group briefing.
September 30, 1987	Meeting with HIMA short-term exposure limit task force to discuss industry's response to the EO and chlorofluorocarbon (CFC) BID mailouts.
November 13, 1987	Second Work Group briefing.
March 11, 1988	NAPCTAC mailout of BID chapters and Appendices.
March 23, 1988	Docket No. A-88-03 (Commercial Sterilization) is submitted.

TABLE A-1. (continued)

Date	Event
May 19, 1988	NAPCTAC meeting.
July 1988	Questionnaires sent out to miscellaneous sterilization and fumigation facilities. Responses were received from 44 facilities.
December 9, 1988	Site visit to Iolab, Inc., to obtain information about the DM3 Catcon catalytic oxidation system used to control emissions from the aeration room.
December 9, 1988	Site visit to Medtronic, Inc., to obtain information about the acid-impregnated carbon adsorbtion system used to control emissions from the aeration room.
February 21, 1989	Teleconference with HIMA to discuss progress on the standard.
November 3, 1989	Meeting with HIMA to discuss progress on the standard.
December 4-6, 1989	Vendor-sponsored test of Donaldson Eto Abator™ catalytic oxidizer.
December 12, 1989	Review of a summary of the prevalence of chamber exhaust use among HIMA members.
June 14, 1990	Site visit to Isomedix Operations, Inc., to obtain information about their sterilization processes.
August 7, 1990	Work Group meeting on regulatory alternatives.
January 30, 1991	NAPCTAC meeting.

APPENDIX B.

INDEX TO ENVIRONMENTAL CONSIDERATIONS

APPENDIX B.

INDEX TO ENVIRONMENTAL CONSIDERATIONS

This appendix consists of a reference system which is cross-indexed with the October 21, 1974, Federal Register (39 FR 37419) containing Agency guidelines for the preparation of Environmental Impact Statements. This index can be used to identify sections of the document which contain data and information germane to any portion of the Federal Register guidelines.

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APPENDIX B.
INDEX TO ENVIRONMENTAL IMPACT CONSIDERATIONS

Agency guidelines for preparing regulatory action environmental impact statements (39 FR 37419)	Location within the background information document (BID).
1. Background and description	
Summary of the regulatory alternatives	The regulatory alternatives are summarized in Chapter 1.
Statutory authority	Statutory authority is given in Chapter 1 and Chapter 2.
Industry affected	A description of the industry to be affected in given in Chapter 8.
Sources affected	Descriptions of the various sources to be affected are given in Chapter 3.
Availability of control technology	Information on the availability of control technology is given in Chapter 4.
2. Regulatory alternatives	
Regulatory alternative A	
Environmental impacts	Environmental effects of regulatory alternative A are considered in Chapter 6.
Costs	Costs associated with regulatory alternative A are considered in Chapter 7.
Regulatory alternative B	
Environmental impacts	Environmental effects of regulatory alternative B emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative B emission control systems are considered in Chapter 7.

Agency guidelines for preparing regulatory action environmental impact statements (39 FR 37419)	Location within the background information document (BID).
Regulatory alternative C	
Environmental impacts	Environmental effects of regulatory alternative C emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative C emission control systems are considered in Chapter 7.
Regulatory alternative D	
Environmental impacts	Environmental effects of regulatory alternative D emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative D emission control systems are considered in Chapter 7.
Regulatory alternative E	
Environmental impacts	Environmental effects of regulatory alternative E emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative E emission control systems are considered in Chapter 7.

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APPENDIX C.

EMISSION SOURCE TEST DATA

APPENDIX C.
EMISSION SOURCE TEST DATA

This appendix contains summaries of performance tests EPA and industry conducted on four acid-water scrubbers and one catalytic oxidizer designed to control ethylene oxide (EO) emissions from sterilizer exhaust and aeration room gas streams, respectively. Performance tests to determine control device efficiency were conducted on two types of acid-water scrubber systems, Damas™ and DEOXX™. Detailed descriptions of these types of scrubbers are presented in Chapter 4. The sterilizers tested use pure EO and a 12/88 mixture of EO and chlorofluorocarbons (CFC's) as sterilant gases. The results of the five tests are presented in the following sections of this appendix:

C.1--EPA test of a DEOXX™ system at Burron Medical;

C.2--Independent laboratory test of a DEOXX™ system at McCormick and Company, Inc.;

C.3--Independent laboratory test of a DAMAS™ system at Johnson and Johnson, Inc.;

C.4--Independent laboratory test of a DEOXX™ system at Chesebrough-Pond's DEOXX™ facility; and

C-5--Vendor test of an EtO ABATOR™ system at Seamless, Inc.

A summary of the test results and selected test conditions for the first four tests is provided in Table C-1.

C.1 EPA TEST OF A DEOXX™ SYSTEM AT BURRON MEDICAL

C.1.1 Facility Description[1]

An EPA-sponsored test was conducted on a Deoxx™ acid-water scrubber in September 1987. The test took place at Burron Medical, a medical supply sterilization facility located in Allentown, Pennsylvania. The facility has three 28 cubic meters

TABLE C-1. SUMMARY OF TEST RESULTS

Plant	Scrubber type	Chamber size, m^3 (ft^3)	Sterilant	No. of runs	Flow rate, m^3/s (ft^3/min)	Range of EO inlet concentrations, ppmv	Range of EO outlet concentrations, ppmv	Average percent removal
Burron Medical	DEOXX™	28.3 (1,000)	12/88	10[a]	b	b	b	99.96[c]
McCormick & Company	DEOXX™	35.3 (1,248)	Pure EO	3	d	26,800 - 385,000	<5 - 458	99.988
Johnson & Johnson	Damas™	b	12/88	6	0.031 (66)	b	14 - 1,938	99.25
			12/88	3	0.047 (100)	b	12 - 1,853	99.26
Chesebrough-Pond's, Inc.	DEOXX™	35.7 (1,260)	12/88	3	d	1,000 - 250,000	<1 - 10,000	>99.93
		35.7 (1,260)	Pure EO	1	d		<1-10,000	>99.99

[a]Seventeen tests were performed; data from 10 of these tests were used in the report.
[b]Data not provided.
[c]Based on throughput efficiency for empty chamber runs.
[d]Flow rate varies widely for the various runs and evacuations.

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(m^3) (1,000 cubic feet [ft^3]) sterilizers that use 12/88. The gas is supplied from a common header serving all four units and is controlled by a liquid flow meter.

A sterilization cycle typically uses 140 liters (L) (38 gallons [gal]) of 12/88 gas mixture. On a weight basis, a sterilization charge consumes 167 kilograms (kg) (368 pounds [lb]) of gas, of which approximately 20 kg (44 lb) are EO. The initial charge of EO to the chamber was calculated using the weight of the supply cylinders before and after charging the chamber.

The exhaust from the sterilizers is controlled by a DEOXX™ system. At the time of the test, the scrubber contained a dilute mixture of phosphoric and sulfuric acid. Each chamber is equipped with a total recirculating liquid vacuum pump. These pumps are equipped with gas/liquid separators, which emit the gas to the DEOXX™ system and recirculate the liquid to the pump inlet. Chambers Nos. 1 and 2 are equipped with oil-sealed pumps. Chamber 3 is equipped with a water-sealed pump. All of the tests were conducted using the chambers (Nos. 1 and 2) equipped with oil-sealed pumps.

The sterilization cycle is controlled automatically by a programmable microprocessor system. The control system can control and record the parameters of the sterilization cycle including chamber temperature, chamber pressure, and elapsed time from the start of the cycle.

The sterilization process begins with a humidifying step, which takes place in a separate room. After the humidifying step, each load to be sterilized is transferred to the sterilization chamber. The sterilization cycle is a batch process that takes 4 to 6 hours. A sterilizer load begun during the morning shift exhausts at about 2:00 p.m. In a typical plant operating mode, seven poststerilization evacuations occur over a 3-hour period. After the chamber is repressurized, following the seventh evacuation, the product is removed from the chamber and allowed to off-gas. Although the control system is designed to handle the exhaust from two sterilizers venting simultaneously,

the tested sterilization cycles were scheduled so that only one sterilizer vented at a time.

Three different sterilization programs were used for testing: one for the empty chamber tests, one for the full chamber tests, and one for the last full chamber test (Test 13). The testing of both full (loaded) and empty chambers was carried out to examine the effects of product retention of EO on the EO emissions. A total of 17 tests were performed, 5 with product in the chamber (full chamber tests) and 12 without product (empty chamber tests). Seven of these tests were considered invalid according to the testing lab, therefore, data from 10 of these tests (4 with and 6 without product) were summarized in the final report. Table C-2 summarizes operating data from the 10 valid tests.

Before the start of each test (except Test 13), the chamber was evacuated to 2 pounds per square inch absolute (psia) and then pressurized to 3.1 psia with steam. The humidifying step was maintained at 3.1 psia for 1 hour for the loaded chamber tests, but the humidifying step was shortened to 5 minutes for the empty chamber tests. After the humidifying, the chamber was charged to 23.9 psia with 12/88 gas. The exposure at 23.9 psia was maintained for 4 hours for the loaded chamber tests but was shortened to 5 minutes for the empty chamber tests. During the last full chamber test (Test 13), the chamber was evacuated to 7 psia and pressurized to 32.9 psia.

Each test program contained seven poststerilization evacuations; an initial chamber evacuation, six air in-bleeds with subsequent evacuations, and a final air in-bleed. Except in Test 13, the chamber was evacuated to 2 psia and pressurized with air to 13.9 psia during each evacuation and air in-bleed cycle. The initial chamber evacuation and pump down lasted 26 to 27 minutes. Each subsequent evacuation lasted 12 to 14 minutes, and each air in-bleed required 12 to 14 minutes. During Test 13, the chamber was evacuated to 7.0 psia, which reduced each evacuation and air in-bleed time by 7 minutes.

TABLE C-2. SUMMARY OF FIELD TESTS AT BURRON MEDICAL[1]

Test No.	Product present	Chamber No.	Weight of 12/88 used, lb	Test date	Test start time	Test end time
6[a]	Yes	2	368	87/10/06	21:39	00:38
7[b]	No	1	365	87/10/07	10:19	14:04
8[a]	Yes	2	388	87/10/07	15:10	18:11
9[b]	No	1	346	87/10/08	09:25	12:42
10[b]	No	1	353	87/10/08	14:41	17:48
11[a]	Yes	2	392	87/10/08	18:00	21:01
12[b]	No	1	346	87/10/09	12:44	15:53
13[c]	Yes	2	442	87/10/09	16:16	18:03
14[b]	No	1	350	87/10/10	08:54	12:01
15[b]	No	1	343	87/10/10	13:35	16:43

[a]The chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidification step lasted 1 hour, and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 4 hours. Poststerilization chamber pressure cycled between 2 psia and 13.9 psia.

[b]The chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidification step lasted 5 minutes, and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 5 minutes. Poststerilization chamber pressure cycled between 2 psia and 13.9 psia.

[c]The chamber was evacuated to 7 psia before being pressurized with steam to 8 psia. Humidification step lasted 1 hour, and then the chamber was charged to 32.9 psia with 12/88. Exposure lasted 5 hours. Poststerilization chamber pressure cycled between 7 psia and 13.5 psia.

C.1.2 Sampling Procedures[1]

The sampling and analysis procedure used in these field tests involved semicontinuous direct sampling of scrubber inlet and outlet gas streams with on-line gas chromatographic analysis to determine EO concentrations. Volumetric flow rates both entering and exiting the scrubber were determined with orifice plates. However, some difficulty was encountered when measuring the inlet volumetric flow rate due to the high EO concentration and low flow rate of the gas stream.

C.1.3 Test Results[1]

Table C-3 presents uncontrolled and controlled emissions (i.e., the amount of EO entering and exiting the control unit) for the six empty chamber tests. Emission measurements were considered for the six empty chamber tests because the total amount of EO entering the scrubber were more consistent for these runs. These emissions measurements were used to evaluate the EO control efficiency of the DEOXX™ system.

Efficiencies were calculated for the six test runs. Throughput efficiency was calculated using the gas stream EO concentrations and volumetric flow rates into and out of the DEOXX™ unit. This method calculates the efficiency of the control device, i.e., the difference in mass of EO into and out of the control device. However, the method used to determine this efficiency suffered due to the inability of the orifice plates to accurately measure the flow rate into the scrubber. The second method of determining control efficiency, recovery efficiency, was calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control unit.

Both of the analytical methods used to determine control efficiency were hindered by the difficulty in determining the GC peak for EO scrubber outlet concentration measurements. This problem arose from a shift in the EO retention time (in the column of the GC) as EO concentrations exiting the scrubber decreased. The difficulty in identifying the EO peak was further

TABLE C-3. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR EMPTY CHAMBER TESTS AT BURRON MEDICAL[1]

Test No.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg (lb)	EO entering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent[a]	Recovery efficiency, percent [b]
7[c]	19.9 (43.8)	0.19 (0.42)	10.98 (24.19)	0.020 (0.043)	99.82	99.90
9	18.8 (41.5)	0.68 (1.50)	27.51 (60.59)[d]	0.005 (0.011)	99.98	99.97
10	19.2 (42.4)	0.10 (0.22)	28.20 (62.12)[d]	0.013 (0.029)	99.95	99.93
12	18.8 (41.5)	0.07 (0.16)	19.98 (44.00)	0.005 (0.011)	99.98	99.97
14	19.1 (42.0)	0.07 (0.16)	22.16 (48.80)	0.010 (0.021)	99.96	99.95
15	18.7 (41.2)	0.03 (0.07)	23.98 (52.82)	0.006 (0.014)	99.97	99.97

[a]Calculated using the measured EO entering and exiting the control device.
[b]Calculated using the weight of the original EO charge and the measured EO emitted at the outlet of the control device.
[c]During Test 7, there was a leak in the inlet sampling pump during the first 10 minutes of the evacuation, and the flame ionization detector (FID) flame was extinguished during portions of the third and fourth evacuations. Loss of these samples may explain the lower mass of EO entering the control unit during this test.
[d]The EO standard calibration curve for inlet samples on October 8, 1987 was lower than on the other test days. This unusually low value would have raised the measured EO concentrations and caused the EO mass flow into the control unit to be overestimated.

complicated by the large range of EO concentrations exiting the scrubber.

Statistical tests were performed to evaluate the effect of product in the chamber on determining the efficiency of the control unit. These tests showed that the presence of product in the chamber had no significant effect on the efficiency determinations.

The absolute difference between measured emissions and expected emissions (based on the initial EO charge to the chamber) was greater than 40 percent for three tests and less than 10 percent for only one test. In five of the six empty chamber tests, the measured emission levels were higher than the expected levels. From these observations, actual uncontrolled EO emissions may therefore be expected to be from 50 to 150 percent of the actual emissions.

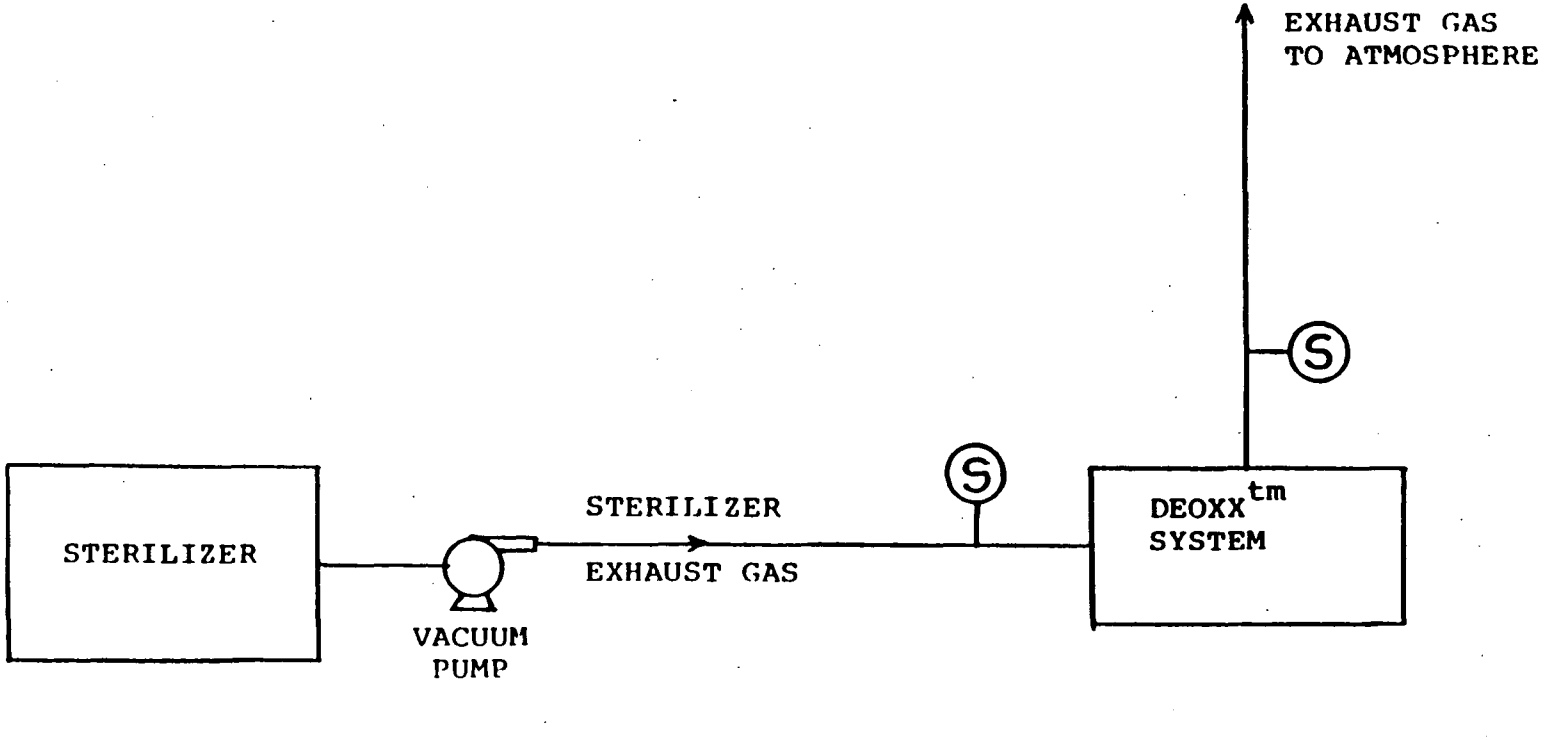
C.2 INDEPENDENT LABORATORY TEST OF A DEOXX™ SYSTEM AT McCORMICK AND COMPANY, INC.

C.2.1 Facility Description[2]

A DEOXX™ detoxification system was installed at the Hunt Valley Spice Mill of McCormick and Company to control EO emissions from sterilizers. The DEOXX™ system was tested by an independent laboratory the week of October 14, 1985, to evaluate performance.

The sterilizers at the Hunt Valley Spice Mill are used to process a variety of spices. Pure EO is used as the sterilant. Each sterilizer is equipped with a total-recirculation liquid ring vacuum pump system to evacuate the chamber and achieve the desired levels of vacuum. At the completion of the sterilization cycle, sterilizer gas is exhausted to the atmosphere through the DEOXX™ system.

A test program consisting of four tests was conducted using Sterilizer B, which had a volume of 35.3 m^3 (1,248 ft^3). The first test was used to check the equipment and instrumentation operation. The remaining three tests (Test Nos. 2, 3, and 4) were used to evaluate the DEOXX™ system performance. Figure C-1 provides locations of the sampling points.



S : SAMPLING POINT TO MEASURE

- ETO CONCENTRATION
- VOLUMETRIC GAS FLOWRATE
- GAS TEMPERATURE
- GAS STATIC PRESSURE

Figure C-1. Sampling point locations.[2]

The sterilization cycle operating conditions for the three performance tests are summarized below:

Initial evacuation conditions:

Pressure, psia (in. Hg)	14.2 (28.9)
Time, min	25

Total EO charged to chamber, kg (lb):

Test 1	13.2 (29.0)
Test 2	13.2 (29.0)
Test 3	12.7 (28.0)

Exposure conditions:

Pressure, psia (in. Hg)	10.4 (21.2)
Temperature, °C (°F)	43.3 (110)

Following the sterilization cycle, the chamber was evacuated to 7.0 psia (14.3 in. Hg) over a period of 12 minutes. Two additional evacuations lasted 10 minutes each, and the air washes required less than 1 minute each.

C.2.2 Sampling Procedures[2]

The sterilization chamber was kept empty during the test cycles. This eliminated possible variations in EO emissions during the exhaust phase due to product off-gassing without adversely affecting the performance evaluation of the DEOXX™ system.

For each performance test cycle, the amount of EO charged to the sterilizer was determined by measuring the weight of the EO supply cylinder before and after charging EO to the sterilizer chamber.

The weights of EO entering and leaving the DEOXX™ system were determined for each chamber evacuation by continuously monitoring the total volumetric gas flow rate and EO concentration at the inlet and the outlet of the DEOXX™ system. The volumetric gas flow rate was measured by using an orifice meter at each location. The gas pressure drop across the orifice plate was monitored throughout the exhaust cycle for accurate measurement of gas flow rate. The EO concentrations were

measured with two gas chromatographs, one each at the inlet and the outlet of the DEOXX™ system.

C.2.3 Test Results

The weights of EO entering and leaving the DEOXX™ system for each evacuation, as well as the removal efficiencies associated with each test run, are presented in Table C-4.

C.3 INDEPENDENT LABORATORY TEST OF A DAMAS™ SYSTEM AT JOHNSON & JOHNSON, INC.[3]

C.3.1 Facility Description

A Damas™ scrubber is used to control EO emissions from the sterilization operations at Johnson & Johnson's Ethicon, Inc., facility in Somerville, New Jersey. During the week of August 27, 1984, a Damas™ scrubber at this facility was tested by an independent laboratory. The sterilizer uses a 12/88 mixture of EO/CFC as the sterilant. All concentrations reported are based on gas chromatograph (GC) analyses.

C.3.2 Sampling Procedures

Nine analyses were performed on the scrubber outlet: six with a scrubber flow rate of 0.031 cubic meters/second (m^3/sec) (66 cubic feet per minute [ft^3/min]) (Set 1) and three with a flow rate of 0.047 m^3/sec (100 ft^3/min) (Set 2). These two sets of analyses were performed on August 29 and August 30, 1984, respectively. Samples were collected by drawing a small amount of the scrubber emission stream through a Teflon™-lined pump to a mobile laboratory using a Teflon™ sample line. A collection sump with a sampling port allowed samples to be drawn with a syringe for injection into a GC with a flame ionization detector. These syringe samples were taken once every 2 minutes during each analysis. The scrubber outlet emission stream was also continuously monitored using an infrared analyzer.

The scrubber inlet gas stream was tested on August 30, 1984, using a scrubber flow rate of 0.047 m^3/sec (100 ft^3/min). Three grab samples were collected (during one evacuation) in Tedlar™ bags and analyzed in the same manner as the scrubber outlet samples. The EO concentration at the scrubber inlet was based on an average concentration of these three samples.

TABLE C-4. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR TESTS AT THE McCORMICK AND COMPANY, INC., SPICE MILL[2]

Test no.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg (lb)	EO entering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent[a]	Recovery efficiency, percent[b]
2	13.2 (29.0)	0.32 (0.71)	12.19 (26.85)	0.00130 (0.00287)	99.989	99.990
3	13.2 (29.0)	0.30 (0.67)	12.02 (26.47)	0.00140 (0.00309)	99.988	99.989
4	12.7 (28.0)	0.32 (0.70)	11.99 (26.41)	0.00169 (0.00372)	99.986	99.987

[a]Calculated using the emission entering and exiting the control device.
[b]Calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control device.

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C.3.3 Test Results

The peak outlet concentration for each analysis was used to calculate the removal efficiency of the scrubber. The average scrubber efficiency was 99.25 percent for Set 1 and 99.28 percent for Set 2. The average removal efficiency for all nine runs was 99.26 percent.[3] (The average removal efficiency determined by infrared analysis of the scrubber outlet EO concentration was 99.16 percent.)

The use of concentration differences, rather than a percent weight removal, as a basis for calculating the removal efficiency did not significantly affect the efficiency estimate; the efficiency still should be equal to or greater than 99.0 percent. The use of an average inlet concentration, which was based on the highest gas flow rate, and the peak outlet concentration to determine the efficiency would provide a conservative estimate as long as the outlet flow rate is less than or equal to the inlet flow rate. However, if the outlet flow exceeds the inlet flow (e.g., if there is dilution at the stack), then the methodology would overestimate the efficiency. It could not be determined from the data provided whether the outlet and inlet flow rates were different, and there were no indications in the report that flow rates were monitored.[3]

Some uncertainties exist regarding the efficiencies obtained in this test because of the conditions under which the scrubber was tested. First, the test was performed on a scrubber that was using fresh scrubbing liquor (i.e., no ethylene glycol in the scrubbing liquor). Secondly, it was unclear from the test report whether all the runs each day (i.e., number of evacuations) were for a single sterilization cycle. Finally, there were no indications that gas stream flow rates were monitored during the test.

C.4 INDEPENDENT LABORATORY TEST OF A DEOXX™ SYSTEM AT CHESEBROUGH-POND'S DEOXX™ FACILITY[4]

C.4.1 Facility Description

A DEOXX™ system was installed on sterilizer 4 at Chesebrough-Pond's Sherburne, New York, plant in 1982 to control EO emissions. Four tests were conducted on December 1982 over three different sterilization cycles to evaluate the performance of the system. These tests were performed using pure EO and 12/88 sterilant, and were all conducted on an empty chamber.[4] This chamber had a volume of 35.7 m^3 (1,260 ft^3) and was capable of using either pure EO or a mixture of 12/88 EO/CFC as the sterilant gas.

C.4.2 Sampling Procedures

A total of four performance tests was conducted on the DEOXX™ system: three using the 12/88 mixture and one using pure EO gas. The scrubber outlet emission stream was sampled once every minute by routing two sampling streams from the scrubber exhaust to two separate GC's. The volumetric flow rate of the scrubber outlet emission stream was also monitored using an orifice plate. Volumetric flow vs EO concentration profiles were then developed to calculate the mass of EO exiting the scrubber.

The amount of EO entering the scrubber was determined by weighing the sterilant supply cylinders before and after use, and then subtracting the remaining sterilant in the chamber after the cycle. The EO concentration remaining in the chamber was measured with a GC, and the chamber pressure was measured; the ideal gas low was used to determine the weight of EO left in the chamber.

C.4.3 Test Results

A summary of the emission measurements and control efficiencies for these emissions tests is presented in Table C-5. The efficiencies were calculated based on the total weight of EO entering and exiting the scrubber over the entire cycle. The removal efficiencies for the three 12/88 mixtures were 99.0 percent, 98.7 percent, and 99.4 percent, respectively, for

TABLE C-5. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR EMPTY CHAMBER TESTS AT CHESEBOROUGH PONDS[4]

Test no.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg(lb)	EO centering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent[a]	Recovery efficiency percent[b]
1	13.7 (30.1)	0.10 (0.22)	13.6 (29.9)	0.14 (0.31)	99.0	98.9 +
2	28.8 (63.4)	0.08 (0.18)	28.7 (63.2)	0.37 (0.81)	98.7	98.7
3	24.0 (53.0)	0.01 (0.02)	24.0 (53.0)	0.0004 (0.001)	99.9 +	99.9 +
4	30.6 (67.4)	0.04 (0.10)	30.5 (67.3)	0.19 (0.42)	99.4	99.4

[a]Calculated using the emissions entering and exiting the control device.
[b]Calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control device.

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an average of 99.0 percent. For the pure EO mixture, the EO removal efficiency was greater than 99.99 percent.[4]

C.5 VENDOR TEST OF AN ETO ABATOR™ SYSTEM AT SEAMLESS, INC.[5]

C.5.1 Facility Description

A Donaldson EtO Abator™ catalytic oxidizer was installed to control aeration room emissions at Seamless' Ocala, Florida, facility. Testing was performed on the catalytic oxidizer on December 4 through 6, 1989. The control system was installed to demonstrate to the State that Seamless could comply with the State's 1 ppm standard at 50 feet from the fenceline.[6] This facility sterilizes products in any one of three sterilizer chambers using pure EO or 12/88 (EO/freon) sterilant, depending on which sterilizer is used. After the product is sterilized, it is taken to the aeration room, where it is then allowed to off-gas for at least 24 hours.

The aeration room is maintained at a temperature of 38°C (100°F), and the EO emissions are controlled by two 56 m^3/min (2,000 ft^3/min) catalytic oxidizers. These units run continuously and provide enough heated, recirculated air to maintain the aeration room at a temperature of 38°C (100°F).

C.5.2 Sampling Procedures

Velocity measurements were performed using Pitot tubes situated at 12 traverse points along the cross-section of the duct both upstream and downstream of the control device. Emission stream temperature measurements were also made at these locations. The averages for each set of measurements were used to determine the emission stream flow rates to and from the control device, respectively.

Six 1-liter grab samples were taken simultaneously both upstream and downstream of the control device via test ports. Two additional 4-liter grab samples (taken in 10-liter Tedlar™ bags) were simultaneously taken both upstream and downstream of the control device. Of the eight sets of samples, five were taken approximately 3 hours prior to introducing sterilized product into the aeration room, two were taken just prior to introducing sterilized product into the aeration room, and one

was taken one-half hour after sterilized product was introduced to the aeration room. These samples were analyzed within a 20-hour period of obtaining the samples using a gas chromatograph with a flame ionization detector (FID). All of the product introduced to the aeration room was previously sterilized with pure EO.

C.5.3 Test Results

Six of the eight sets of grab samples were used to determine the control device efficiency. From the results of the GC analysis provided in the test report the efficiency of the control device was determined to be 99.9+ percent for each of the tests performed. However, these efficiencies are based on EO concentration only and do not reflect the mass of EO entering and exiting the control device. Also, the supporting information provided with the test report is very limited and does not substantiate the 99.9 percent claimed.

Other uncertainties exist in this test report. In all of the downstream grab samples, the EO concentration was determined to be zero (instead of the lower detection limit of the FID). Also, the control inlet EO concentrations are high (10 ppm minimum) for aeration room emission concentrations which typically tend to have an EO concentration of less than 2 ppm.[7]

C.6 REFERENCES

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3. Evaluation of the Efficiency of an Ethylene Oxide Scrubber. Scott Environmental Services, Plumsteadville, PA. October 2, 1984.

4. Certification Testing Report: Ethylene Oxide Detoxification System on Sterilizer 4, Chesebrough-Pond's, Inc., Sherburne, New York, Plant. Buonicore-Cashman Associates, Inc., Bridgeport, CT. January 13, 1983.

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APPENDIX D.

EMISSION MEASUREMENT AND CONTINUOUS MONITORING

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APPENDIX D.
EMISSION MEASUREMENT AND CONTINUOUS MONITORING

D.1 METHODS FOR DETERMINING ETHYLENE OXIDE EMISSIONS FROM ETHYLENE OXIDE STERILIZERS EQUIPPED WITH CONTROL DEVICES

Since the early 1980's, concern about the toxicity of ethylene oxide (EO) has spurred the development of methods to accurately measure emissions from sterilizing units that use EO as a sterilant. The U. S. Environmental Protection Agency (EPA), the California Air Resources Board (CARB), manufacturers of EO control devices, and EO sterilizer operators have independently moved toward developing such a method by conducting tests of emission control technologies. The methodologies used in several of these tests are summarized in the following sections. Test methods used to evaluate dilute acid hydrolytic EO scrubbing units are discussed in Reports 1 through 6, and test methods used to evaluate catalytic oxidation units are discussed in Reports 7 through 9. Report 10 is a summary of CARB Method 431.

The reports summarized below were generated by control device vendors gathering data to support efficiency claims, purchasers of control devices to either verify the manufacturer's claims or to comply with State regulations, or by EPA in support of method and standard development. These reports are referenced fully in Section D.4.

D.1.1 Report 1

In this test effort,[1] dilute acid hydrolytic scrubber efficiencies were determined using (1) calculated values for EO emissions vented to the scrubber (inlet) and (2) measured values for EO emissions exhausted from scrubber (outlet). Sampling was

performed over the entire evacuation cycle, which included the initial evacuation and four air washes.

D.1.1.1 Determination of EO Mass Vented to the Scrubber. The mass of EO vented from the sterilizer to the scrubber was calculated by subtracting the residual mass of EO left in the chamber from the mass of EO charged to the chamber. The mass of EO charged to the chamber was determined by weighing the charging cylinder prior to and after chamber charging. Residual EO concentrations were measured after the sterilization cycle was complete using the following procedure: a diaphragm pump was used to remove a slipstream of gas through a heated Teflon™ line, which was analyzed using a gas chromatograph (GC) equipped with a thermal conductivity detector (TCD). The residual EO mass was calculated based on the chamber volume, temperature, pressure, and the residual EO concentration.

D.1.1.2 Determination of EO Mass Emitted from the Scrubber. The mass of EO emitted from the scrubber was calculated from repeated measurement of the EO concentration and volumetric flow rate found in the scrubber exhaust. Ethylene oxide concentrations were determined by removing a slipstream of exhaust gas through Teflon™ tubing using a diaphragm pump. A sample of the slipstream was analyzed once every 3 minutes throughout the sterilization cycle using a GC equipped with a flame ionization detector (FID).

The volumetric flow rate of the exhaust gas was measured once each minute throughout the sterilization cycle using an orifice meter installed in the exhaust stack. The gas flow rate changed continuously during the exhaust cycles.

Ethylene oxide concentrations and volumetric flow rate data were then plotted for the initial exhaust and subsequent air wash cycles. Mass emissions of EO were calculated for each exhaust cycle and totalled. Control device efficiency was determined based on the calculated total emissions to the scrubber and measured total emissions from the scrubber.

D.1.1.3 Results. The results of three scrubber efficiency tests performed while a 12/88 mixture of EO and

dichlorodi-fluoromethane was used as a sterilant showed an average EO removal efficiency of 99.1 percent. Removal efficiencies ranged from 98.7 to 99.4 percent. More than 78 percent of the total EO was emitted during the first exhaust cycle.

A single scrubber efficiency test was performed using 100 percent EO as a sterilant. This test demonstrated a removal efficiency of 99.998 percent. Due to technical problems, data for the initial evacuation and the first air wash cycles were not available; thus, the reported amount of 0.00105 pound of EO exhausted was determined from measurements of subsequent air washes.

D.1.2 Report 2

D.1.2.1 Methodology. Report 2 discusses the test methods and results of three efficiency test runs performed on a dilute acid hydrolytic scrubber.[2] During testing, the sterilizer chamber was empty of product, and 100 percent EO was used as the sterilant. The weights of EO entering and leaving the scrubber were determined by continuously measuring the total volumetric gas flow rate at both the inlet and outlet of the scrubber with orifice meters. Sampling was performed over the entire evacuation cycle, which included the initial evacuation and two air wash cycles. The inlet EO mass was calculated using the difference by weight of the EO supply cylinders and residual EO left in the chamber (see Section D.1.1). However, because it was unclear exactly how residual chamber concentrations were determined, the calculation method will not be discussed.

D.1.2.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. Samples were withdrawn continuously from the two locations through heated Teflon™ lines using Teflon™-lined pumps. Slipstreams of gas were sampled with gas sampling valves at approximately 1-minute intervals into two GC's. A GC/TCD was used to measure the inlet slipstream and a GC/FID was used to measure the outlet slipstream.

Volumetric flow rate measurements were performed at both sampling locations. Two orifice meters of different sizes were

used at each location to supply flow measurements over the range of expected velocities.

D.1.2.3 Results. The three scrubber performance tests yielded an average removal efficiency of 99.988 percent by weight, with individual values ranging from 99.986 to 99.989 percent. The EO in the initial evacuation accounted for 20 percent or less of the total mass of EO emitted during the sterilization cycle.

D.1.3 Report 3

D.1.3.1 Methodology. In this test program, dilute acid hydrolytic scrubber efficiencies were determined using calculated and measured inlet values for the EO emissions vented to the scrubber and measured values for the EO emissions exhausted from the scrubber.[3] Sampling was performed over the entire evacuation cycle, which consisted of the initial evacuation and six air washes. This report compared the "throughput" and "recovery" methods of calculating dilute acid hydrolytic scrubber efficiency (see Section D.1.3.3). Data from 10 test runs were reported. Four test runs were conducted with an empty chamber. All runs used 12/88 as the sterilant.

D.1.3.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. The concentration of EO entering and leaving the scrubber was measured semicontinuously at the inlet and outlet with a GC/FID. Sample gas was continuously removed from the sampling locations and analyzed at 4-minute intervals. The volumetric flow rate at the outlet of the control device was measured by a vane anemometer in series with orifice plates; the flow rate at the inlet was calculated as discussed below.

D.1.3.3 Efficiency Determinations. The throughput efficiency was calculated using measured EO emissions from the inlet and outlet of the scrubber. Ethylene oxide concentration was measured at the inlet by GC/FID, and inlet volumetric flow rates were calculated using the chamber volume and chamber pressures and temperatures.

The recovery method calculated EO control efficiency based on the weight of EO charged to the sterilization chamber. The EO

charge cylinder was weighed prior to and after charging the chamber, and the weight of EO charged was determined by the difference. The measured outlet EO emissions were used to calculate the recovery efficiency.

D.1.3.4 Results. Only the results for the empty chamber tests will be discussed since tests where the sterilization chamber was loaded with product showed similar removal efficiencies. Throughput efficiencies for the empty chamber tests ranged from 99.82 to 99.98 percent. Recovery efficiencies for the empty chamber tests ranged from 99.90 to 99.97 percent. A one-way analysis of variance (ANOVA) performed on data from the empty chamber tests showed no difference between the recovery method and the throughput method in determining control efficiency.

D.1.4 Report 4

D.1.4.1 Methodology. This report focused on several issues raised by the testing described in Report 3.[4] The first issue concerned the stability of EO samples in 1-liter (L) (0.264 gallons [gal]) polyvinylfluoride gas bags, 5-milliliter (mL) (0.3 cubic inches [in^3]) gas-tight syringes, and evacuated aerosol cans. The second issue investigated was EO concentration profiles plotted at 1-minute intervals throughout the sterilization cycle using both pure EO and 12/88 mixtures. The third issue was the evaluation of various analytic columns.

The sampling and analytical methods reported varied slightly from those in Report 3. Scrubber exhaust samples were removed from the exhaust stack through a heated Teflon™ line with a diaphragm pump. Samples were placed into 1-L polyvinyl fluoride bags, 5-mL gas-tight syringes, or evacuated aerosol cans.

The linearity, efficiency, resolution, retention time, sample stability, and limits of quantitation and detection were evaluated for three columns.

D.1.4.2 Results. Report 4 concludes that a 5 percent fluorinated oil column is adequate for measuring percent levels of EO and dichlorodifluoromethane, the levels expected at the exhaust of an uncontrolled sterilizer or the inlet of a scrubber.

A 1 percent polyethylene glycol and substituted terephthalic acid column is recommended for measuring part-per-million-by-volume (ppmv) levels of EO, the levels expected at the outlet of a scrubber. The report recommends that a 3-percent polyethylene glycol and substituted terephthalic acid column operated at 45°C (116°F) be investigated for quantifying sub-ppm levels of EO, the levels expected in ambient air at sterilization facilities.

The stability of 12/88 and 100 percent EO samples in Tedlar™ bags were investigated by measurement at time zero and selected intervals thereafter. Both types of samples were not stable over a 4-day period; concentrations of the 12/88 mixture differed by 23 to 96 percent, while the concentrations of the 100 percent EO differed by 15 to 30 percent. Only the 12/88 samples were analyzed at a shorter time interval. After 1 day, the 12/88 mixture concentrations differed 3 to 27 percent from those at time zero, which indicated poor stability.

Aerosol cans containing 100 percent EO were analyzed at time zero and 4 days later. Over this period the EO concentrations differed an average of 15 percent (range +2.82 to -44.6). Syringe samples were analyzed at time zero and after 4 days and were also not found to be stable. The percent difference in concentration for both the 100 percent EO and 12/88 mixtures averaged 23 percent.

Concentration profiles showed that EO concentrations in sterilizer exhaust increased linearly between 5 and 13 minutes after the start of the cycle, reached a plateau between 13 and 20 minutes, and dropped off after 20 minutes.

D.1.5 Report 5

D.1.5.1 Methodology. Report 5 addresses six test runs conducted at a scrubber exhaust flow rate of 1.8 cubic meters per minute (m^3/min) (66 cubic feet per minute [ft^3/min]) and three conducted at a scrubber exhaust flow rate of 2.8 m^3/min (100 ft^3/min).[5] Flow through the scrubber appears to have been set for this test program, as no record of volumetric flow rate measurement is present in the report. A 12/88 EO mixture was

used as the sterilant. The number of evacuations tested in each sterilization cycle was not reported.

Scrubber inlet samples were acquired three times during the entire test effort. Grab samples were taken using polyvinylfluoride bags and analyzed in GC/FID, as described below. The EO concentrations of the three grab samples were 15.0, 27.4, and 29.0 percent. The average concentration of the three samples (23.8 percent) was used as the scrubber inlet concentration. The removal efficiencies were calculated using the average inlet concentration and the peak outlet concentrations.

The scrubber outlet emissions were sampled using a heated Teflon™ line and a Teflon™-coated pump. Grab samples were removed from the sample line at approximately 2-minute intervals using a syringe. The remaining sample passed into an infrared (IR) spectrometer. The syringe samples were analyzed by a standardized GC/FID. The IR spectrometer used to provide a second measure of scrubber outlet EO concentrations was set at a wavelength of 3.3 microns to reduce interferences.

D.1.5.2 Results. All of the efficiency results were based on the average measured inlet concentration of 23.8 percent EO and the maximum outlet EO concentration measured for a particular sterilization cycle. The variation in EO inlet concentrations indicates poor precision in determining scrubber inlet EO concentrations by this method. The efficiency determined by using the GC averaged 99.26 percent (99.16 to 99.32 percent range). The average efficiency determined by using IR spectroscopy was 99.16 percent (99.03 to 99.21 percent range).

D.1.6 Report 6

D.1.6.1 Methodology. In Report 6, EO removal efficiencies for a dilute acid hydrolytic scrubber were calculated by measuring EO concentrations at the scrubber inlet and outlet, scrubber outlet volumetric flow rates, and scrubber inlet and outlet temperatures.[6] Testing was performed under laboratory conditions on a full-scale acid-hydrolysis system. Each test cycle included two evacuations and use of a 12/88 mixture of sterilant.

Inlet and outlet EO concentrations were measured by GC/FID. The sample gas was removed from both ducts via Teflon™ tubing. Grab samples were removed from the tubing with a syringe every 40 seconds. Volumetric flow rate was measured at the scrubber outlet location using a calibrated dry test meter. Scrubber inlet flow rate was calculated by adding the EO volumetric flow rate. Using the measurements of EO concentration, temperature, and flow rate, the EO removal efficiency was calculated based on the total amount of EO that entered and left the scrubber system.

Four runs were performed on actual sterilizer exhaust, and three were performed with simulated sterilizer exhaust. For the simulated exhaust, a 12/88 mixture of sterilant gas was injected into the ductwork leading to the scrubber.

D.1.6.2 Results. Destruction efficiencies for the runs with actual exhaust ranged from 99.995 to 99.998 percent. The destruction efficiency for the EO injection runs averaged 99.999 percent. It was noted that of the EO charged to the sterilizer chamber, 25 to 56 percent was exhausted to the scrubber during the initial evacuation. A more accurate inlet flow rate determination would provide more representative efficiency results.

D.1.7 Report 7

D.1.7.1 Methodology. Report 7 describes the method used to determine the EO removal efficiency of a catalytic oxidation unit controlling aeration room emissions.[7] The sterilant was 100 percent EO, and six test runs were performed. Presurvey testing was conducted where a 12/88 mixture was used and four runs were performed.

D.1.7.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. The volumetric flow rates of the inlet and outlet sample gas streams was measured by traversing the ducts with a standard pitot tube according to EPA Methods 1 and 2 (40 CFR Part 60, Appendix A). Gas temperature and relative humidity were measured at the same locations.

Inlet and outlet grab samples were collected simultaneously in polyvinylfluoride gas bags using heated Teflon™ sampling lines

and Teflon™-coated pumps. The bag samples were analyzed by GC/FID within 20 hours of sample acquisition.

D.1.7.3 Results. The concentrations at the control device outlet were below the detection limit of the GC, and EO removal efficiencies were assumed to be greater than 99.9 percent. The EO removal efficiencies determined using presurvey samples ranged from 99.4 to 99.6 percent. The report speculated that the variation in efficiencies was due to the type of sterilant used and differences in chamber operating parameters.

D.1.8 Report 8

D.1.8.1 Methodology. Report 8 presents the results of seven efficiency test runs performed on a catalytic oxidation system used to control EO emissions from a sterilizer.[6] Three test runs were performed on actual sterilizer exhaust and four test runs were conducted while EO cylinder gas was injected into the ductwork leading to the catalytic oxidation system inlet. Each test cycle included two evacuations, and the sterilant was a 12/88 mixture.

The gas stream entering the catalytic oxidation system was continuously monitored for EO using a total hydrocarbon analyzer equipped with an FID. Additional inlet EO concentration measurements were made on grab samples using GC. An EO concentration profile for the catalytic oxidizer outlet was derived from GC analysis of grab samples. The sample gas streams were removed at the catalytic oxidizer inlet and exhaust and sampled using Teflon™ tubing and a pump. Grab samples were removed from this tubing with gas-tight syringes at 40-second intervals during the exhaust cycle.

Flow rate measurements were performed at the catalytic oxidizer inlet using a standard Pitot tube. A traverse of the duct was performed, and the volumetric flow rate was measured subsequently at a point of average velocity of the traverse. The outlet flow rate was assumed to be equal to the inlet flow rate. This sampling point was located after ambient air was added to the unit. Although the flow rate exhausted from the sterilizer diminished over each evacuation cycle, the flow at the catalytic

oxidizer test point did not change significantly. In comparison to dilute acid hydrolytic scrubbers, catalytic oxidizers exhibit relatively stable inlet and outlet flow rates because ambient air is added prior to the unit. Catalytic oxidizer inlet and outlet gas temperatures were also monitored.

Using the measurements of EO concentration (inlet and outlet), temperature, and flow rate, the EO removal efficiency was calculated based upon the total mass of EO that entered the catalytic oxidizer and the total mass of EO that left the unit.

D.1.8.2 Results. The EO removal efficiencies for the sterilizer discharge tests ranged from 99.16 to 99.40 percent. Removal efficiencies for the duct injection tests ranged from 99.89 to 99.98 percent

D.1.9 Report 9

D.1.9.1 Methodology. Report 9 describes the methods used to determine the EO removal efficiency of a catalytic oxidation unit used to control aeration room exhaust.[8] Since EO concentrations to the catalytic oxidizer were approximately 2 ppmv under normal operating conditions, pure EO cylinder gas was added at the inlet duct to yield EO concentrations of 100 ppmv. Gas samples were acquired at the inlet to the control device, after each of the three catalyst beds, and at the exhaust stack. A volumetric flow rate was reported for the exhaust stack, but no mention was made regarding the methods used to acquire these data.

Samples were collected using hydrogen bromide (HBr)-coated charcoal tubes over a period of 24 hours at each of the five locations described above. Each sampling train consisted of a Teflon™ tube connected to two or more charcoal tubes in series, connected to a sampling pump. Inlet sampling was conducted for a 20-minute period every 2 hours for the entire 24-hour test run. Samples were recovered from the charcoal tubes in a manner similar to NIOSH Method 1614, and the analysis was performed by GC/FID.

D.1.9.2 Results. The annual EO emissions to the atmosphere were calculated to be <0.043 kilograms per year (kg/yr)

(<0.095 pounds per year [lb/yr]), based on a volumetric flow rate of 19 actual m^3/min (694 actual cubic feet per minute [aft^3/min]). The EO removal efficiency of the catalytic oxidizer was calculated to be >99.99 percent.

As the methodology for determining volumetric flow rate was not presented in this report, this discussion is limited to the sampling and analytical methodology, specifically, the use of HBR-coated charcoal tubes in conjunction with an integrated sampling rate.

Direct GC/FID analysis of EO gas samples (Reports 1 through 9) yields a detection limit of approximately 1 ppmv. Use of the HBR-coated charcoal tubes allows concentration of the EO sample and a consequent decrease in the detection limit for EO in the gas stream to 3 parts per billion by volume (ppbv). This permits more accurate quantitation of EO concentrations in the diluted exhaust gas streams from catalytic oxidation emission control devices.

D.1.10 Report 10

Report 10 is not a test report but rather a summary of CARB Method 431, "Determination of Ethylene Oxide Emissions From Stationary Sources."[9] Method 431 was based on the same methodologies described in Reports 3 and 4 (References 1 and 2), with the exception that turbine (vane anemometer) or Roots-type flow meters rather than orifice meters are used to determine volumetric flow rate. Emission testing is performed on sterilizers containing normal product loads. Volumetric flow rate and EO concentrations of the vent gas are measured repeatedly for the duration of the sterilization cycle. Total emissions are calculated from curves representing flow and concentration versus time.

As mentioned above, the CARB method requires the use of vane anemometers or Roots-type meters to measure volumetric flow rate; these are certified to 1.5 percent accuracy by the manufacturer. Two or more meters may be installed in parallel if necessary to achieve this requirement over the entire expected range of flow rates. A valve is used to switch between the two meters as flow

rates change. Also required are measurements from temperature and pressure sensors to convert the measured flow rate to standard temperature and pressure conditions.

The sample gas is continuously removed from the exhaust stack via heated fluoroethylene or polytetrafluoride sample line at a rate in excess of 1 L/min (0.036 ft^3/min). A slipstream is removed from this line and directed to the GC sampling loop via a gas sampling valve. The sample is analyzed as frequently as possible (1-minute intervals for 100 percent EO and 3- to 4-minute intervals for EO mixtures). Sample loop pressure, sample flow rate, and slipstream flow rate must be measured/recorded during this process. Excess sample is bubbled through a sulfuric acid solution prior to discharge. A GC is required for the analysis.

Also suggested are calibration gas concentrations for both percent and ppm level analysis. Some lateral freedom is given with respect to calibration gas makeup and concentration. It is required that a similar midrange audit standard be used to verify calibration gas composition and GC performance. Audit standards and calibration gases must be supplied and certified by separate suppliers.

Additional guidelines for a pretest site survey, GC preparation, flow metering, sample train setup and operation, data reduction, and integration of the mass flow rate curve are also provided.

D.2 MONITORING SYSTEMS AND DEVICES

The following parameters may be monitored to indicate proper control device operation. All monitoring equipment should be installed, calibrated, maintained, and operated according to the manufacturer's specifications.

The following parameters indicate proper control device operation for counter-current packed scrubber and reaction/detoxification towers and thus will be monitored:

1. The EO charged to the sterilizer by weighing cylinders or by monitoring liquid flow rate using a rotameter or orifice; and

2. The ethylene glycol concentration in the scrubber liquor using liquid level indicators or specific gravity detectors in the tank. If the ethylene glycol concentration exceeds 60 weight percent, the scrubber liquid must be changed.

The following parameters indicate proper control device operation for catalytic oxidation and should be monitored:

1. The gas temperature both upstream and downstream of the catalyst bed using a device that continuously measures these temperatures while the control device is in operation; and

2. The amount of diluent air using a Pitot tube or other flow measurement device.

Proper operation of a flare is indicated by the continuous presence of a flame. Therefore, a heat-sensing device, such as an ultra-violet beam sensor or thermocouple, shall be installed at the pilot light to indicate the continuous presence of a flame.

D.3 PERFORMANCE TEST METHODS

D.3.1 Test Method Background

The EPA EO test method will reference the EPA Method 2 series and EPA Method 18 (40 CFR 60, Appendix A) as its base. Methods 2, 2A, 2C, and 2D apply for measuring flow rates from control device exhaust. The particular method applied depends on the size of the duct. If orifice meters (or a similar device) are used, it may be necessary to install more than one size in series to measure over flow rate variations.

Method 18 applies for measuring EO concentrations entering and exiting both catalytic oxidizers and dilute acid hydrolytic scrubbers. Using appropriate chromatographic columns and temperature programming eliminates interferences from dichlorodifluoromethane and potential EO degradation products.

D.3.2 Test Method Advantages/Disadvantages

Listed below is a summary of the different methodologies that have been addressed in D.1 and the advantages and disadvantages of each technique. These factors have been considered in developing the EPA test method.

D.3.2.1 Calculation of Inlet Mass. To determine the inlet mass of EO emissions entering the control device by calculation, the amount of sterilant entering the control device must be measured by weighing the cylinder before and after charging the sterilizer. The residual EO left in the chamber can be determined using the ideal gas law and would be subtracted from the cylinder weight to calculate the inlet mass.

The principal advantage of this technique is that it avoids the hazards of handling high levels of EO. The principal disadvantage is that a system leak will diminish the accuracy. However, a leak is unlikely since sterilizer sources must also comply with health and safety rules requiring continuous monitoring of worker exposure to EO.

D.3.2.2 Measuring the Inlet Mass or Outlet Mass. Direct measurement of the outlet mass emission rates requires determination of the flow rate and EO concentration. Direct measurement of the inlet mass emission rate would require an additional set of equipment and would have the additional hazards of handling high levels of EO. However, direct measurement would eliminate the potential for bias created by a leak in the system.

The EO concentration can be determined by semicontinuous sampling with a GC. However, the elution time for EO mixtures such as 12/88 is 3 minutes, which is not frequent enough to define the emission profile of a sterilizer. One-minute analyses are possible for pure EO. Grab samples may be taken at any interval and later analyzed by GC to better define the emission profile. However, the stability of EO in bags, syringes, and vacu-samplers needs additional investigation.

Removing the sample gas through a heated, inert sampling line and analyzing it immediately eliminates the potential for sample degradation and condensation.

An orifice meter is capable of providing continuous volumetric flow rate information. It is appropriate for measuring volumetric flow rate in a system where flow rates vary rapidly. Multiple orifice meters can be used to cover a wide range of flow rates.

The presence of other components in the vent gas stream creates two problems. First, components eluting near the EO peak may create confusion in identifying and quantitating the EO peak. Second, components that elute after EO and dichlorodifluoromethane extend the analysis time and decrease the number of on-line samples that can be analyzed.

D.3.2.3 Efficiency Determinations. An efficiency determination based on the initial evacuation of a sterilizer does not necessarily evaluate the scrubber efficiency during subsequent air washes. Integrating the EO concentration curve instead of using a peak concentration value is more representative of overall efficiency; using the peak concentration will negatively bias the results.

D.4 REFERENCES

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APPENDIX E.

SUPPLEMENTAL INFORMATION TO THE COST ANALYSIS

APPENDIX E.

SUPPLEMENTAL INFORMATION TO THE COST ANALYSIS

This Appendix contains supplemental information used in analyzing costs associated with the regulation of ethylene oxide (EO) commercial sterilization facilities. Included in this appendix are: (1) costs for acid-water scrubbers (Section E.1); (2) sample calculations of the equations used to develop capital and annual costs for acid-water scrubbers (Section E.2); (3) aeration room cost analysis (Section E.3); (4) capital and annual control costs for the sterilizer chamber, chamber exhaust, and aeration room vent(s) at an example facility (Section E.4); (5) a breakdown of manifolding costs for these three vents (Section E.5); and (6) the cost indices and conversion factors used to convert costs to fourth quarter 1987 dollars (Section E.6).

E.1 COSTS FOR ACID-WATER SCRUBBERS

TABLE E-1. COST OF DAMAS SCRUBBER MODELS (F.O.B.)[1,2]
(4th Quarter 1987 Dollars)

Model No.	Chamber size, m^3 (ft^3)[a]	Flow rate (acfm)	Conversion capacity of scrubber, kg (lb) of EO	Automated scrubber cost, $	Cost of explosion-proof valves for scrubber, $[b]
25	< 1.4 (<50)	40	227 (500)	8,980	N/A[c]
50	1.4 to 2.8 (50 to 100)	60	454 (1,000)	13,500	N/A[c]
100	<11.3 (<400)	50-100	908 (2,000)	46,800	12,800
200	11.3 to 17.0 (400 to 600)	>100-200	1,816 (4,000)	67,700	13,800
300	17.0 to 22.7 (600 to 800)	>200-300	2,724 (6,000)	88,500	14,900
400	22.7 to 45.3 (800 to 1,600)	>400	3,632 (8,000)	98,900	16,000
500	45.3 to 56.6 (1,600 to 2,000)	>500	4,540 (10,000)	141,000	18,100
600	>56.6 (>2,000)	>600	5,448 (12,000)	156,000	19,100

[a]The size of sterilization chamber that can be served by the model number, assuming the smallest appropriate vacuum pump is used.[3]
[b]Explosion-proof valves are necessary if the sterilization chamber that is vented to the scrubber uses a gas mixture greater than 20 percent by weight EO.[4,5]
[c]Price of explosion-proof valves included in cost of these models.
[d]Acfm actual cubic feet per minute.

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TABLE E-2. CAPITAL AND ANNUALIZED COSTS OF INSTALLING SCRUBBERS[1]
(4th Quarter 1984 Dollars)

	Item	Cost
A.	CAPITAL COSTS[a]	
	Installed equipment costs	
	Automated scrubber	N/A[b]
	Explosion-proof valves for scrubber	b
	Chlorine filter house	b
	Purchased equipment costs, total	b
	Installation of scrubber	b
	Installation of chlorine filters	b
	Taxes: 5 percent of equipment cost	b
	Freight: 5 percent of equipment cost	b
	Vacuum pump[c]	19,700
	Manifolding of chambers (includes check valve)	b
	Total capital costs, 1984 dollars	19,700
B.	ANNUALIZED COSTS[a]	
	Direct operating costs	
	Labor[d]	b
	Materials	
	50 percent H_2SO_4	
	50 percent NaOH	b
	Chlorine filters	b
	Taxes: 5 percent of materials cost	b
	Freight: 5 percent of materials cost	b
	Compressed air	b
	Disposal of ethylene glycol	b
	Indirect operating costs	
	Overhead: 0.80 x labor	b
	Property tax, insurance, and administration[e]	788
	Capital recovery costs[c]	3,210
	Total annualized costs	4,000
C.	COST EFFECTIVENESS	
	Reduce, Mg EO yr	43.56
	Cost effectiveness, 1984, $/Mg EO	92

[a]Rounded to three significant figures.
[b]Not applicable.
[c]Four vacuum pumps at $4,935 each.
[d]Labor was calculated for 0.25 person-hours/shift, 3 shifts/d, 365 d/yr for system inspection and 16 person-hours for each regeneration of the scrubber at $11.60/person-hour.
[e]Calculated as 4 percent of total capital cost.

TABLE E-3. DATA USED TO CALCULATE SCRUBBER EQUIPMENT CAPITAL COSTS[1]
(4th Quarter 1987 Dollars)

Item	Cost factor
Automated scrubber	--[a]
Explosion-proof valves for scrubber	--[a b]
Chlorine filter house	($41.50 each) x (No. of tanks)[c]
Scrubber installation	50 percent of scrubber cost
Chlorine filter installation	($20.00) x (No. of tanks)[c]
Taxes	5 percent of total equipment cost
Freight	5 percent of total equipment cost
Vacuum pump(s)	$5,170 per pump
Manifolding of chambers	--[d]
Check valve	--[e]

[a]Function of chamber size (see Section E.1).
[b]Explosion-proof valves are necessary if the chamber that is vented to the scrubber uses a gas mixture greater than 20 percent (by weight) EO. (See Section E.1).
[c]Number of scrubber tanks required = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO).
[d]See Section E.5.
[e]See Table E-4.

TABLE E-4. CAPITAL COST OF CHECK VALVE FOR CHAMBER

Cost item	Cost 1987, $	Richardson reference[2]
Swing check valve	367	15-43, p. 31
Labor hours to install	1.1	15-43, p. 31
Labor costs at $21.47/labor hour	24	15-0, p. 2
Overhead costs at $13.31/labor hour	15	1-0, p. 5
Total direct costs	391	
Administration: 10 percent of total direct costs	39	1-0, p. 5
Taxes: 5 percent of equipment cost	18	1-0, p. 6
Total indirect costs	72	
Total installed cost	463	
Annualized capital recovery cost[a]	75	GARD, p. 3-18[3]

[a]Calculated as 0.16275 x (total installed cost), for an interest rate of 10 percent and a 10-year recovery period.

TABLE E-5. DATA USED TO CALCULATE CONTROL DEVICE ANNUALIZED COSTS[1]
(4th Quarter 1987 Dollars)

Item	Cost factor
Direct operating costs	
Labor	\$3,188 + (\$11.65) x (16 person-hours) x (No. of scrubber regenerations)[a b]
Materials:	
50 percent H_2SO_4	(\$0.0702/lb) x (594 lb/drum) x (No. of drums required) x (1.15)[c-e]
50 percent NaOH	(Cost/lb) x (700 lb/drum) x (No. of drums required) x (1.15)[c, f, g]
Chlorine filters	(\$15/filter) x (No. of tank regenerations) x (No. of tanks)[c h]
Taxes	5 percent of materials cost
Freight	5 percent of materials cost
Compressed air	0[i]
Disposal of ethylene glycol	--[j]
Indirect operating costs	
Overhead	(0.6) x (labor costs)
Property tax, insurance, and administration	4 percent of total capital costs
Capital recovery costs	(0.16275) x (total capital costs)[k]

[a]Number of scrubber regenerations = amount of EO to be treated divided by the conversion capacity of the scrubber (See Example Calculation No. 6 in Section E.2)

[b]The \$3,188 is for visual inspection of the system 15 minutes per shift, 3 shifts per day, 365 days per year at \$11.65/person-hour. It was assumed that each regeneration of the scrubber solution would require two people at 8 person-hours each, independent of scrubber size.

[c]Number of scrubber tanks = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO). Number of tank regenerations = number of scrubber regenerations multiplied by the number of scrubber tanks.

[d]Each tank regeneration requires one 55-gallon drum of 50 percent H_2SO_4.

[e]Fifteen percent extra is allowed for spillage.

[f]Each tank regeneration requires 250 pounds of NaOH for neutralization.

[g]Cost basis for 50 percent NaOH (350 pounds NaOH per drum):

[f]No. of drums >9, cost/lb = \$0.0110.
If No. of drums = 3 to 9, cost/lb = \$0.0802.
If No. of drums <2, cost/lb = \$0.0752.

[h]Each chlorine filter can dechlorinate approximately 200 gallons (one tank) of H_2O; replace filter at each tank regeneration.

[i]The cost of 10 seconds of in-house compressed air per cycle is considered negligible.

[j]Unit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at regeneration, approximately 4,845 lb (see Example Calculation No. 3 in Section E.2.
If the total weight <42,000 lb, disposal cost = (weight) x (\$0.110/lb).
If the total weight ≥42,000 lb, disposal cost = (weight) x (\$0.068/lb).

[k]Assumes an interest rate of 10 percent and a 10-year recovery period.

TABLE E-6. MISCELLANEOUS OPERATING COSTS[1]

Item description	Cost, 1987 $
Operating materials	
1. 50 percent H_2SO_4, electrolyte-grade	0.0702/lb
2. 50 percent NaOH, industrial grade:	
<2 drums	0.110/lb
3-9 drums	0.0802/lb
>9 drums	0.0752/lb
3. Chlorine filters:	
Filter housing	41.50 each
Filter	15.00 each
Installation	20.00 each
Shipping charges for waste disposal	
Weight of solution for disposal:	
<42,000 lb (drums)	0.110/lb
≥42,000 lb (bulk)	0.068/lb

TABLE E-7. COST OF EtO ABATOR™ CATALYTIC OXIDIZERS (F.O.B.)[1-3]
(1987 Dollars)

Design flow rate, m^3/min (ft^3/min)	Cost, $[a b]
28 (1,000)	48,000
84 (3,000)	81,000
168 (6,000)	112,000
252 (9,000)	148,000
336 (12,000)	189,000

[a]Costs in 1989 dollars were corrected to 1987 dollars using the "Chemical Engineering" Plant Cost indices.
[b]Cost of replacement catalyst is $1,500/cell in 1989 dollars, or approximately $1,240/cell in 1987 dollars.[2,4,5]

E.1 COSTS OF ACID-WATER SCRUBBERS

REFERENCES

1. Telecon. Srebro, S., MRI, with D. Smith. Damas Corp. June 20, 1986. Discussion about costs of the Damas Tri-Phase ethylene oxide scrubbers.

2. Telecon. Srebro, S., MRI, with D. Smith. Damas Corp. December 12, 1989. Discussion about costs of Models 25 and 50 Damas acid/water scrubbers.

3. Beall, C., Meeting Minutes: Damas Corp. and Johnson & Johnson. Midwest Research Institute. Raleigh, NC. April 30, 1986. 9 p.

4. Telecon. Glanville, J., MRI, with C. Woltz. Union Carbide, Inc. February 10, 1987. Discussion about flammability of EO mixtures.

5. Telecon. Srebro, S., MRI, with M. Popescu. Johnson & Johnson International. June 16, 1986. Discussion about the Damas Tri-Phase ethylene oxide scrubbers.

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E.2 SAMPLE COST CALCULATIONS FOR ACID-WATER SCRUBBERS

E.2 SAMPLE COST CALCULATIONS FOR ACID-WATER SCRUBBERS

	Sterilization chambers at the facility				
	No. 1	No. 2	No. 3	No. 4	No. 5
Size, m^3 (ft^3)	19 (667)	19 (667)	34 (1,200)	37 (1,334)	37 (1,334)
Gas type	100	100	12/88	100	100
EO USE, kg (lb)	12,700 (28,000)	12,700 (28,000)	540 (1,200)	21,000 (46,000)	21,000 (46,000)
EO-EMIT, kg (lb)	12,100 (26,600)	12,100 (26,600)	520 (1,140)	19,800 (43,700)	19,800 (43,700)
MEO-EMIT, Mg (tons)	12.07 (13.52)	12.07 (13.52)	0.52 (0.58)	19.82 (22.20)	19.82 (22.20)

	Facility totals
EO-FAC, kg (lb)	64,310 (141,740)
MEO-FAC, Mg (tons)	64.30 (72.02)
EO-TOT, kg (lb)	67,695 (149,200)
MEO-TOT, Mg (tons)	67.7 (74.6)
CON-EM, Mg (tons)	0.64 (0.70)
REDUCE, Mg (tons)	63.66 (70.15)

1. The size, gas type, and EO use are those for an actual commercial sterilization facility represented in the EPA data base. (See Section 3.1 of this report for a description of how this data base was developed.) The other values were calculated using the following assumptions:

a. EO-EMIT (lb) = EO (lb) emitted annually from an individual sterilization chamber to the vacuum pump drain and to the atmosphere. As shown in Section 3.4 of this document, sterilizer vent emissions and vacuum pump drain emissions were assumed to be 50 percent and 45 percent of EO use (lb), respectively. Residual EO in the sterilized product prior to aeration was assumed to be 5 percent of EO-USE (lb). This 5 percent of the EO use is not included as part of EO-EMIT (lb).

b. MEO-EMIT (Mg EO) = EO-EMIT (lb)/2,204.6

c. EO-FAC (lb) and MEO-FAC (Mg) are the amount of EO released annually by the facility to the vacuum pump drain and to the atmosphere, i.e., the sum of EO-EMIT and the sum of MEO-EMIT, respectively.

d. EO-TOT (lb) is the total amount of EO (lb) used annually by the facility, i.e., the sum of EO use. MEO-TOT (Mg) = EO-TOT (lb)/2,204.6.

e. CON-EM (Mg) is the amount of EO that would be released annually after control, i.e., MEO-TOT*(1-0.99)*0.95. Note that the 5 percent residual EO in the sterilized product, which is later released from the aeration room vent, is excluded from this calculated emission estimate.

f. REDUCE (Mg) is the incremental amount of EO that would be reduced if controls are implemented, i.e., (MEO-FAC)-(CON-EM).

2. For all calculations, a conversion efficiency of 99.0 percent was assumed for the scrubber.

3. Each tank of the scrubber initially holds 0.75 m^3 (198 gal) H_2O and 0.075 m^3 (19.8 gal) H_2SO_4. The manufacturer recommends that the tank be regenerated (i.e., drained, rinsed, and refilled) after 907 kg (2,000 lb) EO have been treated.

a. 0.075 m^3 (19.8 gal) H_2SO_4 = 1.42 kg-mole H_2SO_4 (ρ = 1.834; MW = 98.08) $2NaOH + H_2SO_4$ T $Na_2SO_4 + 2H_2O$; 1.42 kg-mole H_2SO_4 requires 2.84 kg mole NaOH to neutralize. Neutralization will produce 2.84 kg-moles H_2O and 1.42 kg mole Na_2SO_4. Use 50 percent (w/w) NaOH to neutralize; each 0.21-m^3 (55-gal) drum of 50 percent NaOH weighs 318 kg (700 lb), i.e., 159 kg (350 lb) NaOH (MW = 40); need 2.84 kg-moles or 114 kg (250 lb) NaOH to neutralize.

b. C_2H_4O (EO) + H_2O T $C_2H_4(OH)_2$ (ethylene glycol); 907 kg (2,000 lb) EO = 20.51 kg-moles EO (MW = 44.1).

c. At 99 percent conversion, yield is 20.365 kg-moles or 1.14 m^3 (301 gal) ethylene glycol (EG) (MW = 62.07; ρ = 1.1088).

d. At 99 percent conversion, 20.365 kg-moles H_2O have reacted. 41.64 kg moles H_2O originally available (MW = 18; ρ = 1); 21.275 kg-moles or 0.38 m^3 (100 gal) H_2O remain unreacted.

e. Weight of neutralized solution per tank: 1.42-kg mole Na_2SO_4 = 202 kg Na_2SO_4 (MW = 142.04); 2.84 kg-moles H_2O (from neutralization) = 51 kg (112 lb) H_2O; 250 lb (113 kg) H_2O = from 50 percent NaOH solution; 0.38 m^3 (100 gal) unreacted H_2O

= 378 kg H_2O (833 lb); 1.14 m^3 (301 gal)EG = 1,264 kg (2,786 lb) EG; total wt = 2,008 kg = 4,427 lb.

f. Solution is 63 percent (w/w) EG. Add about 0.19 m^3 (50 gal) rinse water for each tank = 189 kg (416 lb); total wt (+ rinse H_2O) = 2,198 kg (4,844 lb); total gal (+ rinse H_2O) = 1.87 m^3 (495 gal) = nine 0.21 m^3 (55-gal) drums; wt per 0.21 m^3 (55-gal) drum = 244 kg (538 lb).

4. Find scrubber model and cost from Table E-1, based on the sum of the volumes of the two largest chambers at the facility:

Chambers 4 and 5 75 m^3 (2,668 ft3) Model 600 $157,500

5. Because at least one chamber uses 100 percent EO, explosion-proof valves are necessary.

6. Find number of regenerations of scrubber required per year:

a. Number of scrubber tanks = scrubber model/100 = 6 (scrubber consists of modular tanks).

b. Conversion capacity of scrubber = (No. of tanks) x 2,000 lb = 12,000 lb.

c. Number of scrubber regenerations = EO-FAC (lb)/12,000, i.e., the amount of EO (lb) to be treated per year divided by the conversion capacity of the scrubber.

141,700/12,000 = 11.81 scrubber regenerations/yr

d. Number of tank regenerations = (No. of scrubber regenerations) x (No. of tanks per scrubber) = (11.81) x (6) = 70.87.

7. Cost of chlorine filter housing = (41.50) x (No. of tanks) = $(41.50) x (6) = $249.

8. Installation costs:

a. Scrubber installation = (0.5) x (cost of scrubber) = $78,750

b. Chlorine filter housing installation = (20) x (No. of tanks) = $120.

9. The incremental capital costs of manifolding are presented in Table E-14 of this report.

10. Vacuum pumps. A closed-loop recirculating water vacuum pump is required on each of the five chambers. The cost of modifying the first vacuum pump is included in the cost of the scrubber; the cost of modifying the other four vacuum pumps is $4,935 each.

11. Calculate direct operating costs:

a. Labor = 3,177 + (11.60)x(16) x (No. of regenerations). The $3,177 is for general inspection of the system 15 minutes/shift, 3 shifts/d, 365 d/yr at $11.60/person-hour. For the purposes of these cost analyses, it was assumed that each regeneration of the scrubber would require 2 people at 8 person-hours each, independent of scrubber size. System inspection was also assumed to be independent of scrubber size.

b. Sulfuric acid (50 percent H_2SO_4-electrolyte grade). Assumed: 1 55-gal drum of 50 percent H_2SO_4, i.e., 19.4 gal H_2SO_4, per scrubber tank.

No. of drums required = No. of tank regenerations = (No. of scrubber regenerations) x (No. of tanks per scrubber) = 70.87
Cost of acid = (No. of drums) x (594 lb/drum) x ($0.069/lb)

c. Caustic (50 percent NaOH-industrial grade). First, the unit cost of NaOH was calculated.

NaOH required per year = [No. of tank regenerations] x [NaOH (lb) required per tank] = 70.87 x 250 = 17,718 lb/yr

Total drums/yr required by facility = total NaOH (lb)/350 lb per drum; total drums = 50.6

If total drums >9, cost/lb = 0.0738

If total drums = 3 to 9, cost/lb = 0.0787

If total drums = <2, cost/lb = 0.108

Cost of caustic = (No. of drums) x (cost/lb) x (700 lb/drum)

d. Cost of chlorine filters. Each filter can dechlorinate f200 gal H_2O (or 1 scrubber tank); replace at each scrubber regeneration.

Cost = (No. of scrubber regenerations) x (No. of tanks) x ($15/filter)

e. Disposal. Unit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at the time of regeneration, including rinse water (see 3.f).

Total wt = 70.87 x 4,844 lb/tank = 343,943 lb/yr

If total wt <42,000 lb, disposal cost = wt (lb) x ($0.096/lb)

If total wt ≥42,000 lb, disposal cost = wt (lb) x ($0.059/lb)

f. Compressed air. The cost of 10 seconds of in-house air per cycle was considered negligible and was not computed for these cost analyses.

12. The capital and annualized costs are reported in Tables E-3 and E-5.

REFERENCES

1. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Cost Effectiveness of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. March 21, 1991.

2. Richardson Engineering Services, Inc. Process Plant Construction Estimating Standards. 1984.

3. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc. Niles, IL. Publication No. EPA-450/5-80-002. December 1978.

E.3 AERATION ROOM COST ANALYSIS

TABLE E-8. AERATION ROOM GAS/SOLID REACTANT CONTROL COST ANALYSIS

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
1.50	1	0	1	0	44200	63600	30000	0.0000202	1500000000
2.00	1	0	1	0	44200	63600	30000	0.0000269	1100000000
2.98	1	0	1	0	44200	63600	30000	0.0000401	750000000
4.80	1	0	1	0	44200	63600	30000	0.0000647	460000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
7.50	1	0	1	0	44200	63600	30000	0.0001010	300000000
9.00	1	0	1	0	44200	63600	30000	0.0001212	250000000
12.00	1	0	1	0	44200	63600	30000	0.0001617	190000000
16.80	1	0	1	0	44200	63600	30000	0.0002263	130000000
17.80	1	0	1	0	44200	63600	30000	0.0002398	130000000
27.36	1	0	1	0	44200	63600	30000	0.0003686	81000000
32.40	1	0	1	0	44200	63600	30000	0.0004365	69000000
32.40	1	0	1	0	44200	63600	30000	0.0004365	69000000
32.40	1	0	1	0	44200	63600	30000	0.0004365	69000000
61.34	1	0	1	0	44200	63600	30000	0.0008264	36000000
64.00	1	0	1	0	44200	63600	30000	0.0008622	35000000
64.80	1	0	1	0	44200	63600	30000	0.0008730	34000000
65.00	1	0	1	0	44200	63600	30000	0.0008757	34000000
70.00	1	0	1	0	44200	63600	30000	0.0009430	32000000
93.60	1	0	1	0	44200	63600	30000	0.0012610	24000000
100.80	1	0	1	0	44200	63600	30000	0.0013580	22000000
105.00	1	0	1	0	44200	63600	30000	0.0014145	21000000
110.00	1	0	1	0	44200	63600	30000	0.0014819	20000000
111.00	1	0	1	0	44200	63600	30000	0.0014954	20000000
113.00	1	0	1	0	44200	63600	30000	0.0015223	20000000
115.00	1	0	1	0	44200	63600	30000	0.0015493	19000000
126.00	1	0	1	0	44200	63600	30000	0.0016975	18000000
160.80	1	0	1	0	44200	63600	30000	0.0021663	14000000
162.00	1	0	1	0	44200	63600	30000	0.0021824	14000000
185.25	1	0	1	0	44200	63600	30000	0.0024957	12000000
188.00	1	0	1	0	44200	63600	30000	0.0025327	12000000
192.00	1	0	1	0	44200	63600	30000	0.0025866	12000000
194.00	1	0	1	0	44200	63600	30000	0.0026135	11000000
195.00	1	0	1	0	44200	63600	30000	0.0026270	11000000
200.00	1	0	1	0	44200	63600	30000	0.0026944	11000000
201.60	1	0	1	0	44200	63600	30000	0.0027159	11000000
264.00	1	0	1	0	44200	63600	30000	0.0035566	8400000
291.60	1	0	1	0	44200	63600	30000	0.0039284	7600000
312.00	1	0	1	0	44200	63600	30000	0.0042032	7100000
312.00	1	0	1	0	44200	63600	30000	0.0042032	7100000
324.00	1	0	1	0	44200	63600	30000	0.0043649	6900000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
388.80	1	0	1	0	44200	63600	30000	0.0052378	5700000
390.00	1	0	1	0	44200	63600	30000	0.0052540	5700000
395.00	1	16000	1	0	44200	63600	33700	0.0053214	6300000
432.00	1	0	1	0	44200	63600	30000	0.0058198	5200000
456.00	1	0	1	0	44200	63600	30000	0.0061432	4900000
504.00	1	0	1	0	44200	63600	30000	0.0067898	4400000
520.00	1	0	1	0	44200	63600	30000	0.0070054	4300000
557.30	1	0	1	0	44200	63600	30000	0.0075079	4000000
562.00	1	0	1	0	44200	63600	30000	0.0075712	4000000
581.00	1	0	1	0	44200	63600	30000	0.0078271	3800000
686.00	1	0	1	0	44200	63600	30000	0.0092417	3200000
804.00	1	0	1	0	44200	63600	30000	0.0108314	2800000
850.00	1	0	1	0	44200	63600	30000	0.0114511	2600000
875.00	1	0	1	0	44200	63600	30000	0.0117879	2500000
1092.00	1	0	1	0	44200	63600	30000	0.0147112	2000000
1155.00	1	16000	1	0	44200	63600	33700	0.0155600	2200000
1231.00	1	0	1	0	44200	63600	30000	0.0165838	1800000
1300.00	1	0	1	0	44200	63600	30000	0.0175134	1700000
1334.00	1	0	1	0	44200	63600	30000	0.0179714	1700000
1521.00	1	0	1	0	44200	63600	30000	0.0204907	1500000
1600.00	1	0	1	0	44200	63600	30000	0.0215549	1400000
1714.00	1	0	1	0	44200	63600	30000	0.0230907	1300000
1714.00	1	0	1	0	44200	63600	30000	0.0230907	1300000
1750.00	1	0	1	0	44200	63600	30000	0.0235757	1300000
1750.00	1	0	1	0	44200	63600	30000	0.0235757	1300000
1800.00	1	0	1	0	44200	63600	30000	0.0242493	1200000
1944.00	1	0	1	0	44200	63600	30000	0.0261892	1100000
1965.00	1	0	1	0	44200	63600	30000	0.0264721	1100000
1980.00	1	0	1	0	44200	63600	30000	0.0266742	1100000
2016.00	1	0	1	0	44200	63600	30000	0.0271592	1100000
2142.00	1	0	1	0	44200	63600	30000	0.0288567	1000000
2254.00	1	0	1	0	44200	63600	30000	0.0303655	1000000
2280.00	1	0	1	0	44200	63600	30000	0.0307158	1000000
2376.00	1	0	1	0	44200	63600	30000	0.0320091	940000
2419.20	1	0	1	0	44200	63600	30000	0.0325911	920000
2450.00	1	0	1	0	44200	63600	30000	0.0330060	910000
2527.00	1	0	1	0	44200	63600	30000	0.0340433	880000
2599.20	1	0	1	0	44200	63600	30000	0.0350160	860000
3120.00	1	0	1	0	44200	63600	30000	0.0420321	710000
3135.00	1	0	1	0	44200	63600	30000	0.0422342	710000
3240.00	1	0	1	0	44200	63600	30000	0.0436487	690000
3640.00	1	0	1	0	44200	63600	30000	0.0490375	610000
3755.00	1	0	1	0	44200	63600	30000	0.0505867	590000
4200.00	1	0	1	0	44200	63600	30000	0.0565817	530000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
4200.00	1	0	1	0	44200	63600	30000	0.0565817	530000
4286.90	1	0	1	0	44200	63600	30000	0.0577524	520000
4320.00	1	0	1	0	44200	63600	30000	0.0581983	520000
4368.00	1	0	1	0	44200	63600	30000	0.0588450	510000
4667.00	1	0	1	0	44200	63600	30000	0.0628730	480000
4860.00	1	0	1	0	44200	63600	30000	0.0654731	460000
5016.00	1	16000	1	0	44200	82000	33700	0.0675747	500000
5088.00	1	0	1	0	44200	63600	30000	0.0685447	440000
5189.00	1	16000	1	0	44200	82000	33700	0.0699053	480000
5250.00	1	16000	1	0	44200	82000	33700	0.0707271	480000
5258.00	1	16000	1	0	44200	82000	33700	0.0708349	480000
5739.00	1	16000	1	0	44200	82000	33700	0.0773148	440000
5850.00	1	16000	1	0	44200	82000	33700	0.0788102	430000
6000.00	1	16000	1	0	44200	82000	33700	0.0808310	420000
6048.00	1	16000	1	0	44200	82000	33700	0.0814776	410000
6176.00	1	16000	1	0	44200	82000	33700	0.0832020	410000
6451.00	1	16000	1	0	44200	82000	33700	0.0869068	390000
6840.00	1	16000	1	0	44200	82000	33700	0.0921473	370000
6900.00	1	16000	1	0	44200	82000	33700	0.0929556	360000
7194.00	1	16000	1	0	44200	82000	33700	0.0969164	350000
7350.00	1	16000	1	0	44200	82000	33700	0.0990180	340000
7387.00	1	16000	1	0	44200	82000	33700	0.0995164	340000
8390.00	1	16000	1	0	44200	82000	33700	0.1130287	300000
8400.00	1	16000	1	0	44200	82000	33700	0.1131634	300000
8736.00	1	16000	1	0	44200	82000	33700	0.1176899	290000
9676.00	1	16000	1	0	44200	82000	33700	0.1303534	260000
10002.00	1	0	1	0	44200	63600	33700	0.1347453	250000
10613.00	1	16000	1	0	44200	82000	33700	0.1429765	240000
10800.00	1	16000	1	0	44200	82000	33700	0.1454958	230000
11016.00	1	16000	1	0	44200	82000	33700	0.1484057	230000
11400.00	2	32000	1	0	44200	121000	41700	0.1535789	270000
11440.00	2	32000	1	0	44200	121000	41700	0.1541178	270000
11547.00	2	32000	1	0	44200	121000	41700	0.1555592	270000
11984.00	2	32000	1	0	44200	121000	41700	0.1614464	260000
12020.00	2	32000	1	0	44200	121000	41700	0.1619314	260000
12249.00	2	32000	1	0	44200	121000	41700	0.1650165	250000
13000.00	2	32000	1	0	44200	121000	41700	0.1751338	240000
13000.00	2	32000	1	0	44200	121000	41700	0.1751338	240000
13059.00	2	32000	1	0	44200	121000	41700	0.1759286	240000
14352.00	2	32000	1	0	44200	121000	41700	0.1933477	220000
14400.00	2	32000	1	0	44200	121000	41700	0.1939944	210000
14860.00	3	48000	1	0	44200	143000	46100	0.2001914	230000
14862.00	3	48000	1	0	44200	143000	46100	0.2002184	230000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
15040.00	2	32000	1	0	44200	121000	41700	0.2026163	210000
15600.00	1	16000	1	0	44200	82000	33700	0.2101606	160000
15724.00	2	32000	1	0	44200	121000	41700	0.2118311	200000
16426.00	1	0	1	0	44200	63600	30000	0.2212883	140000
16956.00	2	32000	1	0	44200	121000	41700	0.2284284	180000
18000.00	2	32000	1	0	44200	121000	41700	0.2424930	170000
18057.00	4	64000	1	0	44200	165000	50500	0.2432609	210000
18268.00	1	32000	1	0	44200	121000	41700	0.2461034	170000
18963.00	2	48000	1	0	44200	143000	46100	0.2554663	180000
19090.00	2	48000	1	0	44200	143000	46100	0.2571773	180000
21135.00	2	48000	1	0	44200	143000	46100	0.2847272	160000
22560.00	2	48000	1	0	44200	143000	46100	0.3039245	150000
23954.00	2	48000	1	0	44200	143000	46100	0.3227043	140000
24000.00	2	48000	1	0	44200	143000	46100	0.3233240	140000
24082.00	2	48000	1	0	44200	143000	46100	0.3244286	140000
26549.00	4	64000	1	0	44200	165000	50500	0.3576637	140000
29500.00	4	64000	1	0	44200	165000	50500	0.3974190	130000
29700.00	4	64000	1	0	44200	165000	50500	0.4001134	130000
30034.00	4	64000	1	0	44200	165000	50500	0.4046130	120000
30570.00	5	80000	0	1	74800	231000	75300	0.4118339	180000
32040.00	4	64000	1	0	44200	165000	50500	0.4316375	120000
34034.00	5	80000	0	1	74800	231000	75300	0.4585003	160000
35040.00	5	80000	0	1	74800	231000	75300	0.4720530	160000
36231.00	5	80000	0	1	74800	231000	75300	0.4880979	150000
38799.00	5	80000	0	1	74800	231000	75300	0.5226936	140000
39105.00	4	64000	1	0	44200	165000	50500	0.5268160	96000
40188.00	5	80000	0	1	74800	231000	75300	0.5414060	140000
41320.00	9	144000	0	1	74800	319000	93300	0.5566561	170000
43050.00	8	128000	0	1	74800	297000	88800	0.5799623	150000
45804.00	3	48000	1	0	44200	143000	46100	0.6170638	75000
50000.00	7	112000	0	1	74800	275000	84300	0.6735916	130000
52547.36	7	112000	0	1	74800	275000	84300	0.7079092	120000
52950.00	7	112000	0	1	74800	275000	84300	0.7133335	120000
54391.00	7	112000	0	1	74800	275000	84300	0.7327464	120000
55567.00	8	128000	0	1	74800	297000	88800	0.7485893	120000
56860.00	9	144000	0	1	74800	319000	93300	0.7660083	120000
64044.00	6	96000	0	1	74800	253000	79800	0.8627900	92000
66503.00	9	144000	0	1	74800	319000	93300	0.8959172	100000
78580.00	1	0	1	0	44200	63600	30000	1.0586165	28000
88000.00	11	176000	0	1	74800	363000	102000	1.1855212	86000
93450.00	11	176000	0	1	74800	363000	102000	1.2589427	81000
100524.00	13	208000	1	1	11900	470000	141000	1.3542424	100000
108408.00	18	288000	0	2	150000	626000	184000	1.4604543	130000
109897.00	6	96000	0	1	74800	253000	79800	1.4805139	54000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
125084.00	9	144000	0	1	74800	319000	93300	1.6851106	55000
134956.00	19	304000	0	2	150000	648000	189000	1.8181045	100000
149000.00	10	160000	0	1	74800	340000	97500	2.0073029	49000
162287.00	10	160000	0	1	74800	340000	97500	2.1863031	45000
184511.60	11	176000	0	1	74800	363000	102000	2.4857092	41000
184766.00	11	176000	0	1	74800	363000	102000	2.4891364	41000
197260.00	22	352000	0	2	150000	713000	201000	2.6574535	76000
215000.00	15	240000	1	1	119000	514000	150000	2.8964438	52000
240030.00	16	256000	1	1	119000	537000	155000	3.2336437	48000
283998.00	17	272000	0	2	150000	603000	179000	3.8259732	47000

Notes for Table E-8

1. The field "AROOM" indicates facilities used in the model with an "*".

2. The field "EO_TOT" is the annual EP use at the facility.

3. The field "NUM CELLS" is the number of aeration cells assigned to that facility.

4. The field "COST CELLS" gives the cost of aeration cells.

5. The field "NUM_1000" is the number of 1,000 ft^3/min control units.

6. The field "NUM_3000" is the number of 3,000 ft^3/min control units.

7. The field "SAFE FOB" is the capital cost (FOB) of a gas/solid reactor control.

8. The field "TCC" gives the total capital cost for the facility.

9. The field "TAC" is the total annual control cost for the facility.

10. The field "ARRED" is the annual emission reduction (mg).

11. The field "CEFF" gives the cost effectiveness ($/Mg).

TABLE E-9. AERATION ROOM CATALYTIC OXIDATION CONTROL COST ANALYSIS

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
1.50	1	0	1	0	17100	27500	9300	0.0000202	460000000
2.00	1	0	1	0	17100	27500	9300	0.0000269	350000000
2.98	1	0	1	0	17100	27500	9300	0.0000401	230000000
4.80	1	0	1	0	17100	27500	9300	0.0000647	140000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
7.50	1	0	1	0	17100	27500	9300	0.0001010	92000000
9.00	1	0	1	0	17100	27500	9300	0.0001212	77000000
12.00	1	0	1	0	17100	27500	9300	0.0001617	58000000
16.80	1	0	1	0	17100	27500	9300	0.0002263	41000000
17.80	1	0	1	0	17100	27500	9300	0.0002398	39000000
27.36	1	0	1	0	17100	27500	9300	0.0003686	25000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
61.34	1	0	1	0	17100	27500	9300	0.0008264	11000000
64.00	1	0	1	0	17100	27500	9300	0.0008622	11000000
64.80	1	0	1	0	17100	27500	9300	0.0008730	11000000
65.00	1	0	1	0	17100	27500	9300	0.0008757	11000000
70.00	1	0	1	0	17100	27500	9300	0.0009430	9900000
93.60	1	0	1	0	17100	27500	9300	0.0012610	7400000
100.80	1	0	1	0	17100	27500	9300	0.0013580	6800000
105.00	1	0	1	0	17100	27500	9300	0.0014145	6600000
110.00	1	0	1	0	17100	27500	9300	0.0014819	6300000
111.00	1	0	1	0	17100	27500	9300	0.0014954	6200000
113.00	1	0	1	0	17100	27500	9300	0.0015223	6100000
115.00	1	0	1	0	17100	27500	9300	0.0015493	6000000
126.00	1	0	1	0	17100	27500	9300	0.0016975	5500000
160.80	1	0	1	0	17100	27500	9300	0.0021663	4300000
162.00	1	0	1	0	17100	27500	9300	0.0021824	4300000
185.25	1	0	1	0	17100	27500	9300	0.0024957	3700000
188.00	1	0	1	0	17100	27500	9300	0.0025327	3700000
192.00	1	0	1	0	17100	27500	9300	0.0025866	3600000
194.00	1	0	1	0	17100	27500	9300	0.0026135	3600000
195.00	1	0	1	0	17100	27500	9300	0.0026270	3500000
200.00	1	0	1	0	17100	27500	9300	0.0026944	3500000
201.60	1	0	1	0	17100	27500	9300	0.0027159	3400000
264.00	1	0	1	0	17100	27500	9300	0.0035566	2600000
291.60	1	0	1	0	17100	27500	9300	0.0039284	2400000
312.00	1	0	1	0	17100	27500	9300	0.0042032	2200000
312.00	1	0	1	0	17100	27500	9300	0.0042032	2200000
324.00	1	0	1	0	17100	27500	9300	0.0043649	2100000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
388.80	1	0	1	0	17100	27500	9300	0.0052378	1800000
390.00	1	0	1	0	17100	27500	9300	0.0052540	1800000
395.00	1	16000	1	0	17100	45900	13000	0.0053214	2400000
432.00	1	0	1	0	17100	27500	9300	0.0058198	1600000
456.00	1	0	1	0	17100	27500	9300	0.0061432	1500000
504.00	1	0	1	0	17100	27500	9300	0.0067898	1400000
520.00	1	0	1	0	17100	27500	9300	0.0070054	1300000
557.30	1	0	1	0	17100	27500	9300	0.0075079	1200000
562.00	1	0	1	0	17100	27500	9300	0.0075712	1200000
581.00	1	0	1	0	17100	27500	9300	0.0078271	1200000
686.00	1	0	1	0	17100	27500	9300	0.0092417	1000000
804.00	1	0	1	0	17100	27500	9300	0.0108314	860000
850.00	1	0	1	0	17100	27500	9300	0.0114511	810000
875.00	1	0	1	0	17100	27500	9300	0.0117879	790000
1092.00	1	0	1	0	17100	27500	9300	0.0147112	630000
1155.00	1	0	1	0	17100	27500	9300	0.0155600	600000
1231.00	1	0	1	0	17100	27500	9300	0.0165838	560000
1300.00	1	0	1	0	17100	27500	9300	0.0175134	530000
1334.00	1	0	1	0	17100	27500	9300	0.0179714	520000
1521.00	1	0	1	0	17100	27500	9300	0.0204907	450000
1600.00	1	0	1	0	17100	27500	9300	0.0215549	430000
1714.00	1	0	1	0	17100	27500	9300	0.0230907	400000
1714.00	1	0	1	0	17100	27500	9300	0.0230907	400000
1750.00	1	0	1	0	17100	27500	9300	0.0235757	390000
1750.00	1	0	1	0	17100	27500	9300	0.0235757	390000
1800.00	1	0	1	0	17100	27500	9300	0.0242493	380000
1944.00	1	0	1	0	17100	27500	9300	0.0261892	360000
1965.00	1	0	1	0	17100	27500	9300	0.0264721	350000
1980.00	1	0	1	0	17100	27500	9300	0.0266742	350000
2016.00	1	0	1	0	17100	27500	9300	0.0271592	340000
2142.00	1	0	1	0	17100	27500	9300	0.0288567	320000
2254.00	1	0	1	0	17100	27500	9300	0.0303655	310000
2280.00	1	0	1	0	17100	27500	9300	0.0307158	300000
2376.00	1	0	1	0	17100	27500	9300	0.0320091	290000
2419.20	1	0	1	0	17100	27500	9300	0.0325911	290000
2450.00	1	0	1	0	17100	27500	9300	0.0330060	280000
2527.00	1	0	1	0	17100	27500	9300	0.0340433	270000
2599.20	1	0	1	0	17100	27500	9300	0.0350160	270000
3120.00	1	0	1	0	17100	27500	9300	0.0420321	220000
3135.00	1	0	1	0	17100	27500	9300	0.0422342	220000
3240.00	1	0	1	0	17100	27500	9300	0.0436487	210000
3640.00	1	0	1	0	17100	27500	9300	0.0490375	190000
3755.00	1	0	1	0	17100	27500	9300	0.0505867	180000
4200.00	1	0	1	0	17100	27500	9300	0.0565817	160000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
4200.00	1	0	1	0	17100	27500	9300	0.0565817	160000
4286.90	1	0	1	0	17100	27500	9300	0.0577524	160000
4320.00	1	0	1	0	17100	27500	9300	0.0581983	160000
4368.00	1	0	1	0	17100	27500	9300	0.0588450	160000
4667.00	1	0	1	0	17100	27500	9300	0.0628730	150000
4860.00	1	0	1	0	17100	27500	9300	0.0654731	140000
5016.00	1	16000	1	0	17100	45900	13000	0.0675747	190000
5088.00	1	0	1	0	17100	27600	9300	0.0685447	140000
5189.00	1	16000	1	0	17100	45900	13000	0.0699053	190000
5250.00	1	16000	1	0	17100	45900	13000	0.0707271	180000
5258.00	1	16000	1	0	17100	45900	13000	0.0708349	180000
5739.00	1	16000	1	0	17100	45900	13000	0.0773148	170000
5850.00	1	16000	1	0	17100	45900	13000	0.0788102	160000
6000.00	1	16000	1	0	17100	45900	13000	0.0808310	160000
6048.00	1	16000	1	0	17100	45900	13000	0.0814776	160000
6176.00	1	16000	1	0	17100	45900	13000	0.0832020	160000
6451.00	1	16000	1	0	17100	45900	13000	0.0869068	150000
6840.00	1	16000	1	0	17100	45900	13000	0.0921473	140000
6900.00	1	16000	1	0	17100	45900	13000	0.0929556	140000
7194.00	1	16000	1	0	17100	45900	13000	0.0969164	130000
7350.00	1	16000	1	0	17100	45900	13000	0.0990180	130000
7387.00	1	16000	1	0	17100	45900	13000	0.0995164	130000
8390.00	1	16000	1	0	17100	45900	13000	0.1130287	120000
8400.00	1	16000	1	0	17100	45900	13000	0.1131634	110000
8736.00	1	16000	1	0	17100	45900	13000	0.1176899	110000
9676.00	1	16000	1	0	17100	45900	13000	0.1303534	100000
10002.00	1	0	1	0	17100	27500	9300	0.1347453	69000
10613.00	1	16000	1	0	17100	45900	13000	0.1429765	91000
10800.00	1	16000	1	0	17100	45900	13000	0.1454958	89000
11016.00	1	16000	1	0	17100	45900	13000	0.1484057	88000
11400.00	2	32000	1	0	17100	74600	18800	0.1535789	120000
11440.00	2	32000	1	0	17100	74600	18800	0.1541178	120000
11547.00	2	32000	1	0	17100	74600	18800	0.1555592	120000
11984.00	2	32000	1	0	17100	74600	18800	0.1614464	120000
12020.00	2	32000	1	0	17100	74600	18800	0.1619314	120000
12249.00	2	32000	1	0	17100	74600	18800	0.1650165	110000
13000.00	2	32000	1	0	17100	74600	18800	0.1751338	110000
13000.00	2	32000	1	0	17100	74600	18800	0.1751338	110000
13059.00	2	32000	1	0	17100	74600	18800	0.1759286	110000
14352.00	2	32000	1	0	17100	74600	18800	0.1933477	97000
14400.00	2	32000	1	0	17100	74600	18800	0.1939944	97000
14860.00	3	48000	1	0	17100	94800	22900	0.2001914	110000
14862.00	3	48000	1	0	17100	94800	22900	0.2002184	110000
15040.00	2	32000	1	0	17100	74600	18800	0.2026163	93000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
15600.00	1	16000	1	0	17100	45900	13000	0.2101606	62000
15724.00	2	32000	1	0	17100	74600	18800	0.2118311	89000
16426.00	1	0	1	0	17100	27500	9300	0.2212883	42000
16956.00	2	32000	1	0	17100	74600	18800	0.2284284	82000
18000.00	2	32000	1	0	17100	74600	18800	0.2424930	78000
18057.00	4	64000	1	0	17100	115000	27000	0.2432609	110000
18268.00	1	32000	1	0	17100	74600	18800	0.2461034	76000
18963.00	2	48000	1	0	17100	94800	22900	0.2554663	90000
19090.00	2	48000	1	0	17100	94800	22900	0.2571773	89000
21135.00	2	48000	1	0	17100	94800	22900	0.2847272	80000
22560.00	2	48000	1	0	17100	94800	22900	0.3039245	75000
23954.00	2	48000	1	0	17100	94800	22900	0.3227043	71000
24000.00	2	48000	1	0	17100	94800	22900	0.3233240	71000
24082.00	2	48000	1	0	17100	94800	22900	0.3244286	71000
26549.00	4	64000	1	0	17100	115000	27000	0.3576637	75000
29500.00	4	64000	1	0	17100	115000	27300	0.3974190	69000
29700.00	4	64000	1	0	17100	115000	27300	0.4001134	68000
30034.00	4	64000	1	0	17100	115000	27300	0.4046130	67000
30570.00	5	80000	0	1	37000	167000	46400	0.4118339	110000
32040.00	4	64000	1	0	17100	115000	27400	0.4316375	63000
34034.00	5	80000	0	1	37000	167000	46400	0.4585003	100000
35040.00	5	80000	0	1	37000	167000	46400	0.4720530	98000
36231.00	5	80000	0	1	37000	167000	46400	0.4880979	95000
38799.00	5	80000	0	1	37000	167000	46400	0.5226936	89000
39105.00	4	64000	1	0	17100	115000	28000	0.5268160	53000
40188.00	5	80000	0	1	37000	167000	46400	0.5414060	86000
41320.00	9	144000	0	1	37000	248000	62900	0.5566561	110000
43050.00	8	128000	0	1	37000	228000	58900	0.5799623	100000
45804.00	3	48000	1	0	17100	94800	24300	0.6170638	39000
50000.00	7	112000	0	1	37000	208000	54800	0.6735916	81000
52547.36	7	112000	0	1	37000	208000	54800	0.7079092	77000
52950.00	7	112000	0	1	37000	208000	54800	0.7133335	77000
54391.00	7	112000	0	1	37000	208000	54800	0.7327464	75000
55567.00	8	128000	0	1	37000	208000	58900	0.7485893	79000
56860.00	9	144000	0	1	37000	248000	32900	0.7660083	43000
64044.00	6	96000	0	1	37000	188000	50800	0.8627900	59000
66503.00	9	144000	0	1	37000	248000	62900	0.8959172	70000
78580.00	1	0	1	0	17100	27500	13200	1.0586165	12000
88000.00	11	176000	0	1	37000	289000	71900	1.1855212	61000
93450.00	11	176000	0	1	37000	289000	72300	1.2589427	57000
100524.00	13	208000	1	1	54100	357000	88600	1.3542424	65000
108408.00	18	288000	0	2	73900	489000	124000	1.4604543	85000
109897.00	6	96000	0	1	37000	188000	52900	1.4805139	36000
125084.00	9	144000	0	1	37000	248000	66300	1.6851106	39000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
134956.00	19	304000	0	2	73900	510000	129000	1.8181045	71000
149000.00	10	160000	0	1	37000	268000	72100	2.0073029	36000
162287.00	10	160000	0	1	37000	268000	73100	2.1863031	33000
184511.60	11	176000	0	1	37000	289000	79100	2.4857092	32000
184766.00	11	176000	0	1	37000	289000	79100	2.4891364	32000
197260.00	22	352000	0	2	73900	570000	144000	2.6574535	54000
215000.00	15	240000	1	1	54100	397000	105000	2.8964438	36000
240030.00	16	256000	1	1	54100	418000	111000	3.2336437	34000
283998.00	17	272000	0	2	73900	469000	130000	3.8259732	34000

E.3 AERATION ROOM COST ANALYSIS

Notes for Table E-9

1. The field "AROOM" indicates facilities used in the model with an "*".

2. The field "EO_TOT" is the annual EO use at the facility.

3. The field "NUM_CELLS" is the number of aeration cells assigned to that facility.

4. The field "COST_CELLS" gives the cost of aeration cells.

5. The field "NUM_1000" is the number of 1,000 ft^3/min control units.

6. The field "NUM_3000" is the number of 3,000 ft^3/min control units.

7. The field "CAT_FOB" is the capital cost (FOB) of a catalytic oxidation control.

8. The field "TCC" gives the total capital cost for the facility.

9. The field "TAC" is the total annual control cost for the facility.

10. The field "ARRED" is the annual emission reduction (mg).

11. The field "CEFF" gives the cost effectiveness ($/Mg).

REFERENCES

1. Letter and attachments from Olson, C., Donaldson Company, Inc., to S. Srebro. MRI. March 23, 1989. Capital and operating costs of 1,000 ft^3/min EtO Abator™ catalytic oxidizer.

2. Telecon. Srebro, S., MRI, with C. Olson. Donaldson Company, Inc. April 4, 1989. Discussion about costs of EtO Abator™.

3. Telecon. Nicholson, R., MRI, with C. Olson. Donaldson, Company, Inc. May 12 and June 13, 1988. Costs of EtO Abators™.

4. Chemical Engineering. Economic Indicators. April 25, 1988. p. 9.

5. Chemical Engineering. Economic Indicators. June 1989. p. 224.

E.4 EXAMPLE FACILITY CALCULATIONS

TABLE E-10. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS[1]
(4th Quarter 1987 Dollars)

Item	Cost
A. CAPITAL COSTS[a]	
1. Installed equipment costs	
a. Acid/water scrubber[b]	98,900
b. Explosion-proof valves for scrubber[c]	N/A[c]
c. Chlorine filter house[d]	166
d. Purchased equipment costs, total	99,100
e. Installation of scrubber[e]	49,500
f. Installation of chlorine filters	80
g. Taxes: 5 percent of equipment cost	4,960
h. Freight: 5 percent of equipment cost	4,960
i. Vacuum pump[f]	0
j. Manifolding of chambers (includes check valve)[g]	463
k. Subtotal Capital Costs	159,000
l. Contingencies[h]	15,900
TOTAL CAPITAL INVESTMENT	175,000
B. ANNUAL COSTS[a]	
1. Direct operating costs	
a. Labor[i]	3,540
b. Materials	
50 percent H_2SO_4[j]	364
50 percent NaOH[k]	350
Chlorine filters[l]	
Taxes: 5 percent of materials cost	117
Freight: 5 percent of materials cost	42
c. Water[m]	42
d. Electricity[n]	0
e. Compressed air[o]	124
f. Disposal of ethylene glycol[p]	0
	4,040
2. Indirect operating costs	
a. Overhead: 0.60 x labor[40]	
b. Property tax, insurance, and administration[q]	2,120
c. Capital recovery costs[r]	7,000
	28,500
TOTAL ANNUAL COSTS	46,200
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (tons EO/yr)	6.8 (7.5)
2. Cost effectiveness, 1987, $/Mg ($/ton EO)	6,800 (6,200)

TABLE E-10. (continued)

[a]Costs rounded to three significant figures.
[b]Model 400 based on largest chamber size of 1,000 ft^3.
[c]Not applicable.
[d]One per tank at $41.50 each (four tanks--Model 400).
[e]Fifty percent of scrubber cost.
[f]One at $5,170. The cost of the first vacuum pump is included in the installation cost of the scrubber.
[g]See Table E-4. One chamber costed for a check valve at $463.
[h]Assumed to be 10 percent of subtotal capital costs to account for uncertainties in the capital cost estimates.
[i]Labor was calculated for 0.25 person-hours/shift, 3 shifts/day, 365 days/year for system inspection and 16 person-hours for each regeneration of the scrubber at $11.65/person-hour.
[j]The cost of acid is calculated, (UNC_FAC)÷(2,000)x(594)x($0.070)x1.15. (15 percent extra is for spillage.) (UNC_FAC) is equal to uncontrolled emissions (lb) from vent and drain at baseline.)
[k]The cost of caustic is calculated, No. drum = (UNC_FAC)÷(2,000)x (250)÷(350). No. drum = 5.4; therefore, unit cost = $0.0802. Total cost = (No.drums)x(700)x(0.0802)x1.15 (15 percent extra for spillage).
[l]Chlorine filter cost is (UNC_FAC)x(15)÷(2,000).
[m]Calculated as (scrubber model)x(2)x(UNC_FAC)/[(2,000)x(No. of tanks)]x(0.25/1,000).
[n]See preceeding notes for calculation methodology.
[o]The cost of 10 seconds of house-supplied compressed air per cycle was considered negligible.
[p]Disposal cost is (UNC_FAC)÷(2,000)x(4,845)x(0.110).
[q]Calculated as 4 percent of total capital costs.
[r]Calculated as (0.16275)x(total capital costs) for an interest rate of 10 percent and a 10-year recovery period.

TABLE E-11. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS TO CONTROL CHAMBER EXHAUST VENTS[2]
(4th Quarter 1987 Dollars)

Item	Cost
A. CAPITAL COSTS[a]	
1. Installed equipment costs	
a. Acid/water scrubber[b]	44,900
b. Chlorine filter house[c]	42
c. Purchased equipment costs, total[d]	44,900
d. Installation of chlorine filters[d]	20
e. Sales tax: 5 percent of equipment cost[d]	2,240
f. Freight: 5 percent of equipment cost[d]	2,240
g. Manifolding of vents[e]	8,410
TOTAL CAPITAL INVESTMENT[f]	117,000
B. ANNUAL COSTS[a]	
1. Direct operating costs	
a. Labor[g]	3,310
b. Materials	
(1) 50 percent H_2SO_4[h]	31
(2) 50 percent NaOH[i]	42
(3) Chlorine filters[j]	10
(4) Taxes: 5 percent of materials cost	4
(5) Freight: 5 percent of materials cost	4
c. Water[k]	0
d. Electricity[l]	82
e. Compressed air[m]	0
f. Disposal of ethylene glycol[n]	350
2. Indirect operating costs	
a. Overhead: 0.60 x labor	1,990
b. Property tax, insurance, and administration[o]	4,680
c. Capital recovery costs[p]	19,000
TOTAL ANNUAL COSTS	29,500
C. COST EFFECTIVENESS[a]	
1. Emission reduction, Mg EO/yr (ton EO/yr)	0.71 (0.78)
2. Cost effectiveness, 1987, $/Mg EO ($/ton EO)	30,000 (27,000)

TABLE E-11. (continued)

[a]Capital and annual costs rounded to three significant figures. Cost effectiveness rounded to two significant figures.
[b]Facility has four chambers. Therefore, costed for a 6,000 ft^3/min scrubber.
[c]One per tank at $41.50 each.
[d]Capital equipment cost.
[e]See Section E.5 for a detailed summary of manifolding costs.
[f]Capital costs were increased by a factor of 2.2 (except manifolding costs) to account for additional capital expenditures necessary to install the control. The total capital costs were calculated as (2.2 x [sum of items with superscript d]) + manifolding costs.
[g]Labor was calculated for 0.25 person-hours/shift, 3 shifts/day, 365 days/year for system inspection and 16 person-hours for each regeneration of the scrubber at $11.65/person-hour.
[h]The cost of acid is calculated, (UNC_RCE) ÷ (2,000) x (594) x ($0.070) x 1.15. (Extra 15 percent for spillage.) (UNC_RCE is equal to uncontrolled emissions (lb) from rear chamber exhaust vents.)
[i]The cost of caustic is calculated, No. drum = (UNC-RCE) ÷ (2,000) x (250) ÷ (350). No. drum = 0.6; therefore, unit cost = $0.110. Total cost = (No. drums) x (700) x ($0.11) x 1.15 (15 percent extra for spillage).
[j]Chlorine filter cost is (UNC_RCE/2,000) x 15.
[k]Calculated as (scrubber model) x (2) x (UNC_RCE/2,000) x (0.25/1,000).
[l]See preceeding notes for calculation methodology.
[m]The cost of 10 seconds of house-supplied compressed air per cycle was considered negligible.
[n]Disposal cost is (UNC_RCE) ÷ (2,000) x (4,845) x (0.110).
[o]Calculated as 4 percent of total capital investment.
[p]Calculated as (0.16275) x (total capital investment) (i.e., an interest rate of 10 percent and a 10-year recovery period).

TABLE E-12. CAPITAL AND ANNUAL COSTS OF GAS/SOLID REACTOR TO CONTROL AERATION UNITS AT AN EXAMPLE FACILITY[3]
(4TH QUARTER 1987 Dollars)

Item	Cost, $
A. CAPITAL COSTS	
1. Installed Equipment Costs	
a. Gas/solid reactor	17,100
b. Installation of gas/solid reactor[a]	5,130
c. Taxes: 5 percent of equipment cost	855
d. Freight: 5 percent of equipment cost	855
e. Aeration units, installed cost[b]	32,000
f. Manifolding of aeration units[c]	9,830
g. Subtotal capital costs	65,800
h. Contingencies[d]	9,870
TOTAL CAPITAL COSTS	75,700
B. ANNUAL COSTS	
1. Direct operating Costs	
a. Maintenance labor[e]	151
b. Maintenance materials[f]	76
c. Reactant replacement[g]	2,480
d. Labor for reactant replacement[h]	70
e. Electricity[i]	416
f. Disposal of reactant[j]	812
2. Indirect Operating Costs	
a. Overhead[k]	136
b. Property tax, insurance, and administration[l]	3,030
c. Capital recovery costs[m]	11,900
TOTAL ANNUAL COSTS	19,100
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (ton EO/yr)	0.176 (0.194)
2. Cost effectiveness, $/Mg EO ($ton EO)	110,000 (100,000)

TABLE E-12. (continued)

[a]Calculated as 30 percent of gas/solid reactor cost.

[b]Includes ductwork. Each aeration unit cost $16,000 installed. The example facility would require two aeration units.

[c]See Section E.5 for a detailed summary of manifolding costs.

[d]Assumed to be 15 percent of the subtotal capital costs to account for uncertainties in the capital cost estimates.

[e]Assumed 15 minutes per week (52 weeks per year) for a 1,000 ft^3/min system and 20 minutes per week for a 3,000 ft^3/min control system for system inspection and general maintenance. Labor rate ($11.65 per hour) was calculated as (323.8/218.8) x ($7.87 per hour).

[f]Maintenance materials were calculated as (0.5) x (maintenance labor).

[g]The maximum reactant life is 1.5 years but could be shorter depending on the amount of EO being controlled (in pounds). Assumed that control requires 4 pounds of reactant per ft^3/min of airflow and that each pound of reactant can control 0.3 lb of EO. If the pounds of EO through the control (in a 1 1/2-year period) exceed the maximum capacity of the unit, then the reactant life is calculated as follows: [({0.3 lb EO/lb reactant} x {4 lb reactant/ft^3/min of flow} x {flow rate, ft^3/min})/maximum capacity of the unit, in pounds of EO]*1.5 years. Reactant replacement costs were calculated as (flow rate, ft^3/min) x (4 lb reactant/ft^3/min of flow rate) x ($1/lb of reactant) x (340.8/412). Where 340.8/412 is the Chemical Engineering cost indice to convert from 1989 to 1987 dollars.[h]Each 1,000 ft^3/min control unit requires about 8 person hours to refill. Depending on the interval of reactant replacement, capital recovery factors were determined as [CRC = $i(i + 1)^n/(i + 1)^{n-1}$] where i = 0.1 (10 percent interest) and n = life (years). Labor costs were calculated as ($7.87 per hour) x (323.8/218.8) x (CRC).

[i]The 1,000 and 3,000 ft^3/min systems are equipped with 1.1 and 10 kW (1.5 and 13.5 horsepower) fans, respectively. Electricity costs were calculated based on 365 days per year at continuous (24 hour) operation and an electricity cost of $0.0432 kWh. Costs were calculated as (365 days per year)(24 hours per day)(fan power)($0.0432 kWh).

[j]Disposal costs were developed assuming the reactant would be recycled and that there would be no credit or charge for the reactant. Transportation costs were calculated assuming a distance of 1,500 miles at a charge of $0.15 per pound for less than 5,000 pounds and $0.12 per pound for a shipment greater than 5,000 pounds.

[k]Calculated as 60 percent of the sum of the maintenance labor and maintenance materials.

[l]Calculated as 4 percent of total capital costs.

[m]Assumed life of 10 years for gas/solid reactor oxidizer and aeration unit and an interest rate of 10 percent. Assumed a life of 20 years and a 10 percent interest rate for manifolding materials. Capital recovery cost was calculated as 0.16275/[(total capital costs)-(cost to change catalyst+labor to change catalyst+manifolding costs)] + (0.1175) x (manifolding costs) where 0.16275 and 0.1175 are the capital recovery factors for the catalytic oxidizer and manifolding, respectively.

TABLE E-13. CAPITAL AND ANNUALIZED COSTS OF CATALYTIC OXIDATION AT AN EXAMPLE FACILITY[3]
(4th Quarter 1987 Dollars)

Item	Cost, $
A. CAPITAL COSTS	
1. Installed Equipment Costs	
a. Catalytic oxidizer(s)	47,800
b. Installation of catalytic oxidizer[a]	7,170
c. Taxes: 5 percent of equipment cost	2,390
d. Freight: 5 percent of equipment cost	2,390
e. Aeration units, installed cost[b]	32,000
f. Manifolding of aeration units[c]	19,700
g. Subtotal capital costs	111,000
h. Contingencies[d]	16,700
TOTAL CAPITAL COSTS	128,000
B. ANNUAL COSTS	
1. Direct Operating Costs	
a. Maintenance labor[e]	1,060
b. Maintenance materials[f]	150
c. Catalyst replacement[g]	1,460
d. Labor for catalyst replacement[h]	15
e. Electricity[i]	13,900
f. Disposal of catalyst[j]	21
2. Indirect Operating Costs	
a. Overhead[k]	726
b. Property tax, insurance, and administration[l]	5,120
c. Capital recovery costs[m]	20,600
TOTAL ANNUAL COSTS	43,100
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (ton EO/yr)(0.194)	0.176 (0.194)
2. Cost effectiveness, $/Mg EO ($/ton EO)	240,000 (220,000)

TABLE E-13. (continued)

[a]Calculated as 15 percent of catalytic oxidation cost.

[b]Includes ductwork. Each aeration unit cost $16,000 installed. The example facility would require two aeration units.

[c]See Section E.5 for a detailed summary of manifolding costs.

[d]Assumed to be 15 percent of the subtotal capital costs to account for uncertainties in the capital cost estimates.

[e]Assumed 15 minutes per day (365 days per year) for system inspection and general maintenance of a 1,000 ft^3/min system and an additional 5 minutes for each step up in catalytic oxidizer size. Labor rate ($11.65 per hour) was calculated as (323.8/218.8)x($7.87/h).

[f]Assumed $150 a year (base cost) for 1,000 ft^3/min unit and an additional $50 a year for each step up in catalytic oxidizer size.

[g]The 1,000, 3,000, 6,000, 9,000, and 12,000 ft^3/min catalytic oxidizers have 4, 16, 32, 48, and 64 catalytic cells, respectively. Each cell costs approximately $1,240 to refill. Costs were annualized over a 4-year life at 10 percent interest using a capital recovery factor of 0.31547.

[h]Each cell requires about 1-person hour to refill. Refill labor costs were annualized over 4 years assuming a 10 percent interest rate using a capital recovery factor of 0.31547.

[i]The 1,000, 3,000, 6,000, 9,000, and 12,000 ft^3/min systems have 80, 120, 180, 230, and 290 kilowatt (kW) catalytic oxidizer preheaters, respectively. System designed for 70 percent heat recovery uses only 46 percent of rated kW. Electricity cost calculated as ($0.0432/kWh)x(kW of heater)x(0.46)x(24 hours per day)x(365 days per year). No costs were attributed to fan electrical consumption because the preheating electrical costs were considerably larger.

[j]Disposal costs calculated as [($80/400 lb)x(90 lb cell)x(No. of cells)]/4 years. Includes transportation to an industrial landfill calculated as $25 per 55-gallon drum (7.35 ft^3/drum). Density of catalyst is 1 g/cm^3 (62.4 lb/ft^3). Transportation equals [(90 lb/cell)x($25/drum)x(No. of cells)]/[(62.4 lb/ft^3)x(7.35 ft^3/drum) x(4 yr)]. All disposal costs were multiplied by (329.8/354.2) to correct to 1987 dollars.

[k]Calculated as 60 percent of the sum of the maintenance labor and maintenance materials.

[l]Calculated as 4 percent of total capital costs.

[m]Assumed life of 10 years for catalytic oxidizer and aeration unit and an interest rate of 10 percent. Assumed a life of 20 years and a 10-percent interest rate for manifolding materials. Capital recovery cost was calculated as 0.16275x[(total capital costs)-(cost to change catalyst + labor to change catalyst + manifolding costs)] + (0.1175)x(manifolding costs) where 0.16275 and 0.1175 are the capital recovery factors for the catalytic oxidizer and manifolding, respectively.

E.4 EXAMPLE FACILITY CALCULATIONS

REFERENCES

1. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Cost Effectiveness of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. March 21, 1991.

2. Memorandum. deOlloqui, V., and Srebro, S., to D. Markwordt. EPA/CPB. Costing of Control Alternatives for the Rear Chamber Exhaust Emissions. March 21, 1991.

3. Memorandum. Srebro, S., and deOlloqui, V., to D. Markwordt. EPA/CPB. Costing Methodology for the Control of Aeration Room Emissions. March 21, 1991.

E.5 MANIFOLDING COSTS

TABLE E-14. INCREMENTAL CAPITAL COSTS OF MANIFOLDING STERILIZATION CHAMBERS, 1987, $

	Cost 1987, $	Reference[1]
1. Opening in explosion-proof wall		
Cost	2[a c]	3-100, p. 12
Adjustable sheet metal sleeve		
Labor hours		
Concrete core drilling, 1-in. to 3-in. hole	4.4	3-100, p. 22
Adjustable sheet metal sleeve	0.75	3-100, p. 22
Total labor hours	5.15	
Labor costs at $18,91/labor hour	97[a]	3-0, p. 2
Overhead costs at $8.75/labor hour	45[b]	1.0, p. 5
2. Drill hole for pipe hangers		
Labor hours		
3/8 in. diameter hole through 1/2 in. thick steel beam, 20 holes	7.5	5-10, p. 16
Labor costs at $20.32/person-hour	153[a]	5-0, p. 1
Overhead costs at $15.78/person-hour	118[b]	1-0, p. 5
3. Piping		
Cost		
100 ft, 2 in. diameter, 40 standard carbon steel pipe	251[a c]	15-43, p. 4
90° elbows, 3 at $4.40	14[a c]	15-43, p.9
Tee with full-size outlet	15[a c]	15-43, p. 13
Swing check valve	367[a c]	15-43, p. 31
Bolts and gaskets, two sets at $7.08	15[a c]	15-72, p. 3
Pipe hangers, 1 carton of 50 hangers	147[a c]	15-76, p. 25
Total cost	808	
Labor hours to install		
Cut, three at 0.16 labor hours	0.48	15-77, p. 27
Bevel, three at 0.10 labor hours	0.30	15-77, p. 30
Pipe	8.3	15-43, p. 4
Field erection joint buttweld	2.9	15-43, p. 29
Penetration through one wall	1.7	15-43, p. 8
Elbows, three at 2.00 labor hours	6.0	15-43, p. 9
Tee	3.0	
Valve	1.1	15-43, p. 13
Boltup of valve, two sets at 1.35 labor hours	2.7	15-43, p. 31
Pipe hangers, 10 at 0.16 labor hours	1.6	15-72, p. 3
Total labor hours	28.0	15-76, p. 35
Labor costs at $21.47/labor hour	601[a]	15-0, p. 2
Overhead costs at $13.31/labor hour	373[b]	1-0, p. 5
4. Total installed cost for piping system		
Total direct costs	1,663[d]	
Total overhead costs	536[e]	
Administration	152[f]	1-0, p. 6
10 percent of total direct costs		
Taxes: 5 percent of equipment costs	33[g]	1-0, p. 6
Total indirect costs	721[h]	
Total installed cost	2,384[i]	

TABLE E-14. (continued)

	Cost 1987, $	Reference[1]
5. Total installed cost for new vacuum pump	5,170[j]	MRI report[2]
6. Total installed capital cost	7,554[k]	

[a]Direct cost.
[b]Overhead cost.
[c]Equipment cost.
[d]Total of costs with superscript a.
[e]Total of costs with superscript b.
[f]Administration = 0.10x(sum of costs with superscript a)
[g]Taxes = 0.05xsum of costs with superscript c.
[h]Total indirect costs = sum of costs with superscripts e, f, and g.
[i]Total installed cost = total direct costs (superscript d)+total indirect costs (superscript h).
[j]$5,000 (1986 $)x1.034 (see Section E.2).
[k]Equal to total installed cost for piping (superscript i)+total installed cost for new vacuum pump (superscript j).

TABLE E-15. DUCTWORK COSTS OF MANIFOLDING CHAMBER EXHAUST VENTS TO A SCRUBBER

Item	Cost, $, 1987	Reference[1,3]
Chamber exhaust vent to manifold[a]		
1. 15 ft 10-in. diameter, 1/8 in. thick carbon steel	210	Gard, p. 4-19
2. 90° elbow, 10-in. diameter	204	Gard, p. 4-22
3. Labor[b]	164	Richardson, 15-9 p. 2
Manifold		
1. 36 ft 41-in. diameter, 1/8 in. thick carbon steel	2,290	Gard, p. 4-19
2. Labor[b]	1,352	Richardson, 15-9 p. 2
Manifold to control unit		
1. 30 ft 24-in. diameter, 1.8 in. thick carbon steel	1,110	Gard, p. 4-19
2. 90° elbow, 24-in. diameter		
3. Tec, 24-in. diameter	580	Gard, p. 4-22
4. Labor[b]	192	Gard, p. 4-22
	769	Richardson, 15-9 p. 2

[a]Costs to duct chamber exhaust vent(s) to a manifold were calculated for each sterilizer at a facility. (It was assumed that ductwork costs for one of the sterilizers was included in the control device installation cost.)
[b]Labor costs developed as $3.51/ft^2 of ductwork.

TABLE E-16. DUCTWORK COSTS OF MANIFOLDING AERATION UNITS TO A GAS/SOLID REACTOR

Item	Cost, $, 1987	Reference[1,3]
Aeration room (AR) ductwork		
A. AR unit to manifold[a]		
1. 32 ft 15-in. diameter, 1/8 in. thick carbon steel	710	Gard, p. 4-19
2. 90° elbow, 15-in. diameter	326	Gard, p. 4-22
3. Labor[b]	481	Richardson, 15-9 p. 2
B. AR manifold		
1. 5 ft 41-in. diameter, 1/8 in. thick carbon steel	318	Gard, p. 4-19
2. Labor[b]	187	Richardson, 15-9 p. 2
C. Manifold to control unit		
1. 67 ft 24-in. diameter, 1/8 in. thick carbon steel	2,480	Gard, p. 4-19
2. 90° elbow, 24-in. diameter costed at $580/elbow	1,160	Gard, p. 4-22
3. Labor[b c]	2,140	Richardson, 15-9 p. 2

[a]These costs were developed for each aeration unit at a facility.
[b]Labor costs developed as $3.51/ft^2 of ductwork.
[c]Labor costs include the cost to concrete core drill (24 in. hole) the aeration room wall at $784.

E.5 MANIFOLDING COSTS

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3. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc., Niles, IL. Publication No. EPA-450/5-80-002. December 1978.

300

E.6 COST INDICES

TABLE E-17. CHEMICAL ENGINEERING COST INDICES

	Cost indices	Conversion factor
Scrubbers	352.2 (1987)[a] 392.1 (1989)[b]	0.90
Chlorine filters	352.2 (1987)[c] 344.1 (1987)[d]	1.02
Chemicals	340.8 (1987)[e] 340.0 (1986)[f]	1.002
Operations and maintenance labor	323.8 (1987)[g] 218.8 (1988)[h]	1.48
Disposal of ethylene glycol	323.8 (1987)[i] 318.4 (1986)[j]	1.02
Gas/solid reactor or catalytic oxidizer	352.2 (1987)[k] 390.7 (1989)[l]	0.90
Reactant or catalyst replacement	340.8 (1987)[m] 412.0 (1989)[n]	0.83
Ductwork	323.8 (1987)[o] 218.8 (1978)[p]	1.48
Disposal of reactant or catalyst	329.8 (1987)[q] 354.2 (1989)[r]	0.93
Labor for installation of ductwork	323.8 (1987)[s] 322.7 (1984)[t]	1.00
Vacuum pumps	433.0 (1987)[u] 418.6 (1986)[v]	1.03

[a]Reference 1. CE Plant Cost Index, Equipment Machinery, Supports. October 1987 final.
[b]Reference 2. CE Plant Cost Index, Equipment. September 1989 final.
[c]Reference 1. Structural Supports and Miscellaneous. October 1987 final.
[d]Reference 3. Structural Supports and Miscellaneous. February 1986 final.
[e]Reference 4. Current Business Indicators. October 1987 latest.
[f]Reference 3. Current Business Indicators. February 1986 previous.
[g]Reference 1. CE Plant Cost Index, 1987 Annual Index.
[h]Reference 1. CE Plant Cost Index, 1978 Annual Index.
[i]Reference 1. CE Plant Cost Index, 1987 Annual Index.
[j]Reference 1. CE Plant Cost Index, 1986 Annual Index.
[k]Reference 1. CE Plant Cost Index, Equipment, Machinery, Supports. October 1987 final.
[l]Reference 5. CE Plant Cost Index. Equipment, March 1989 final.
[m]Reference 6. Current Business Indicators, Producer Prices, Industrial Chemicals, October 1987 (latest).
[n]Reference 5. Current Business Indicators, Producer Prices, Industrial Chemicals, March 1989.
[o]Reference 5. CE Plant Cost Index, 1987 Annual Index.

TABLE E-17. (continued)

[p]Reference 3. CE Plant Cost Index, 1978 Annual Index.
[q]Reference 1. CE Plant Cost Index, October 1987 final.
[r]Reference 3. CE Plant Cost Index, March 1989 final.
[s]Reference 3. CE Plant Cost Index, 1987 Annual Index.
[t]Reference 3. CE Plant Cost Index, 1984 Annual Index.
[u]Reference 4. CE Plant Cost Index, October 1987 final.
[v]Reference 3. CE Plant Cost Index, February 1986 final.

E.6 COST INDICES

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5. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. June 1989. p. 224.

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16. ABSTRACT

National emission standard to control emissions of ethylene oxide from new and existing sterilization/fumigation operations are being proposed under Section 112 of the Clean Air Act. This document contains information on the background and authority, regulatory alternatives considered, and environmental and economic impacts of the regulatory alternatives.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
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Alternative Control Technology Document — Ethylene Oxide Sterilization/Fumigation Operations

EPA-450/3-89-007

Alternative Control Technology Document – Ethylene Oxide Sterilization/Fumigation Operations

Emissions Standards Division

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina 27711
March 1989

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1.0 INTRODUCTION

The Clean Air Act (CAA) identified December 31, 1987, as the latest date for attainment of the national ambient air quality standard (NAAQS) for ozone. As of this writing, many areas of the country are not in attainment with the ozone NAAQS. The U. S. Environmental Protection Agency (EPA) has proposed to require States that have ozone nonattainment areas to submit revised State implementation plans (SIP's) that describe what steps will be taken to attain the standard (52 FR 45044, November 24, 1987).

Under the proposed rule (52 FR 45044), to demonstrate attainment of the NAAQS for ozone, emissions of volatile organic compounds (VOC's) must be reduced to a level that will produce ozone concentrations consistent with NAAQS as demonstrated by atmospheric dispersion modeling. Once the State has determined the VOC emission reduction required to meet the NAAQS, it must identify and select control measures that will produce the required reductions as expeditiously as practicable.

In 1985, EPA published a Federal Register notice titled "Assessment of Ethylene Oxide as a Potentially Hazardous Air Pollutant." The conclusion of that notice, based on the information available, was that EPA intended to list ethylene oxide (EO) under Section 112 of the CAA if emission standards were warranted. Therefore, a reduction in EO emissions (which also is a VOC) contributes to attainment of the NAAQS for ozone and reduces potential health risks from direct exposure to EO.

This report presents technical information that State and local agencies can use to develop strategies for reducing VOC (i.e., EO) emissions for sterilization/fumigation facilities. The information in this document will allow planners to (1) identify available control alternatives and (2) evaluate the VOC reduction and cost of implementing controls.

This document provides information on sterilization/fumigation processes, EO emissions, and emission reductions, and cost associated with the application of control units. Section 2.0 presents a summary of the findings of this study. Section 3.0 provides a description of sterilization/fumigation facility operations and emission sources.

Section 4.0 provides a description of alternative control techniques for the reduction of ethylene oxide emissions. Section 5.0 presents a cost analysis that includes a methodology for computing annualized equipment and operating costs.

A list of contacts at various Federal agencies who are knowledgeable about sterilization/fumigation processes is presented in Appendix A.

2.0 SUMMARY

Ethylene oxide (EO) is used as a sterilant/fumigant in the production of medical equipment supplies, in miscellaneous sterilization and fumigation operations, and at hospitals. Available information indicates that EO is used at over 200 commercial sterilization facilities in the U.S. and at approximately 7,000 hospitals. These facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. These materials may be sterilized at the facility that produces or uses the product or by contract sterilizers (i.e., firms under contract to sterilize products manufactured by other companies). Libraries and museums use EO to fumigate books and other historical items. State departments of agriculture control diseases of bees by fumigating beehives with EO.

Practically all of the EO used in sterilization/fumigation processes is estimated to be emitted from three sources: (1) the sterilizer vent(s) (i.e., the vent from the vacuum pump gas/liquid separator), (2) the vacuum pump drain, and (3) the aeration room or chamber. Uncontrolled emissions from these sources are assumed to be 50 percent, 45 percent, and 5 percent of the EO use, respectively. The total amount of EO used by the 203 commercial sterilization facilities (i.e., not hospitals) represented in the EPA sterilization data base is 2,270 Megagrams per year (Mg/yr) (5 million lb/yr). Estimated emissions from these 203 facilities are 760 Mg/yr (1.7 million lb/yr) from sterilizer vents, 1,000 Mg/yr (2.2 million lb/yr) from vacuum pump drains, and 110 Mg/yr (0.25 million lb/yr) from aeration room vents. The sterilizer vent emissions are less than 50 percent of the EO use because several of these 203 facilities control EO emissions from the sterilizer vent. However, drain and aeration room emissions at these facilities are assumed to be uncontrolled. Based on approximately 80 responses to a 1986 information request to Federal hospitals and information in the 1988 American Hospital Association data base, EO use at hospitals is estimated to be approximately 1,000 Mg/yr. Because the majority of hospitals do not use

EO emission controls, EO emissions from hospitals are assumed to equal the EO use of approximately 1,000 Mg/yr.

Three primary techniques are applicable to the control of EO emissions from sterilization/fumigation processes: acid hydroysis (i.e., acid-water scrubbers), oxidation, and a gas/solid reactor system that chemically reacts EO and binds it to the solid reactor packing. Control efficiencies for those techniques range from 98.0 percent to 99.0 percent for sterilizer vent emissions. However, the control efficiencies of these devices have not been demonstrated for the low EO concentrations from aeration processes. Acid hydrolysis and thermal oxidation are applicable to the control of sterilizer vent emissions from the larger sterilizers (>2.8 m^3 [100 ft^3]) at commercial sterilization facilities. Several hospitals use catalytic oxidation or scaled-down acid-water scrubbers to control emissions from hospital sterilization chambers. Catalytic oxidation and the gas/solid reactor system are used by several hospitals and a few commercial sterilization facilities to control EO emissions from aeration rooms or aeration chambers. Closed-loop recirculating fluid vacuum pumps can virtually eliminate drain EO emissions by routing the gaseous phase exiting the gas/liquid separator to the sterilizer emission control device.

Federal regulations for stratospheric ozone-depleting chlorofluorocarbons (CFC's) have been developed under EPA's Stratospheric Ozone Protection Program (SOPP). The majority of commercial sterilization facilities and almost all hospitals use a sterilant gas mixture known as 12/88, which is 12 weight percent EO and 88 weight percent dichlorodifluorocarbon (CFC-12). The use of CFC's in sterilant gases is one of the source categories subject to the CFC regulations. However, the requirements of a CFC regulation would not affect the ability of a sterilization facility to control EO emissions.

The cost of controlling EO emissions from sterilizer vents at three of the commercial sterilization facilities represented in EPA's data base are presented in Table 2-1. Acid hydrolysis was chosen as the basis for the cost calculations because that control technique currently is practiced at many commercial facilities and has been demonstrated at both small and large commercial sterilization facilities. Detailed cost

TABLE 2-1. CONTROL COSTS FOR ACID HYDROLYSIS AT COMMERCIAL STERILIZATION FACILITIES[a b]

Model plant	Total sterilizer volume, m^3 (ft^3)	Annual EO use, Mg (lb/1,000)	Capital costs, $	Annualized costs, $	Annual emission reduction, Mg (lb/1,000)[c]
Small[d]	2.8 (100)	0.18 (0.39)	76,000	21,200	0.17 (0.37)
Medium[e]	28 (1,000)	3.9 (8.7)	160,000	40,800	3.7 (8.2)
Large[f]	168 (6,000)	109 (240)	291,000	117,000	102 (226)

[a]These cost estimates are not applicable to hospitals because the acid-water scrubbers costed are not designed for the low flowrates from the vacuum pumps on hospital sterilizers.
[b]See Chapter 5 and Appendix B for the methodology used to calculate these control costs.
[c]Calculated as (0.99)x(0.95)(EO use). Five percent of the EO use is assumed to be retained in the product after sterilization and emitted from the aeration room, which is assumed to be uncontrolled.
[d]The small model plant has one chamber and uses 12/88 (EO/CFC-12). Therefore, a model 100 scrubber (see Table 5-2) was chosen as the basis for the calculations.
[e]The medium model plant has one chamber and uses 12/88 gas. Therefore, a model 400 scrubber was chosen as the basis for the calculation.
[f]The large model plant has seven chambers and uses 100 percent EO. The sum of the volumes of the two largest chambers is 2,000 ft^3. Therefore, a model 500 scrubber (with explosion-proof valves) was chosen as the basis for the calculations.

estimates have not been developed for the control of EO emissions from hospitals or aeration processes. However, preliminary control cost estimates for hospitals have been developed by EPA's Office of Research and Development (see Chapter 5). Also, the Office of Air Quality Planning and Standards currently is developing control cost estimates for aeration rooms, which should be available by June 1989. (See Appendix C for preliminary aeration control costs.)

Possible alternatives to EO sterilization include radiation, chlorine dioxide, gas plasma, hydrogen peroxide, ozone, X-ray (a new, developing technology), deep freezing (museums and spice industry), and increased use of disposable medical items in hospitals. However, none of these alternatives can replace the use of EO in all applications.

3. ETHYLENE OXIDE STERILIZATION/FUMIGATION PROCESSES AND EMISSIONS

3.1 BACKGROUND INFORMATION

Ethylene oxide (EO) is used as a sterilant/fumigant in the production of medical equipment supplies, in miscellaneous sterilization and fumigation operations, and at hospitals. Available information indicates that EO is used at over 200 commercial sterilization facilities in the U.S. and at approximately 7000 hospitals.[1-3] These facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. These materials may be sterilized at the facility that produces or uses the product or by contract sterilizers (i.e., firms under contract to sterilize products manufactured by other companies). Libraries and museums use EO to fumigate books and other historical items. State departments of agriculture control diseases of bees by fumigating beehives with EO.

Information about facilities that use EO as a sterilant/fumigant was obtained from three sources: (1) a survey of medical equipment suppliers conducted by the Health Industry Manufacturer's Association (HIMA) in 1985, (2) an information request submitted by EPA under Section 114 of the Clean Air Act to miscellaneous sterilizers and fumigators (identified during an extensive survey of potential users) in July 1986, and (3) an information request in January 1986 to Federal hospitals and nine of the largest non-Federal hospitals. A total of 203 commercial sterilization facilities (i.e., not hospitals) responded to the HIMA survey and the July 1986 EPA information request. Data from these responses comprise the EPA sterilization data base. Approximately 80 hospitals responded to the January 1986 information request.

As shown in Table 3-1, the facilities represented in the EPA commercial sterilization data base are located in 43 States and Puerto Rico. These facilities were grouped by Standard Industrial Classification (SIC) into the following categories:

TABLE 3-1. LOCATIONS OF COMMERCIAL STERILIZATION FACILITIES--EPA DATA BASE[1,2]

State	No. of facilities[a]		No. of facilities[a]
Arizona	3	Missouri	5
California	21	New Hampshire	2
Colorado	3	New Jersey	18
Connecticut	6	New York	14
Delaware	2	North Carolina	7
Florida	5	Ohio	2
Georgia	4	Pennsylvania	10
Illinois	8	Puerto Rico	14
Indiana	4	Rhode Island	2
Iowa	3	South Carolina	3
Maryland	5	Tennessee	3
Massachusetts	9	Texas	11
Michigan	8	Utah	2
Minnesota	6	Virginia	5
Mississippi	2	Washington	2
Subtotal	89	Subtotal	100

The EPA data base includes one facility located in each of the following States: Alabama, Alaska, Arkansas, Hawaii, Kentucky, Maine, Nebraska, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Wisconsin, West Virginia.

Subtotal	14
Total No. of facilities	203

[a]Does not include hospitals.

1. medical equipment suppliers;
2. pharmaceuticals;
3. other health-related industries;
4. spice manufacturers;
5. contract sterilizers;
6. libraries, museums, and archives;
7. laboratories (research, testing, and animal breeding); and
8. State departments of agriculture.

Table 3-2 shows the number of facilities in the EPA commercial sterilization data base for the eight categories listed above. Table 3-2 also shows the SIC codes represented by these industry categories.

3.2 PROCESS DESCRIPTION

There are two main types of EO sterilization processes: (1) bulk sterilization and (2) single-item sterilization. These processes are described below.

3.2.1 Bulk Sterilization

Bulk sterilization is the more commonly used EO sterilization process; 98 percent of the commercial sterilization facilities represented in the EPA data base use this process.[1,2] The products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas at a predetermined temperature, humidity level, and pressure. The equipment, sterilant gases, and sterilization cycle used for bulk sterilization processes are described below.

3.2.1.1 Equipment. A schematic of a gas sterilizer is shown in Figure 3-1. The main components of the sterilizer are the chamber and vacuum pump. Chambers used by commercial sterilization facilities typically range in volume from 2.8 cubic meters (m^3) (100 cubic feet [ft^3]) to 28 m^3 (1,000 ft^3).[1,2] Table 3-3 presents size data for the chambers in the EPA commercial sterilization data base. Sterilization chambers at hospitals range from less than 0.3 to 2 m^3 (10 to 70 ft^3) but are typically about 0.6 to 0.8 m^3 (20 to 30 ft^3).[5]

A vacuum pump is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete. Typically, a once-through, water-ring vacuum pump is used. Oil-sealed vacuum pumps or vacuum pumps that use

TABLE 3-2. NUMBER OF FACILITIES AND STANDARD INDUSTRIAL CLASSIFICATION (SIC) PER INDUSTRY CATEGORY--EPA COMMERCIAL STERILIZATION DATA BASE*

Industry category	No. of facilities[a]	SIC
Medical equipment suppliers	64	3841, 3842
Pharmaceuticals	40	2834, 5122, 2831, 2833
Other health-related industries	25	3079, 3693, 5086, 2211, 2821, 2879, 3069, 3569, 3677, 3999
Spice manufacturers	25	2099, 5149, 2034, 2035, 2046
Contract sterilizers	17	7399, 7218, 8091
Libraries, museums, and archives	13	8411, 8231
Laboratories (research, testing, and animal breeding)	11	0279, 7391, 8071, 8922, 7397
State departments of agriculture	8	9641
Total	203	

[a]Does not include hospitals.

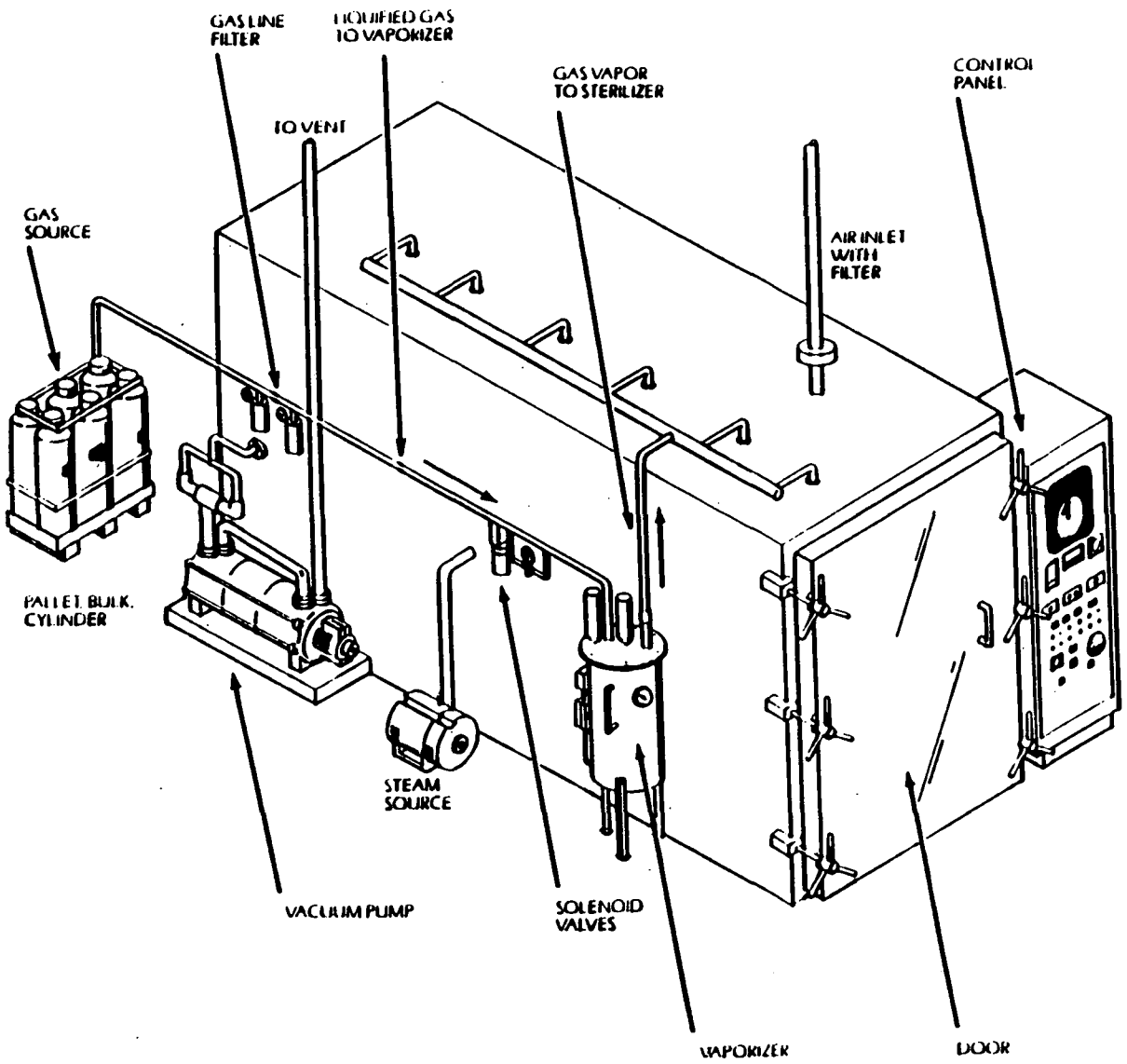

Figure 3-1. Schematic of a gas sterilizer. (Courtesy of Union Carbide Corporation, Linde Division.)[12]

TABLE 3-3. CHAMBER SIZES--EPA COMMERCIAL STERILIZATION DATA BASE[1,2]

Size range, m^3 (ft^3)	No. of chambers[a]	Percent	Cumulative No. of chambers	Cumulative, percent
≤1.4 (≤50)	87	20	87	20
1.5-2.8 (51-100)	29	7	116	27
2.9-14 (101-500)	111	26	227	53
15-28 (501-1,000)	130	29	357	84
29-57 (1,001-2,000)	60	14	417	98
≥58 (≥2,001)	10	2	427[b]	100

[a]Does not include hospitals.
[b]This number excludes four single-item sterilization units, one 55-gal drum user, and two facilities that did not report a chamber size.

recirculated water also are used. There are indications that some commercial sterilization facilities and hospitals are converting from once-through water-ring vacuum pumps to full sealant recovery vacuum pumps in order to meet the 1 part per million by volume (1 ppmv) Occupational Safety and Health Administration (OSHA) standard for EO and proposed State regulations.[6,7]

3.2.1.2 Sterilant Gases. Ethylene oxide is an extremely effective sterilant gas. The EO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and final product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping.

The most widely used sterilant gas is a mixture of 12 percent by weight EO and 88 percent by weight dichlorodifluoromethane (CFC-12), referred to as 12/88. Two other commonly used sterilant gases are (1) pure EO (i.e., 100 percent EO) and (2) a mixture of 10 percent by weight EO and 90 percent by weight carbon dioxide (CO_2), referred to as 10/90. Other sterilant gas mixtures that are used include 20/80, 30/70, and 80/20 (weight percents EO/CO_2).[1,2] Gas mixtures that contain 20 percent or greater EO (by weight) are considered flammable. The 80/20 (EO/CO_2) mixture has the same flammability range as pure EO.[12] Physical and chemical properties of EO, CFC-12, and CO_2 are given in Table 3-4. Table 3-5 shows the number of commercial sterilization facilities represented in the EPA data base that use a particular gas type and the amount of EO used for each gas type. Since many commercial sterilization facilities operate more than one sterilization chamber, the gas usage rates in Table 3-5 also are presented on a chamber basis.[1,2] Seventy-five percent of the hospitals that responded to the 1986 information request use 12/88. The rest use pure EO in the form of ampules or single-use cartridges. At hospitals, pure EO is generally used only in very small (<0.3m^3 [10ft^3]) chambers.

The 12/88 mixture is the most popular sterilant gas for several reasons. Unlike pure EO, 12/88 is nonflammable and nonexplosive. Therefore, the use of 12/88 does not require explosion-proof rooms and additional safety precautions that are necessary when pure EO is used.

TABLE 3-4. PHYSICAL AND CHEMICAL PROPERTIES OF ETHYLENE OXIDE, DICHLORODIFLUOROMETHANE, AND CARBON DIOXIDE[8-11]

	Ethylene oxide	Dichlorodifluoromethane	Carbon dioxide
Other designations	1,2-epoxyethane, oxirane, dimethylene oxide	CFC-12, refrigerant 12, propellant 12	Carbonic acid gas, carbonic anhydride
Appearance	Colorless liquid or gas	Colorless gas, readily liquified under pressure and/or cooling	Colorless gas
Chemical formula	C_2H_4O	CCl_2F_2	CO_2
Molecular weight	44.0	120.9	44.0
Vapor pressure at 20°C (68°F)	146.0 kPa (21.2 psia)	567.6 kPa (82.3 psia)	5,731.0 kPa (831 psia)
Boiling point at 101.3 kPa (14.7 psi)	10.4°C (50.7°F)	-29.8°C (-21.6°F)	-78.5°C (-109.3°F)
Flammability limits in air	Lower 3 percent by volume Upper 80+ percent by volume[a]	Nonflammable	Nonflammable
Water solubility	Completely miscible	Low solubility	--
Heat of combustion, vapor at 25°C (77°F)	1,306 kJ/mol (12,760 Btu/lb)	111 kJ/mol (396 Btu/lb)	--
Threshold limit value (TLV) 8-h time weighted average (TWA)	1 ppmv	1,000 ppmv	5,000 ppmv

[a]Pure EO explodes by decomposition at 560°C (1040°F) with ignition.

TABLE 3-5. STERILANT GAS TYPE USAGE--EPA COMMERCIAL STERILIZATION DATA BASE[1,2]

Sterilant gas	No. of facilities[a b]	Percent of facilities	No. of chambers[c]	Percent of chambers	EO use, Mg/yr[d]	Percent of total EO use
12/88 (EO/CFC-12)	154	76	295	68	720	30
Pure EO	44	22	122	28	1,350	60
10/90 (EO/CO_2)	14	7	19	4	4	<0.01
Other mixtures[e]	16	8	25	6	190	10

[a]Does not include hospitals.
[b]There are 203 commercial sterilization facilities in the EPA data base. Approximately 10 percent of these facilities use more than one type of sterilant gas.
[c]There are 434 operational sterilization "chambers" (the four single-item sterilization systems are counted as chambers) in the EPA commercial sterilization data base. More than one type of sterilant gas is used in 5 percent of these chambers.
[d]Amount of EO in the sterilant gas mixture.
[e]Includes mixtures of EO and CO_2 with a weight percent of EO ranging from 20 to 80 percent and custom mixes.

The 10/90 mixture also is nonflammable and nonexplosive.[12] But, because 10/90 is only 10 percent EO by volume whereas 12/88 is 27.3 percent EO by volume, 10/90 requires higher operating pressures to obtain an EO concentration that is sufficient for effective sterilization (approximately 304 kilopascals [kPa], or 44 pounds per square inch absolute [psia], for 10/90, as compared to 170 kPa [24.7 psia] for 12/88).[13] The chambers used for 10/90 sterilization must be ASME-rated pressure vessels, (i.e., manufactured in accordance with Section VIII, Division I, of the ASME Pressure Vessel Code) and are, therefore, more expensive to construct than the chambers used with 12/88. However, because of insurance requirements, many commercial sterilization facilities use chambers that meet requirements for ASME-rated pressure vessels when sterilizing with 12/88 or with explosive mixtures below ambient pressure.[14]

3.2.1.3 Sterilization Cycle. The typical sterilization cycle consists of five phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, (4) air wash, and (5) aeration. Figures 3-2 and 3-3 show pressure/time curves for the first four phases of the 12/88 sterilization cycle and the pure EO sterilization cycle, respectively. Steps 1 through 4 typically require about 8 hours at larger commercial sterilization facilities, and about 2 to 4 hours at hospitals.

3.2.1.3.1 Presterilization conditioning. After the products have been loaded into the chamber and the airtight door sealed, a partial vacuum is drawn inside the chamber. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable sterilant gases are used, the removal of air reduces the potential for ignition.[12] The chamber pressure is reduced to a pressure of about 6.9 to 69 kPa (1 to 10 psia) for 12/88 and 3 kPa (0.4 psia) for pure EO. The initial drawdown takes from about 5 to 45 minutes, depending on the product being sterilized. Certain products require a longer drawdown time because they are damaged by sudden pressure changes. The chamber temperature is then adjusted to between 38°C (100°F) and 54°C (130°F). A higher temperature will increase the diffusion rate of EO into the products and, thus, will reduce the time the products must be exposed to the sterilant gas to ensure proper sterilization. Finally, the relative humidity is raised to

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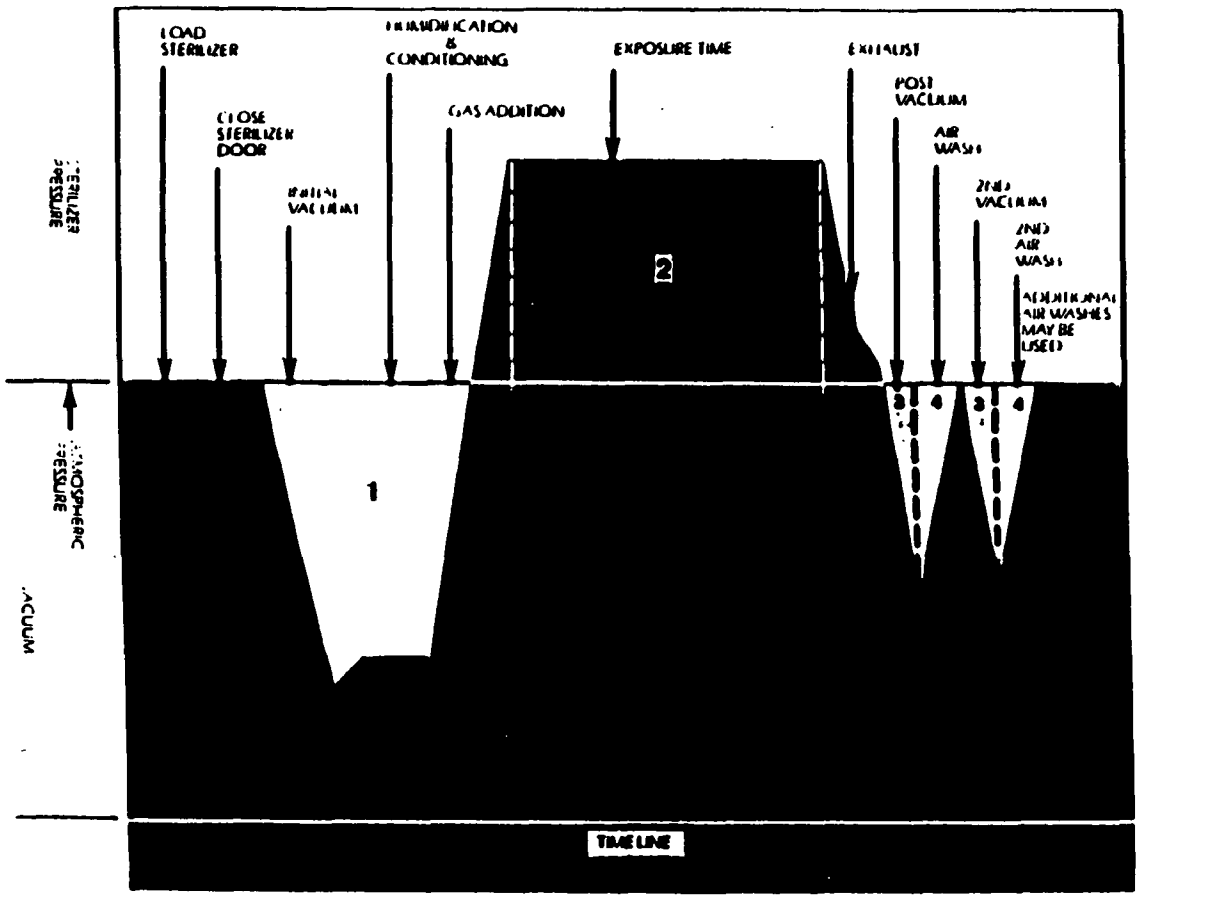
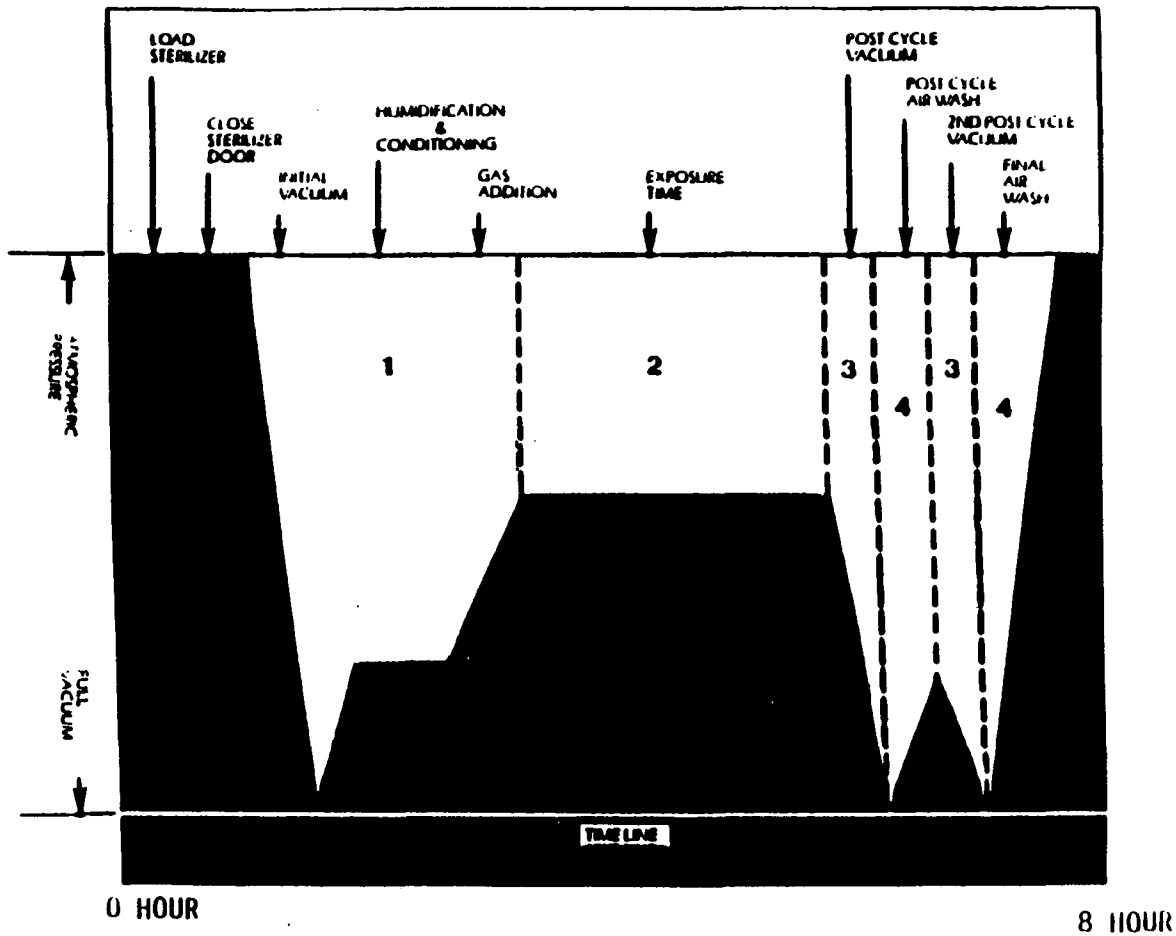


1. PRESTERILIZATION CONDITIONING
2. STERILIZATION
3. EVACUATION
4. AIR WASH

Figure 3-2. Sterilization cycle for 12/88. (Courtesy of Union Carbide Corporation, Linde Division.)[12]



1. PRESTERILIZATION CONDITIONING
2. STERILIZATION
3. EVACUATION
4. AIR WASH

Figure 3-3. Sterilization cycle for pure EO. (Courtesy of Union Carbide Corporation, Linde Division.)[12]

about 45 percent by injecting steam. Proper humidification is important to the process because the susceptibility of microorganisms to the sterilant gas is increased under moist conditions.[12]

3.2.1.3.2 Sterilization. The sterilant, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration of EO. The chamber pressure depends on the type of sterilant gas used. Pure EO is used under a slight vacuum at pressures of about 94 kPa (13.7 psia); the 12/88 mixture is used at pressures of about 170 kPa (24.7 psia). The pressure is held for about 4 to 6 hours. This exposure time is dependent on the temperature, pressure, humidity level, type of sterilant gas, and products being sterilized. For example, porous products require shorter exposures than nonporous products. Also, some bacteria are more resistant to EO and take longer to destroy.

3.2.1.3.3 Evacuation. Following sufficient exposure time, the sterilant gas is evacuated from the chamber with a vacuum pump. Typical evacuation pressures are 13 kPa (1.9 psia) for 12/88 gas and 3 kPa (0.4 psia) for pure EO. This postcycle vacuum phase lasts about 10 minutes.

3.2.1.3.4 Air wash. The pressure in the chamber is brought to atmospheric pressure by introducing air (when nonflammable sterilant gases are used) or either nitrogen or CO_2 (when flammable sterilant gases are used). The combination of evacuation and air wash phases is repeated from two to four times to remove as much of the EO from the product as possible. The air wash typically lasts 2 to 15 minutes.

The purpose of the air wash is to allow residual EO to diffuse from the product. Removal of EO from the product during the air wash helps meet Food and Drug Administration (FDA) guidelines on residual EO levels for medical devices, EPA residual tolerances for agricultural products, and the OSHA standard for exposure in the workplace.

3.2.1.3.5 Aeration. After the last air wash, the chamber doors are opened, and the sterile products are placed in an aeration room and kept there for several hours to days depending on the product. The purpose of aeration is to allow further diffusion of residual EO from the products prior to shipping to comply with the FDA and EPA residual EO guidelines. Ethylene oxide concentrations in the aeration room are maintained at

relatively low levels by ventilating the room at a rate of about 20 air changes per hour.

Recent information from industry contacts indicate that some commercial sterilization facilities are aerating some or all of the sterile products in heated enclosed aeration cells. In comparison to traditional warehouse-type aeration rooms, these cells are smaller in volume (<70m^3 [2500 ft^3]) with much lower ventilation rates. Consequently, the EO concentrations are usually higher than the 1 ppmv OSHA standard. However, worker exposure is reduced by not opening the door until the EO concentration drops and by limiting the frequency of opening the door. The main purpose of this type of aeration process is to increase the diffusion rate of EO out of the sterile product (by increasing the temperature) and, thus, reduce the aeration time.

Facilities that sterilize products infrequently may aerate in the sterilization chamber. Two basic chamber aeration processes are used. The first process involves cycling the chamber between atmospheric pressure and a slight vacuum pressure (i.e., a pressure of about 94 kPa [13.7 psia]) several times over a 12- to 24-hour period. The length of the cycles depends on the chamber size and vacuum pump capacity. The second process involves drawing an extreme vacuum (about 0.6 kPa [0.1 psia]) in the chamber and holding the vacuum for 24 to 48 hours.

Some hospitals and commercial sterilization facilities with smaller sterilizers (less than 1 m^3 [40 ft^3]) use aeration chambers (or cabinets), which are similar to the sterilization chambers in size and design. Sterile products at hospitals are aerated for about 24 hours.

3.2.2 Single-Item Sterilization System

Four of the 203 commercial sterilization facilities (2 percent) that responded to the HIMA survey or the July 1986 EPA information request reported the use of a single-item sterilization system.[1,2] Three of these facilities use the Sterijet® system manufactured by H. W. Andersen Products; one facility uses another patented system that is similar to the Sterijet® system.[2] In contrast to the bulk sterilization chambers used by most commercial sterilization facilities, these systems are designed to sterilize small individual items (such as medical equipment supplies) in sealed pouches. Marketing of these systems is primarily focused on hospital sterilization.[15]

The single-item sterilization systems consist of (1) a machine that delivers the sterilant gas through a nozzle, (2) flexible plastic pouches, and (3) an aeration cabinet. The process involves the following steps. The product to be sterilized is placed in a plastic pouch. With the open ends of the pouch sealed around the nozzle, a slight vacuum is drawn in the pouch followed by injection of a premeasured quantity of sterilant gas. The amount of sterilant gas injected depends on the size of the pouch. After the gas is injected, the nozzle is automatically withdrawn, and the pouch is heat sealed. The sealed pouches are placed directly into an aeration cabinet or temperature-controlled aeration room. The enclosed product is sterilized prior to the escape of the gas through the pouch, which is designed to retain the EO long enough to ensure proper sterilization. The products are sterilized for approximately 12 hours at about 50°C (122°F) and aerated for 36 hours.[15]

3.2.3 Beehive Fumigators

The process for beehive fumigators is essentially the same as bulk sterilization; however, a unique feature of the fumigators warrants a separate discussion. Whereas the sterilization processes described above are performed at one location, six of the eight State departments of agriculture represented in the EPA sterilization data base use portable chambers to fumigate beehives.[2] These fumigators are transported to and used at numerous and variable locations in each of the six States. The State departments of agriculture use an EO/CO_2 sterilant gas mixture. Typically, a garden hose is connected to the fumigation chamber and is placed along the ground for venting the sterilant gas during the evacuation phase of the sterilization cycle. After the evacuation, the beehive is removed from the chamber and aerated in the open air.

3.3 EMISSION SOURCES

The three principal sources of EO emissions from sterilization/fumigation processes are (1) the sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator), (2) the sterilization chamber vacuum pump drain (assuming that a once-through, water-ring vacuum pump is used), and (3) the aeration room vent. A schematic of these emission sources is shown in Figure 3-4. Other potential emission sources are equipment leaks and storage and handling. For the purposes of developing emission

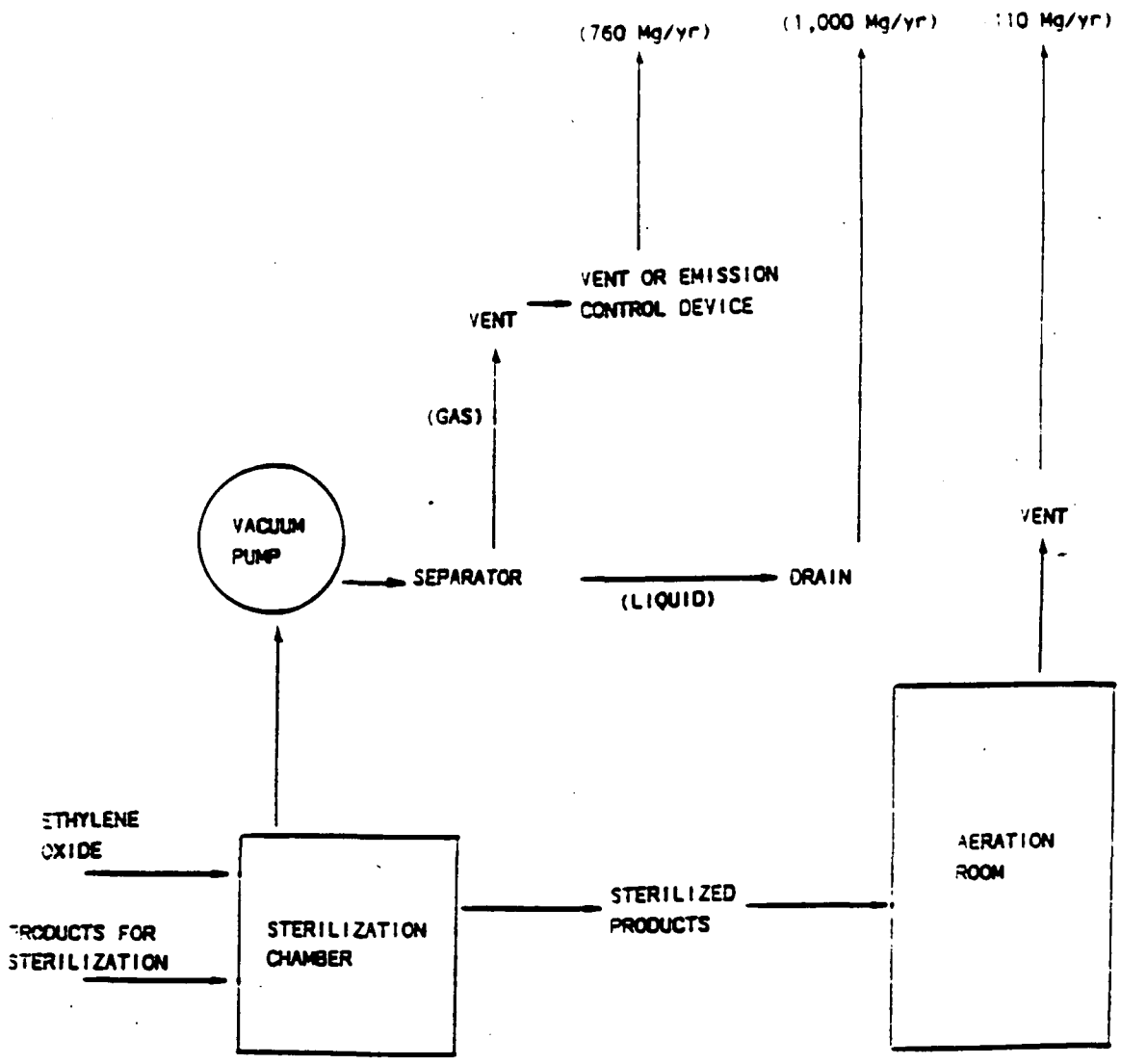


Figure 3-4. Schematic of emission sources at commercial sterilization facilities. (Does not include hospitals).

estimates and because bulk sterilization processes are the main source of emissions, emission sources were assumed to be the same for both sterilization processes (i.e., bulk and single-item).

3.3.1 Sterilization Chamber Vents

Sterilization chamber vent emissions are associated with the chamber vacuum pump. These vacuum pumps are typically once-through, liquid-ring designs that use water as the working fluid. During the evacuation phase of the sterilization cycle, a mixture of chamber gas and water is expelled from the pump to a centrifugal gas/liquid separator. In the separator, gas-phase EO is directed to a vent and emitted to the atmosphere. The liquids from the separator are directed to a sewer drain.

3.3.2 Sterilization Chamber Vacuum Pump Drains

Some of the EO that is released from the chamber during the evacuation phase enters the liquid-phase separator line with the vacuum pump water. Although some EO may be hydrolyzed to ethylene glycol, the conversion rate at ambient temperatures is extremely slow, requiring weeks for completion (see Figure 3-5).[8] Also, EO is rapidly released from an aqueous solution when agitated.[16] Therefore, virtually all of the EO that dissolves in the vacuum pump water is emitted from the water. The absorbed EO may be released at the 1-inch air break between the liquid pipe and drain (required by local plumbing codes) or may diffuse into other areas of the building as the water passes through the drain system. Any remaining EO would desorb into the head space of the sewer pipes (possibly creating flammable mixtures with air) and be emitted as it passes through the sewer or waste treatment systems.[6,8]

3.3.3 Aeration Room Vent

All emissions from residual EO in the product are referred to as aeration room vent emissions. As residual EO diffuses out of the sterile products in the aeration room or is emitted to the sterilization room when the chamber door is opened, it is emitted to the atmosphere via room ventilation. High ventilation airflow rates are used to maintain EO concentrations below the OSHA limit.

3.3.4 Equipment Leaks

Although equipment component counts (number of flanges, valves, etc.) were not obtained for the commercial sterilization facilities, observations

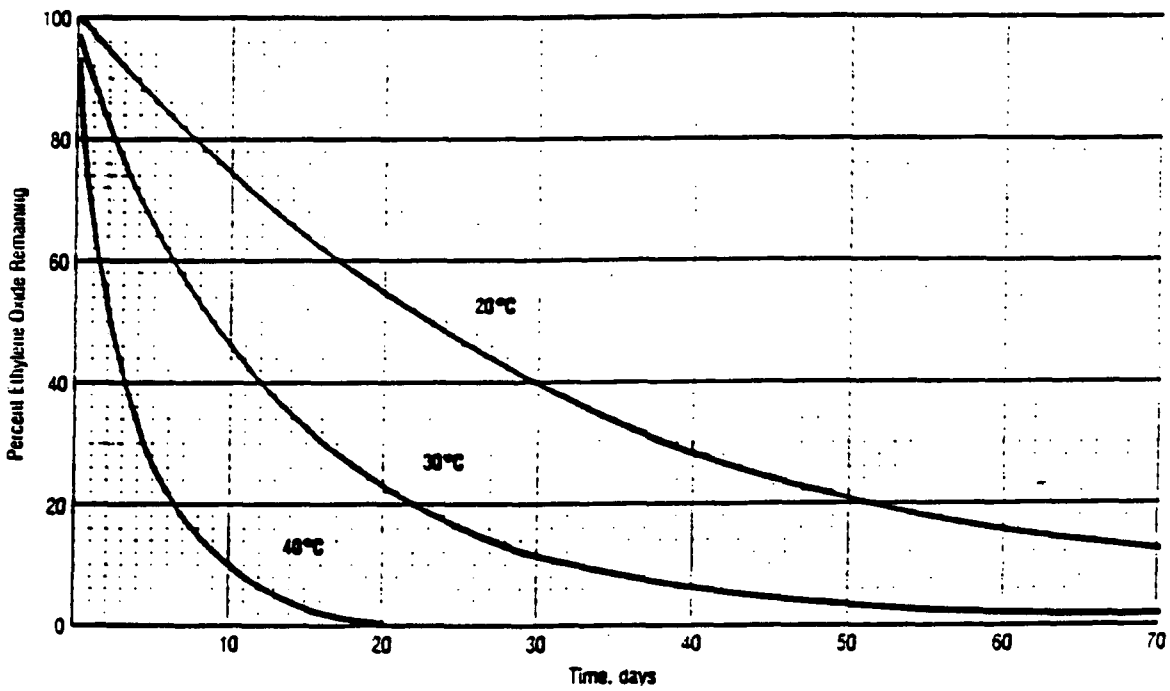


Figure 3-5. Hydrolysis rates of dilute, neutral aqueous solutions of ethylene oxide.
(Courtesy of Union Carbide Corporation, Ethylene Oxide/Glycol Division.)[3]

made during site visits indicated that the number of components is small. However, control of equipment leaks may be important to meet the 1 ppmv OSHA standard. For the purposes of this analysis, equipment leak emissions are assumed to be negligible.

3.3.5 Storage and Handling

Ethylene oxide at commercial sterilization facilities and hospitals is typically stored in pressurized cylinders rather than bulk containers. Therefore, material losses associated with loading and unloading bulk quantities of EO and storage tank breathing losses would not occur. Although bulk storage of sterilant gas at sterilization facilities is rare, at least one commercial sterilization facility stores bulk quantities of 12/88 in a pressure vessel. During transfer of the 12/88 from the tank truck to the pressure vessel, the vessel and the tank truck are vapor balanced. Therefore, emissions during transfer are expected to be negligible. Also, because the storage tank is a pressure vessel, no emissions should occur during routine operation. Consequently, commercial sterilization facilities and hospitals are likely to have negligible storage and handling emissions.

3.4 EMISSION ESTIMATES

3.4.1 Commercial Sterilization Facilities

The emission estimate for commercial sterilization facilities is based on the facility-specific annual EO usages and emission control levels reported in the 203 responses to the HIMA survey and the July 1986 EPA information request. Average EO emissions from these commercial sterilization facilities, based on total sterilizer volume, are presented in Table 3-6. The total amount of EO used by the 203 commercial sterilization facilities (i.e., not hospitals) represented in the EPA data base is 2,270 Mg/yr; approximately 16 percent (i.e., 370 Mg/yr) of this amount is controlled. Therefore, the EO emission estimate for the 203 facilities represented in the EPA commercial sterilization data base is 1,900 megagrams per year (Mg/yr).[1,2] Of this amount, it is estimated that 760 Mg/yr are emitted from sterilizer vents, 1,000 Mg/yr are emitted from sterilization chamber vacuum pump drains, and 110 Mg/yr are emitted from aeration room vents (see Figure 3-4). These estimates were developed using the HIMA survey, the July 1986 EPA information request responses, and the following assumptions:

TABLE 3-6. AVERAGE EMISSIONS FROM COMMERCIAL STERILIZATION FACILITIES--EPA DATA BASE[1,2]

Total chamber volume at facility, m^3 (ft^3)	No. of facilities[a]	Mean EO use, kg/yr (lb/yr)	Mean EO emissions, kg/yr (lb/yr)[b,c]
<11 (<400)	88	660 (1,500)	640 (1,400)
11-56 (400-2,000)	77	7,600 (17,000)	6,800 (15,000)
>56 (>2,000)	38	43,000 (94,000)	34,000 (75,000)

[a]Does not include hospitals.
[b]Mean emissions are less than mean EO use because of existing controls.
[c]Emissions from all sources (i.e., sterilizer vent, vacuum pump drain, aeration).

1. All of the EO reported as used in the sterilization process is evacuated from the sterilization chamber or released from the product during aeration.

2. Within each facility, EO emissions are distributed among three emission points. The three emission points and the percentage of total EO emissions allocated to each are:

a. Sterilizer vent(s)--50 percent;

b. Sterilization chamber vacuum pump drain--45 percent; and

c. Aeration room vent(s)--5 percent.

This 50/45/5 percent split is based on industry estimates, limited test data, and engineering judgment.[17]

3. For the 355 sterilization chambers in the EPA commercial sterilization data base that are uncontrolled, all of the EO that enters the chamber vent(s) is released to the atmosphere. For the 79 sterilization chambers with emission control devices, the chamber vent emissions are controlled at the efficiencies reported on the HIMA survey and EPA information request responses.

4. At each facility, all of the EO that dissolves in the vacuum pump water and subsequently enters the drain is assumed to be emitted uncontrolled to the atmosphere at an outdoor ground-level drain near the facility. This assumption is consistent with test data that suggest EO is rapidly released from an aqueous solution when agitated.[16]

5. At each facility, all of the EO that enters the aeration room vent is released uncontrolled to the atmosphere.

3.4.2 Hospitals

The EO emission estimate for hospitals is based on data from the approximately 80 responses to the 1986 information request to hospitals and information in the 1988 American Hospital Association (AHA) hospital data base. Linear regression analyses of the 1986 data indicated that the annual EO use correlates better with the number of hospital beds (r^2 = 0.77) than with the number of surgical procedures (r^2 = 0.68).[18] A nationwide EO use rate of approximately 1,000 Mg/yr was obtained by extrapolating the 1986 data to the 1988 AHA data base, which contains hospital-specific information on the number of beds for 7064 hospitals.[19] Because the majority of hospitals do not use EO

emission controls, EO emissions from hospitals are assumed to equal the EO use of approximately 1,000 Mg/yr. Average EO emissions for hospitals, based on the number of hospital beds, is presented in Table 3-7.

3.5 CURRENT REGULATIONS

3.5.1 Occupational Safety and Health Administration Standard

In 1984, OSHA established a permissible exposure limit for occupational exposure to EO of 1 ppmv determined as an 8-hour time-weighted average (TWA) concentration. In addition, an action level of 0.5 ppmv as an 8-hour TWA was established as the level above which employers must monitor employee exposure.[20] In April 1988, OSHA established a short-term excursion limit (EL) for occupational exposure to EO emissions of 5 ppmv averaged over a 15-minute sampling period.[21]

3.5.2 State Regulations

Existing State regulations for EO are summarized in Table 3-8. Several States are currently regulating EO or developing air toxics programs.[22-28]

TABLE 3-7. AVERAGE EMISSIONS FROM HOSPITAL STERILIZERS[3,19]

Hospital size range	No. of hospitals	Mean EO use, kg/yr (lb/yr)[a]
Small (<200 beds)	4,907	70 (150)
Medium (200 to 500 beds)	1,645	200 (430)
Large (>500 beds)	512	790 (1,740)

[a]Because most hospitals do not control EO emissions, the EO emissions are assumed to equal the EO use.

TABLE 3-8. STATE REGULATIONS FOR ETHYLENE OXIDE EMISSIONS[22-28]

State	Regulatory description
California[a]	• Developing air toxics program but a regulation may not be proposed for 1 year. • South Coast--proposed rule for new (or modified) sources based on maximum 10^{-6} risk level, including aeration processes. • Bay Area--draft rule for new and existing sterilizers; no drain emissions; 99.5 percent control of vent emissions if EO_2 use exceeds 250 lb/yr: exemptions--sterilizers smaller than 250 ft^3 and aeration processes.
Colorado	• Regulate as a volatile organic compound (VOC). • Reasonably available control technology (RACT) required for new sources.
Connecticut	• Best available control technology (BACT) required for all new or modified sources exceeding a maximum allowable stack concentration (MASC). • MASC is calculated using exhaust gas flow rate, stack height, and the distance from the discharge point to the property line. MASC would be exceeded for industrial sterilizers using typical sterilization cycles. Therefore, BACT required on new or modified sources. Existing sources exceeding the maximum allowable ambient concentration of 0.01 ppm have 3 years to comply with orders given by the Connecticut Department of Environmental Protection.
Florida[a]	• Maximum risk level of 10^{-6} for new or modified sources.
Michigan[a]	• BACT for all new sources. Requires emissions be indectable or subjected to risk analysis (maximum allowable risk level is 10^{-6}). For industrial sterilizers using typical sterilization cycles, a control efficiency based on a risk assessment analysis would be greater than 99 percent by weight.
Missouri	• Regulate as a VOC.
New Jersey	• Regulate as a VOC. • BACT required for new or modified sources.
New York[a]	• New or modified sources must receive 99 percent control or greater, or BACT (also at permit reviews) • Maximum annual impact must not exceed guideline Acceptable Ambient Level (AAL) of 6.67 $\mu g/m^3$ (a revised AAL of 0.019 $\mu g/m^3$ is anticipated for the next edition of Air Guide-1 [to be released by 01/90]. • Certificate of operation includes the following statement: "Should significant new scientific evidence from a recognized institution result in the decision by DEC that lower ambient levels must be established, it may be necessary to reduce emissions from this source prior to the expiration of this Certification of Operation."
Oklahoma	• Maximum ambient air concentration at property line is 1/100 of TLV.
Puerto Rico	• Regulate as a VOC. • Emission controls required for emissions greater than 3 lb/h or 15 lb/d.
Rhode Island[a]	• Maximum risk level of 10^{-6} for new and existing sources. • If BACT is used, may consider 10^{-5} risk level.
Tennessee	• Regulate under standards for process and nonprocess emissions.
Texas	• BACT required for all new sources.
Utah	• BACT required for all new or modified sources. BACT requirements to go into effect for existing sources. • Following the programs developed in New York.
Vermont	• Regulate as a VOC.
Virginia	• For any 24-hour concentration exceeding 1/100 of the TLV-TWA both existing and new facilities are required to control emissions as directed by the Virginia Air Pollution Control Board.
Wyoming	• BACT required for all new sources. • Controls must meet AAL at property line.

[a]Information obtained from State contacts in February 1989. All other information is from 1986 through 1987 data.

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3.6 REFERENCES FOR CHAPTER 3

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4. EMISSION CONTROL TECHNIQUES

4.1 BULK STERILIZATION PROCESSES

The three principal sources of ethylene oxide (EO) emissions from bulk sterilization processes are:

1. The sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
2. The sterilization chamber vacuum pump drain; and
3. The aeration room vent.

The following sections describe the techniques available to control EO emissions from these three sources. Table A-2 in Appendix A presents a list of the emission control devices and manufacturers.

4.1.1 Sterilization Chamber Vent Emissions

Three primary techniques are used to control EO emissions from sterilizer vents: hydrolysis, oxidation, and condensation. Ethylene oxide is catalytically hydrolyzed to form ethylene glycol; oxidation decomposes EO into carbon dioxide and water; and condensation allows the recovery of the sterilant gas mixture. A fourth control technique for sterilizer vents is a gas/solid reactor system that chemically reacts EO and binds it to the solid packing of the reactor.[1]

Table 4-1 shows the emission control techniques and devices used by the 203 commercial sterilization facilities (i.e., not hospitals) represented in the EPA data base (refer to Chapter 3 for a description of the contents and origin of the data base). Twenty-seven of these 203 commercial sterilization facilities (13 percent) reported the use of a control device for sterilizer vent emissions. Nineteen of these 27 facilities use one emission control device for multiple chambers by manifolding the chamber vents and staggering the evacuation of the sterilant gas from the chambers. The remaining eight facilities control emissions from single chambers.[2,3]

Nine additional commercial sterilization facilities reported the use of a neutral-water scrubber to control EO vent emissions. Neutral-water scrubbers reduce EO vent emissions by "washing" a portion of the EO to the drain (facilities reported 20 to 100 percent of the total EO emissions from the sterilizer chamber were "controlled" by a neutral-water

TABLE 4-1. ETHYLENE OXIDE EMISSION CONTROL DEVICES FOR STERILIZER VENTS--EPA COMMERCIAL STERILIZATION DATA BASE[2,3]

Emission control technique and device	Control efficiency, percent[a]	No. of facilities (percent)[b]	No. of chambers (percent)[b]	Chamber size, m^3 (ft^3)	EO usage/ facility, Mg/yr (lb/yr)
Hydrolysis					
Packed scrubber	99.0[c]	14 (7)	45 (10)	4-170 (140-6,000)	0.9-59 (2,000-130,000)
Reaction/detoxification tower	99.0	2 (1)	4 (1)	4-27 (140-960)	4 and 57 (9,500-126,000)
Caustic scrubber	30.0 and 95.0	1 (0.5)	2 (0.5)	32 and 60 (1,150 and 2,120)	44 (98,200)
Oxidation					
Flare	98.0[d]	2 (1)	5 (1)	2-77 (60-2,720)	34 and 80 (74,200 and 176,000)
Catalytic oxidizer	99.0	1 (0.5)	1 (0.2)	4 (130)	0.4 (1,000)
Condensation					
Condensation/reclamation system	50.0 - 88.0	7 (3)	20 (5)	5-45 (190-1,580)	7-46 (15,000-100,800)
TOTAL		27 (13)[e]	77 (18)[f]		790 (1,750,000)

[a]Control efficiencies are those reported by the 203 commercial sterilization facilities represented in the EPA data base, and are not necessarily supported by EPA-sponsored test data.
[b]Does not include hospitals.
[c]Although the 14 commercial sterilization facilities that use scrubbers reported control efficiencies ranging from 96.0 to 99.9 percent, a detailed review of the available test data for acid-water scrubbers indicates that 99.0 percent is the maximum removal efficiency that can be achieved on a continuous basis.[4]
[d]Although the two commercial sterilization facilities that use flares reported destruction efficiencies of 99.0 and 99.7 percent, the EPA's position is that flares operated within specified conditions of waste gas heat content and flare exit velocity will achive at least 98 percent destruction efficiency.[5]
[e]Total number of facilities = 203.
[f]Total number of chambers = 434.
[g]Represents 35 percent of the total EO used by the 203 commercial sterilization facilities represented in the EPA data base.

scrubber).[2,3] Some of the EO that is washed to the drain may be converted by hydrolysis to ethylene glycol; however, the conversion rate of EO to ethylene glycol in neutral water at ambient temperatures is extremely slow, requiring weeks for completion.[6] Since EO is rapidly released from an aqueous solution when agitated, the vast majority of the EO washed to the drain will off-gas uncontrolled from the air break in the drain line, sewer lines, or the waste treatment system.[6-8] Because the use of neutral-water scrubbers merely changes the EO emission source, they are not discussed here as a control technique.

The majority of hospitals do not control EO emissions from sterilizer vents. However, some hospitals use emission controls because of State and local regulations. Catalytic oxidation and the gas/solid reactor system are two techniques that are known to be used by hospitals to control EO emissions from sterilizer vents.[9-11]

4.1.1.1 Hydrolysis. Hydrolysis is the most common EO emission control technique used by commercial sterilization facilities.[2,3] This technique is applicable for both pure EO and EO/inert gas mixtures such as 12/88 (12 percent by weight EO and 88 percent by weight dichlorodifluoromethane [CFC-12]) and 10/90 (10 percent by weight EO and 90 percent by weight carbon dioxide). The majority of commercially available hydrolysis control devices are not designed for the low flow rates associated with chamber volumes less than 1.4 m^3 (50 ft^3) and are, therefore, not applicable to the control of most hospital sterilization chambers. However, two manufacturers have designed scaled-down acid-water scrubbers for flow rates less than 0.3 cubic meters per minute (m^3/min) [10 cubic feet per minute (ft^3/min.)].[11,12]

Ethylene oxide can be hydrolyzed under relatively mild conditions to ethylene glycol products (without affecting the inert gas) as shown in the following reaction:

$$C_2H_4O + H_2O \xrightarrow[H+ \text{ or } OH-]{} HOCH_2CH_2OH + HO(CH_2CH_2)_nOH$$

Ethylene oxide — Ethylene glycol — Polyethylene glycols

Ethylene oxide will hydrolyze in neutral water, but this reaction is very slow. (The half-life of EO in neutral water at ambient temperatures is approximately 14 days.)[8] The reaction rate is increased in an acidic or basic solution. The reaction is approximately two orders of magnitude faster under acidic conditions than under basic conditions, making acid hydrolysis the preferred method. Sixteen of the 203 commercial sterilization facilities represented in the EPA data base reported using acid-water scrubbers; one facility reported using caustic scrubbers to control EO emissions.[2,3]

4.1.1.1.1 Packed scrubbers. Figure 4-1 is a schematic of a packed scrubbing system used to control EO emissions. The system consists of a countercurrent packed tower, a reaction vessel, and a holding tank. In the countercurrent tower, the sterilant gas is contacted with an acidic water solution, generally aqueous sulfuric acid. Because EO is extremely water soluble, most of the EO is absorbed into the scrubber liquor. Next, the liquor is sent to the reactor vessel, which is a small storage tank operated at atmospheric pressure, to complete the hydrolysis of EO. After the reaction is complete, the liquor is sent to the storage vessel. The liquor in the storage vessel is recirculated to operate the tower until the concentration of the ethylene glycol in the liquor reaches a predetermined weight percentage, past which point the scrubber efficiency declines. Manufacturers of packed scrubbing systems suggest that the scrubbing liquor is spent when the solution is 30 to 40 percent by weight ethylene glycol.[13,14] Possible methods of determining when the liquor needs replacing include liquid level indicators or specific gravity detectors in the tank. (Both parameters increase as the amount of ethylene glycol increases.) Alternatively, the amount of EO charged to the sterilizer can be used to determine the liquor changeout point. The spent solution is neutralized and then disposed or sold. (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Generally, sodium hydroxide is used to neutralize the glycol solution; sodium carbonate also can be used.

Countercurrent packed scrubbers are used by commercial sterilization facilities with sterilizers ranging from 4.0 cubic meters (m^3) (140 cubic feet [ft^3]) to 170 m^3 (6,000 ft^3). Ethylene oxide use at these commercial

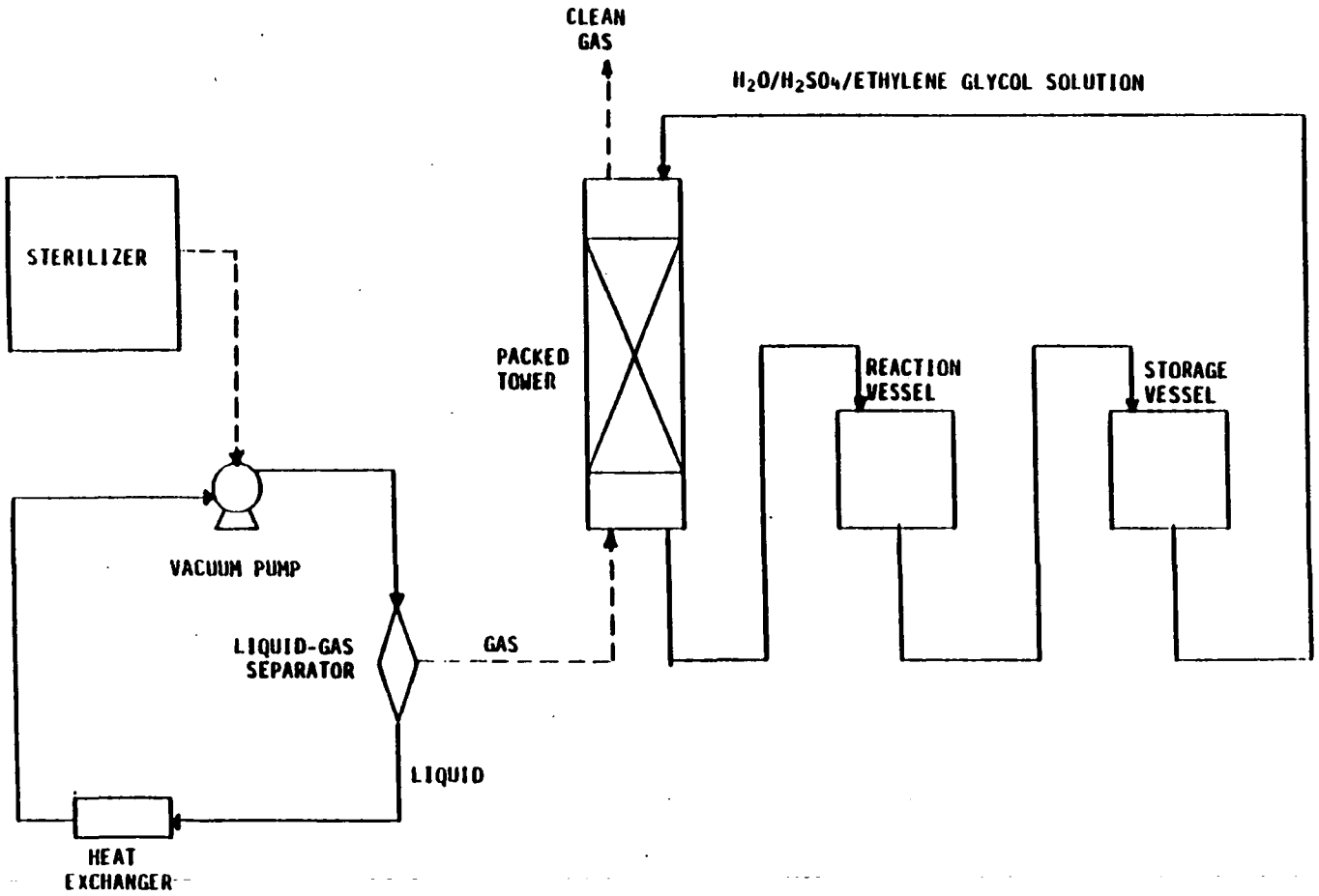

Figure 4-1. Countercurrent packed scrubbing system.

sterilization facilities ranges from 0.9 Mg/yr (2,000 lb/yr) to 59 Mg/yr (130,000 lb/yr).[2,3]

Manufacturers of countercurrent packed scrubbers designed to control EO emissions from sterilizer vents claim EO removal efficiencies greater than 99 percent.[1,13,15] For a 12/88 sterilant gas mixture, the average EO removal efficiency for three tests was 99.0 percent by weight (individual test results were 99.0, 98.7, and 99.4 percent).[16] These tests were conducted using a scrubber that was designed to achieve an EO removal efficiency of 99 percent. A representative of the manufacturer of the tested acid-water scrubber stated that the company can design scrubbers to achieve virtually any EO removal efficiency with any type of sterilant gas.[17] The results of an EPA-sponsored test on another acid-water scrubber designed by this company indicated an EO removal efficiency greater than 99.9 percent for 12/88.[18] For pure EO, the EO removal efficiency was greater than 99.98 percent for each of four tests performed at two facilities.[16,19] However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved on a continuous basis.[4]

4.1.1.1.2 Reaction/detoxification towers. Another acid hydrolysis scrubbing technique for EO emission control is a reaction, or detoxification, tower. A schematic of this system is shown in Figure 4-2. This system consists of a tank that holds the scrubbing liquor, which is a sulfuric acid solution at a pH of 0.5 to 2.5. The sterilant gas is bubbled upward through the liquor. The EO is absorbed into the liquor where it hydrolyzes to ethylene glycol. The gas stream then flows through the liquid surface and a demister. The demisting pad prevents acid mist from exiting with the scrubbed gas and provides a final hydrolysis reaction site for any EO remaining in the gas stream. Inert gases (i.e., CFC-12 and CO_2) are exhausted unreacted to the atmosphere. After ethylene glycol builds up in the stream to a maximum recommended level of 60 percent, the scrubber liquor is neutralized and disposed or sold.[20] (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Possible methods of determining the scrubbing liquor changeout point include (1) liquid level indicators, (2) specific gravity detectors, and (3) measuring the amount of EO charged to the sterilizer. Reaction

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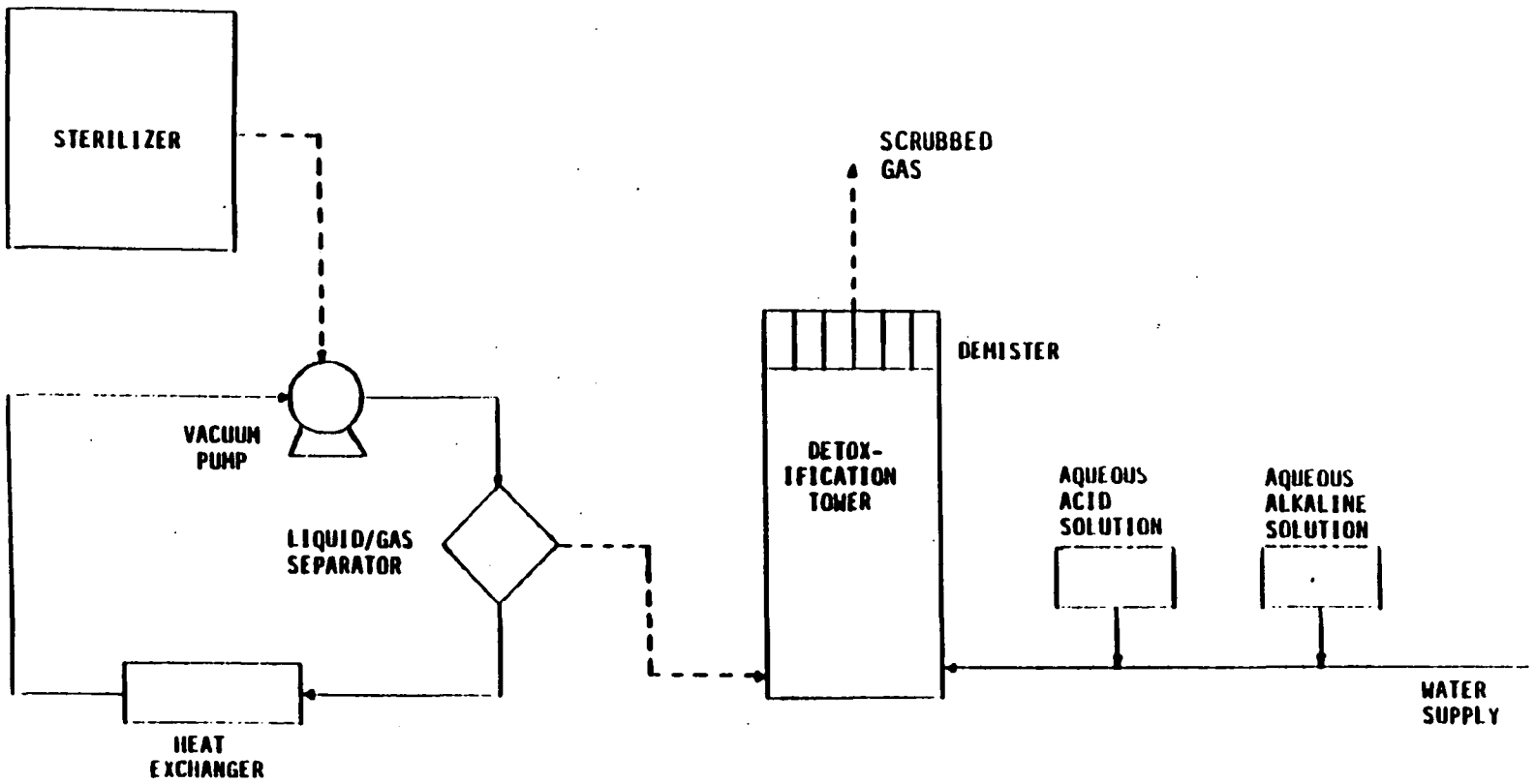

Figure 4-2. Detoxification tower control system.

towers are effective for chambers ranging from 1.4 m^3 (50 ft^3) to 45 m^3 (1,600 ft^3).[21,23] Two of the 203 commercial sterilization facilities represented in EPA's data base use reaction towers to control EO emissions from sterilizer vents. The sterilizers at these two facilities range in volume from 4 m^3 (140 ft^3) to 27 m^3 (960 ft^3). One of these facilities uses 4 Mg (9,500 lb) of EO per year; the other uses 57 Mg (126,000 lb) annually.[2,3]

Manufacturers of reaction/detoxification towers claim 99+ percent EO removal efficiency by weight.[21,22] Third-party laboratory test results indicate that EO emission reductions greater than 99.8 percent can be achieved with reaction towers.[23] However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved by acid hydrolysis techniques on a continuous basis.[4]

4.1.1.1.3 Waste disposal. The spent liquor from acid hydrolysis of EO is typically 40 to 60 weight percent ethylene glycol and has a pH of 0.5 to 2.0. Because of the low pH, the solution is considered a hazardous waste and, thus, requires special handling procedures for shipping if not neutralized. However, the spent liquor can easily be neutralized with sodium hydroxide (caustic) prior to disposal.

Two recovery companies have been identified that are willing to purchase the aqueous ethylene glycol solution.[24,25] One of these companies will pay $0.03 to $0.06 per gallon for neutralized scrubbing liquor that is at least 45 percent, by weight, ethylene glycol.[24] Both of these companies require that sodium hydroxide be used for neutralization and will pick up the solution at the sterilization facility. A third recovery company will accept the spent scrubbing solution on a no cost/no payment basis, except for shipping charges.[26] (See Table A-3 in Appendix A for the names and addresses of the above mentioned recovery companies.) The neutralized scrubbing solution also may be disposed to a landfill or incinerator.

4.1.1.2 Oxidation. Two methods of oxidizing EO are (1) thermal oxidation with flares and (2) catalytic oxidation with a solid-phase catalyst.

4.1.1.2.1 Thermal oxidation. Ethylene oxide, which has a high heating value, a relatively low ignition temperature, and a very wide range of mixtures combustible in air (see Table 3-4), can be easily and efficiently destroyed by thermal oxidation using flares. Thermal oxidation of EO produces carbon dioxide and water as follows:

$$2\ C_2H_4O + 5\ O_2 \xrightarrow[\text{thermal oxidation}]{} 4\ CO_2 + 4\ H_2O$$

Two of the 203 commercial sterilization facilities represented in the EPA data base reported using flares to control EO emissions from the use of pure EO as a sterilant gas.[2] One of these facilities has one 76.7-m^3 (2,710-ft^3) chamber and uses 80 Mg (176,000 lb) of EO per year. The other facility has three chambers ranging in size from 75.2 to 76.9 m^3 (2,655 to 2,715 ft^3) and one smaller 1.7-m^3 (60-ft^3) chamber; this facility uses 98 Mg/yr (215,600 lb/yr) of EO.[2] Because of difficulties with sustaining combustion, commercially available flares are not applicable for facilities emitting only small amounts of EO.

A manufacturer of flare burners for the control of EO emissions claims greater than 99 percent control efficiency for pure EO but no data were provided to substantiate this claim.[27] The EPA's position is that flares operated within specified conditions of waste gas heat content and flare exit velocity will achieve at least 98 percent destruction efficiency.[5]

Flares can also be used with EO/CO_2 sterilant gas mixtures (e.g., 10/90) but are not designed for use with EO/CFC-12 mixtures (e.g., 12/88).[27,28] The EPA has not in the past and does not now recommend the use of flares to control emission streams containing halogenated compounds (e.g., CFC-12) because corrosive or toxic by-products may form. As shown below, thermal oxidation of CFC-12 may produce the following corrosive or toxic by-products at the high temperatures (400° to 800°C [800° to 1500°F]) associated with the use of flares:

$$CF_2Cl_2 + O_2 \xrightarrow[\text{thermal oxidation}]{} \begin{array}{ll} COCl_2 & \text{Phosgene} \\ COF_2 & \text{Carbonyl fluoride} \\ HCl & \text{Hydrogen chloride} \\ HF & \text{Hydrogen fluoride} \\ CF_4 & \text{Carbon tetrafluoride} \\ Cl_2 & \text{Chlorine} \\ CO & \text{Carbon monoxide} \end{array}$$

4.1.1.2.2 Catalytic oxidation. Catalytic oxidation of EO occurs in the presence of a solid-phase catalyst as follows:

$$2\ C_2H_4O + 5\ O_2 \xrightarrow[\text{catalytic oxidation}]{} 4\ CO_2 + 4\ H_2O$$

This control technique is applicable to pure EO, EO/CO_2 mixtures, and EO/CFC-12 mixtures. The CFC-12 does not react at the temperatures (150° to 180°C [300° to 350°F]) that occur during catalytic oxidation, and, therefore, the toxic CFC by-products that result from the higher temperatures associated with thermal oxidation are not produced. During an EPA-sponsored test of a catalytic oxidation unit, no CFC decomposition by-products were detected; the detection limit was 200 parts per billion (ppb) for the analyte chloride ion. The maximum operating temperature of the unit during testing was 155°C (311°F).[12]

A schematic of a catalytic oxidizer is shown in Figure 4-3. The spent sterilizer gas is first mixed with a large volume of air to reduce the control device inlet EO concentration to 5,000 ppmv or less. This dilution prevents excessive catalyst bed temperatures (which can damage the catalyst) from occurring during the oxidation of EO. The gas stream passes through a filter for dust removal and then is preheated to the reaction temperature with steam or electricity. The gas then enters the catalyst bed(s) where the EO is oxidized. Part of the exiting gas stream may be recycled for heat recovery before being vented to the atmosphere. One manufacturer also sells a catalytic oxidizer that uses excess catalyst, instead of diluent air, to absorb the heat of oxidation.[29] Because of cost considerations, the excess-catalyst system has been used, thus far, only for chambers less than 1 m^3 [40 ft^3]) in volume.[29]

Recent information indicates that the use of catalytic oxidation to control EO emissions is increasing, particularly for hospital sterilizers and other small chambers.[9,10] In general, the large amount of diluent air required for most catalytic oxidation systems has limited the use of this technique to smaller, hospital-size chambers. Also, some of the manufacturers of hospital sterilizers are developing sterilizers that are evacuated with air ejectors instead of a vacuum pump.[30] The emissions are then routed to a catalytic oxidizer.[30]

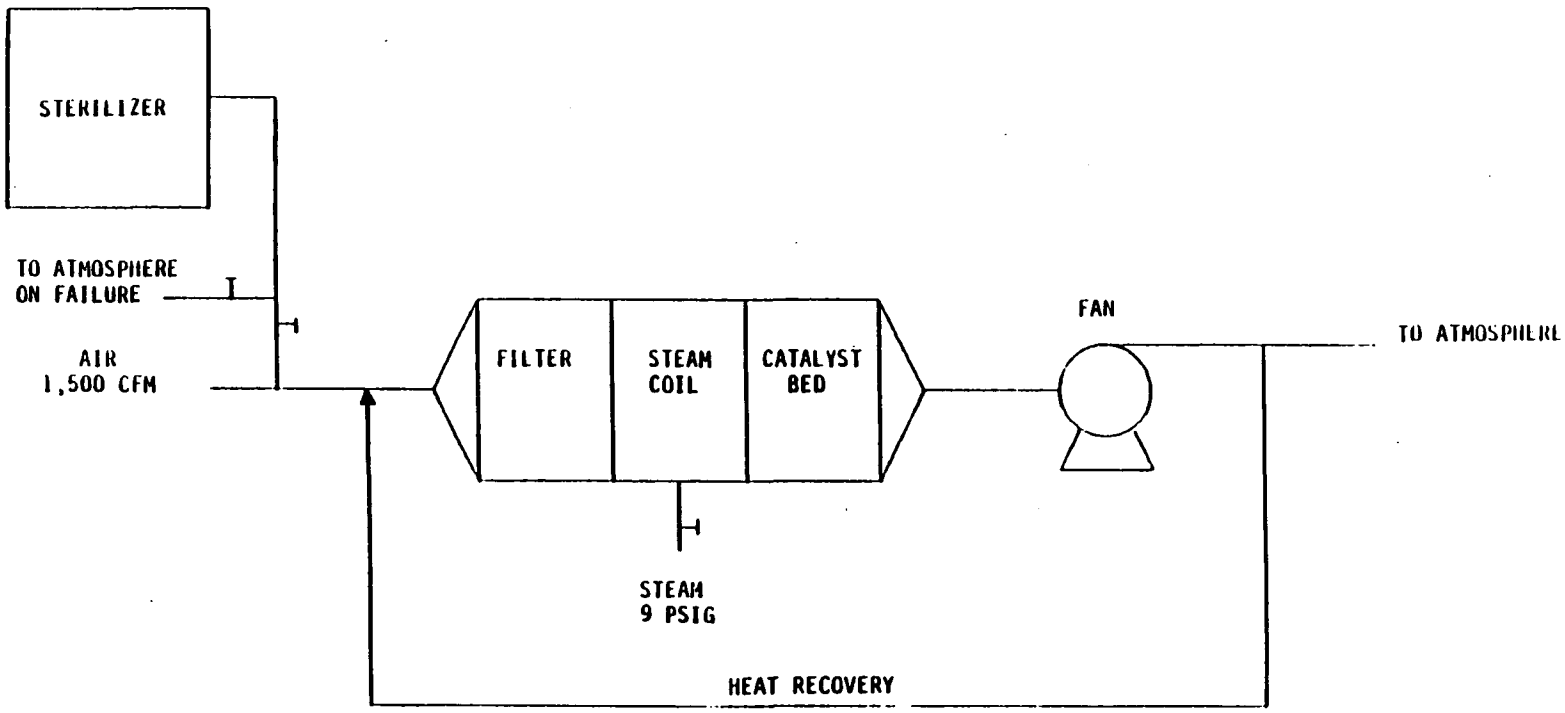

Figure 4-3. Catalytic oxidation system.

Only one of the 203 commercial sterilization facilities represented in the EPA data base reported the use of a catalytic oxidizer in 1986 to control EO emissions from the chamber vent.[2] This facility has one 4-m^3 (130-ft^3) chamber and uses 0.4 Mg/yr (1,000 lb/yr) of EO in an EO/CO_2 sterilant gas mixture.[2] However, data obtained in 1988 indicated that at least one additional commercial sterilization facility has installed a catalytic oxidation system to control EO emissions from a larger industrial-size sterilizer (17 m^3[600 ft^3]); the EO concentration to the control unit is regulated by throttles.[31]

Because catalytic oxidation is applicable to the control of low EO concentrations, many facilities manifold other EO emission sources (e.g., aeration chambers or room, sterilizer hood and door vent, and the gas cylinder room) to the control device. In addition, if the catalytic oxidizer requires diluent air, these low-concentration emission sources can provide part or all of the necessary diluent.

Manufacturers of catalytic oxidation units claim EO destruction efficiencies greater than 99.9 percent.[32,33] Third-party testing and an EPA-sponsored test support these claims for small (<30 ft^3) sterilizers.[12,32]

4.1.1.3 Condensation/Reclamation Systems. Recovery of sterilant gas mixtures is possible using a reclamation system. The sterilant gas mixtures will condense under conditions of reduced temperature and increased pressure, but precautions are necessary to avoid explosions.

Figure 4-4 is a schematic of a sterilization chamber room and a condensation/reclamation system for a 12/88 sterilant gas mixture. (See Table 3-4 for physical and chemical properties of CFC-12.) After each sterilization cycle, the 12/88 gas is withdrawn and passed through one of the two desiccant beds next to the chamber. (One of the desiccant beds is regenerated while the other is in use.) The dried 12/88 gas then passes to a compressor where it is compressed to 50 psig to improve condensation efficiency.[34] The compressed gas is piped to a separate explosion-proof room where it passes through a pressurized condenser that is chilled by ethylene glycol to about -18°C (0°F).[34] The liquid 12/88 mixture is collected in a pressurized, chilled holding tank. The noncondensed gas is recirculated to the chamber and back through the condenser. The liquid

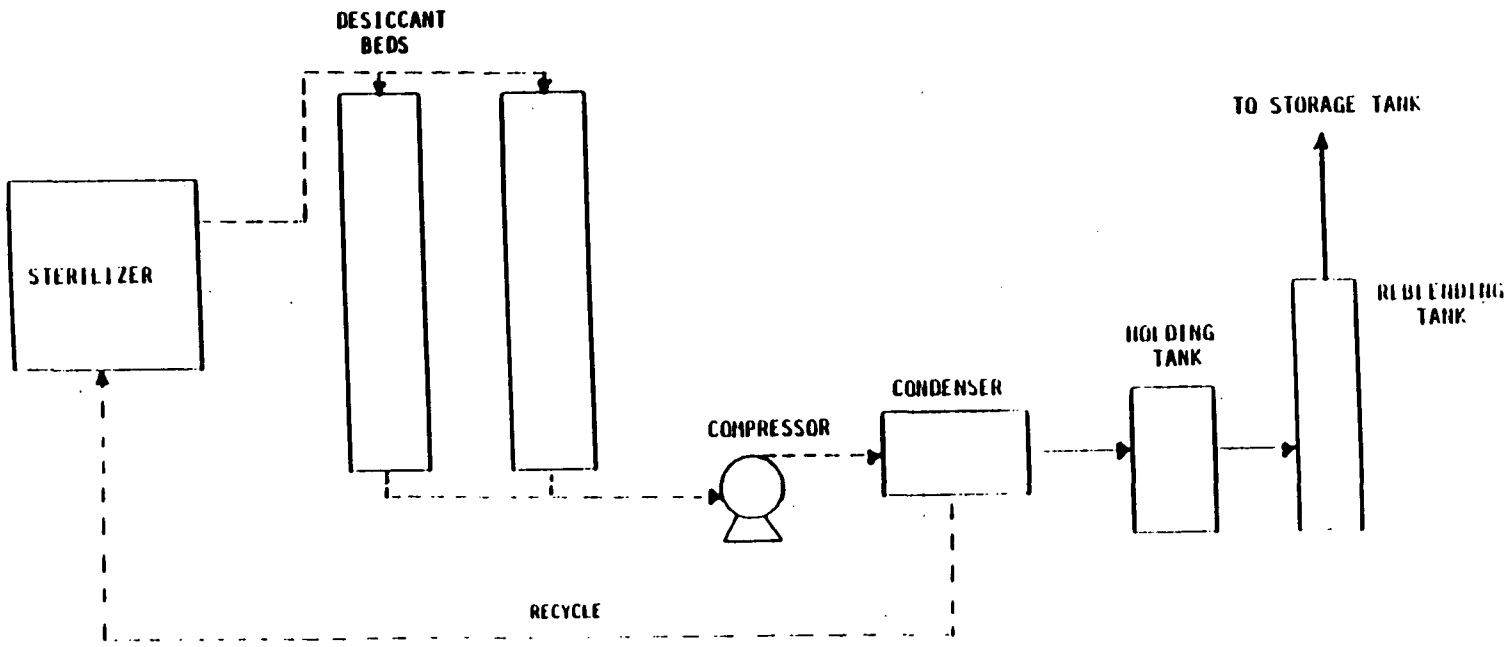

Figure 4-4. Condensation/reclamation system.

collected in the holding tank is transferred to a pressurized reblending tank where the liquid is mixed and its composition determined by infrared analysis. The liquid is then adjusted to the 12/88 (weight percent) ratio by adding the necessary amount of EO or CFC-12. When the correct ratio is obtained, the liquid is transferred to a pressurized storage tank in the chamber room.[34]

Although the reclamation cycle could be continued indefinitely, the amount of EO recovered declines to the point where it is not cost effective to continue the reclamation cycle after about three passes through the system (i.e., typically 60 to 90 minutes). The majority of the EO (80 to 85 percent) is recovered during this time. Also, increasing the reclamation time would require that products spend additional time in the sterilizer and could affect the plant's operating schedule. However, even if the reclamation time was increased, this system is not designed for low EO concentrations. Therefore, if this type of control system is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete.

Seven of the 203 commercial sterilization facilities represented in the EPA data base reported the use of condensation/reclamation systems; three of these facilities reported an 85 percent EO recovery efficiency, three reported 80 percent, and one reported 50 percent.[2,3] These seven facilities recover EO/CO_2 and EO/CFC-12 sterilant gases. Six of these facilities each use over 23 Mg/yr (50,000 lb/yr) of EO. The seventh facility uses just over 6.8 Mg/yr (15,000 lb/yr).[2,3] The chamber sizes range from 5 to 45 m^3 (190 to 1,580 ft^3) at these seven facilities.[2,3]

The condensation/reclamation systems currently available are designed for the high volumetric flow rates of larger, industrial-size chambers. The systems are not technically or economically feasible for use with smaller chambers or at facilities that use small amounts of EO. In addition, the safety hazards (i.e., explosion potential) associated with this control technique preclude its use in hospitals.

4.1.1.4 Gas/Solid Reactor. A fourth control technique that is used by some hospitals to control vent emissions (after acid-water scrubbing) is a dry, solid-phase system that chemically converts EO and then binds the product to the solid packing.[1] The system operates at room temperature. There are no liquid waste streams produced; the vendor handles the disposal of the solid waste that is produced.[35] Although the gas/solid reactor can handle EO concentrations in the percent range (i.e., >100,000 ppmv) for brief periods of time, it is designed for low (ppm range) concentrations such as the exhaust from an acid-water scrubber. The manufacturer of this device markets a two-stage control system, which consists of an acid-water scrubber and the gas/solid reactor. (The company also sells the stages separately.) The majority of the EO is removed by the scrubber, which is specifically designed for the small sterilizers (<2 m^3 [70 ft^3]) used at hospitals. The gas/solid reactor removes the residual EO exiting the scrubber and, because it is designed for low EO concentrations, can also be manifolded to other emission sources (e.g., aeration chambers, sterilizer hood and door, and gas cylinder storage room).

The manufacturer of this system claims greater than 99.9 percent efficiency for the gas/solid reactor.[1] However, this efficiency is based on a test performed with an inlet EO concentration of 140,000 ppmv, which is much higher than the concentration of the scrubber outlet stream. In another test, no EO was detected (with a lower detection limit of 0.1 ppmv) in the gas/solid reactor outlet stream when the inlet stream (i.e., scrubber outlet stream) was 2 ppmv EO.[35] Because of the innate problems associated with measuring low EO concentrations, the actual efficiency of the system under normal operating conditions presently cannot be determined. (See Section 4.1.3 for a more detailed discussion of measuring low EO concentrations.) However, the maximum removal efficiency that the gas/solid reactor can achieve on a continuous basis is assumed to be 99.0 percent.

4.1.2 Sterilization Chamber Vacuum Pump Drain Emissions

Ethylene oxide drain emissions result from the use of vacuum pumps that use once-through water as the working fluid. (Some of the manufacturers of hospital sterilizers are developing sterilizers that are

evacuated by air ejectors instead of vacuum pumps.)[30] Ethylene oxide is infinitely soluble in water, and, therefore, a portion of the EO evacuated from the chamber enters the drain with the vacuum pump water (see Figure 4-5a). The EO that enters the drain with the vacuum pump water is subsequently released uncontrolled from the air break in the drain line, sewer lines, or the waste treatment plant.[6-8]

The EO drain emissions can be controlled by replacing the existing once-through vacuum pump with a closed-loop (recirculating) vacuum pump. The recirculating fluid (sealant) can be water, oil or ethylene glycol.[36] In this closed-loop system, the water or liquid from the liquid-gas separator is cooled in a heat exchanger and recirculated through the vacuum pump (see Figure 4-5b). Because ethylene oxide is not soluble in oil or ethylene glycol and will off-gas from water as it is recirculated, nearly all of the EO will be emitted through the liquid-gas separator (chamber) vent. (Techniques for control of chamber vent emissions are discussed above.) In addition, mechanical seals are used to eliminate leakage (and, thus, any EO emissions) from the pump.[37]

Because the sterilization cycle operates under humid conditions, some water will be condensed in the liquid-gas separator and, thus, mix with the liquid sealant in the pump. An overflow collection tank is used to maintain a constant amount of sealant recirculating in the pump.[37] If ethylene glycol is used as the sealant, the contaminated glycol will eventually need to be disposed and replaced with a fresh charge.[36] However, if oil is used as the sealant, the condensed water can be drained off the bottom with minimal oil loss because of the immiscibility of oil and water.[36]

4.1.3 Aeration Room Vent Emissions

4.1.3.1 Aeration Rooms. Most commercial sterilization facilities aerate the sterile products in large, warehouse-type aeration rooms that are typically 280 to 2,800 m^3 (10,000 to 100,000 ft^3) in volume but may be larger than 14,000 m^3 (500,000 ft^3).[31] The ventilation rates are, generally, in the range of 112 to 560 m^3/min (4,000 to 20,000 ft^3/min) but may be as high as 1,680 m^3/min (60,000 ft^3/min).[31] These large flow rates are necessary to maintain a low EO concentration in the room to comply with the Occupational Safety and Health Association (OSHA) standards (see

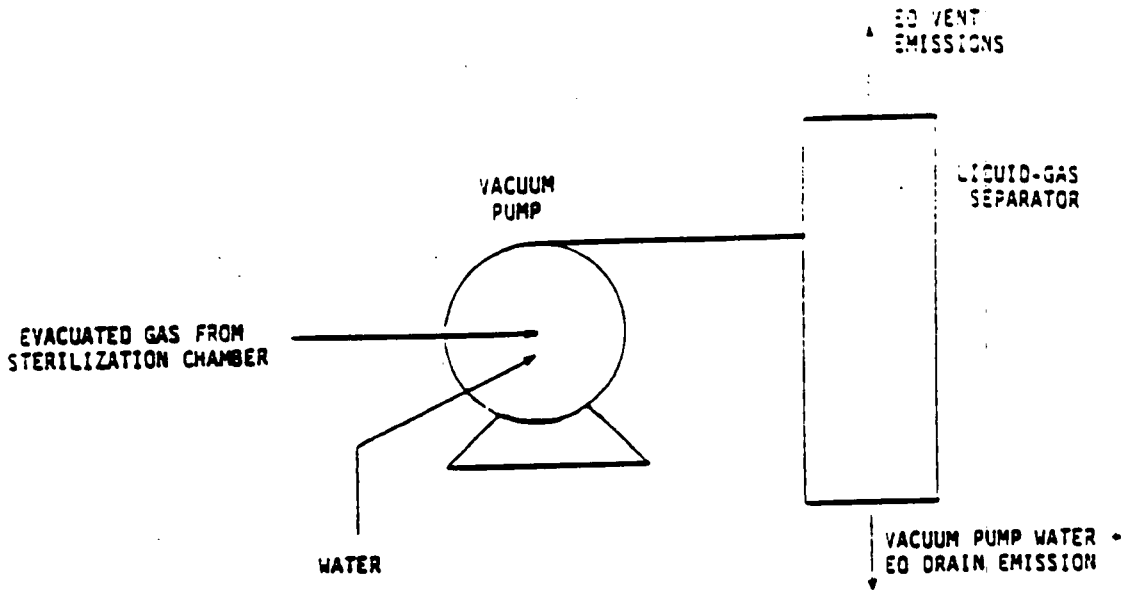

Figure 4-5a. Once-through liquid-ring vacuum pump.

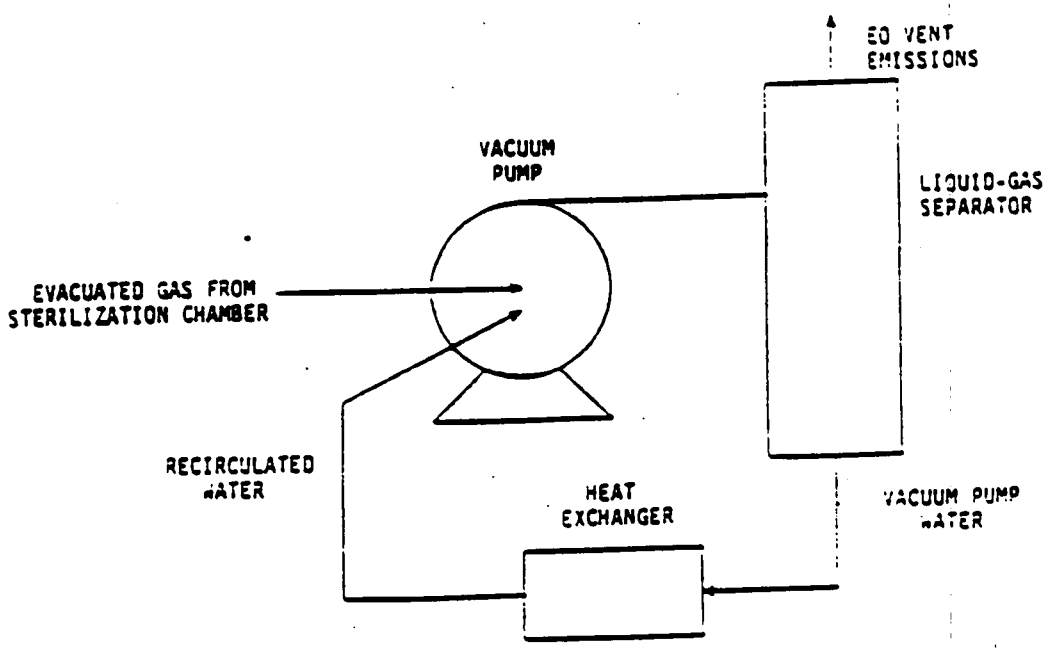

Figure 4-5b. Recirculating liquid-ring vacuum pump.

Section 3.5). Data from a cross-sectional survey (44 facilities) of the 203 commercial sterilization facilities represented in EPA's data base indicated an average 8-hour time-weighted average (TWA) EO concentration of 2.5 to 3 ppmv in aeration rooms.[31]

Two issues of concern regarding the control of aeration room emissions are: (1) most EO emission control devices are impracticable for the low-concentration, high-flow-rate exhaust streams from aeration rooms; and (2) the lower detection limit of most analytical methods makes it impossible to determine the true control efficiency of the low EO concentrations (<1 ppmv) found in most aeration rooms. Hydrolysis, thermal oxidation, and condensation/reclamation presently have not been demonstrated to be practicable control techniques for low-concentration, high-flow-rate gas streams. However, catalytic oxidation and the gas/solid reactor system have the potential to control aeration room emissions. Catalytic oxidation units are commercially available to handle flow rates from less than 1 m^3/min (40 ft^3/min) to approximately 340 m^3/min (12,000 ft^3/min).[9,38] The catalytic oxidizers are modular, and systems can be designed to handle higher flow rates; however, the increased size of the system for high flow rates can restrict its practical use. Gas/solid reactors are being used for flow rates up to 42 m^3/min (1,500 ft^3/min), and systems can be designed to handle any flow rate; however, as with catalytic oxidation, the system size can become impractical.[39]

The manufacturers of the catalytic oxidizers and of the gas/solid reactor claim EO destruction efficiencies greater than 99.9 percent and offer the results of third-party tests to support these claims.[35,40,41] However, test data on the efficiencies of the control units operating under conditions (i.e., low concentrations and high flow rates) that are typical of aeration room exhaust streams are not available.

Generally, the control units are tested by sending the control device a stream of EO with a much higher concentration (e.g., 100 to 140,000 ppmv) than that associated with normal operating conditions.[35,40,41] The results of these tests are the efficiencies reported by the manufacturers. However, these test results are inconclusive because (1) it has not been demonstrated whether the control

units perform at the same efficiencies under normal operating conditions (i.e., very low inlet concentrations) as during test conditions (i.e., controlled flow, high concentration); (2) EPA has not verified the available test data; (3) there has not been an EPA-sponsored test of these control devices with aeration room emissions; and (4) a test reference method has not been developed (but is being developed) to evaluate the efficiencies of these control devices with aeration room emissions.

The lower detection limits of most analytical procedures that are used to measure EO concentrations are approximately 0.5 ppmv to 1 ppmv, which is equal to or greater than the EO concentrations in many aeration rooms. Although one testing laboratory reportedly used a method with a detection limit less than 0.1 ppmv, the test data have not been verified by EPA, and it is unknown whether this method can be applied to high flow rates. (The flow rate tested was 14 m^3/min [500 ft^3/min].)[41] Also, because of the reactivity of EO, the validity of detection limits below 1 ppmv, and particularly below 0.5 ppmv, is questionable.[42] Because the detection limits of the analytical methods (in ppmv) are so close to the room concentrations, testing under normal operating conditions may yield an efficiency that only can be calculated to be equal to 50 percent or less.

Three possible techniques for reducing EO emissions from aeration rooms are (1) recirculate the air from the aeration room control device to the aeration room, (2) replace the warehouse-type aeration rooms with smaller, heated aeration cells, or (3) modify the evacuation and air wash phase of the sterilization cycle. The first two techniques increase the EO concentration in the aeration room and lower the flow rate, which makes both control of the emissions and testing of the control efficiency more practical. The third alternative lowers the EO emissions from the aeration room by decreasing the residual EO in the product prior to aeration. These techniques are discussed in more detail below.

The first alternative refers to routing the aeration room air through an emission control device and back to the aeration room. A small amount of makeup air is added to the control device exit stream to regulate the room temperature. This practice increases the room temperature and, therefore, increases the diffusion rate of EO from the product, producing

a higher EO concentration in the room. (Worker exposure and compliance with the OSHA standards will need to be considered if frequent worker access to the room is required.) Catalytic oxidation and the gas/solid reactor are more applicable to the increased EO concentrations and decreased flow rates associated with this process than to typical aeration room emissions. (In addition, increasing the room temperature reduces the energy costs of preheating the inlet stream to the catalytic oxidizer.) Hydrolysis, thermal oxidation, and condensation/reclamation are not applicable because the EO concentrations are too low (<20 ppmv) for these techniques to be practicable. Because the room air is recirculated and not vented to the atmosphere, this technique eliminates practically all aeration room emissions; only a small amount of the emissions from the control device are vented to allow fresh makeup air to enter the room. This practice of recirculating the aeration room air is used by two of the 203 commercial sterilization facilities represented in the EPA data base.[3] The aeration rooms at these two commercial facilities are each approximately 140 m^3 (5,000 ft^3) in volume.[31] These 2 facilities manufacture synthetic rubber products, which retain a large amount of residual EO and, therefore, require a longer aeration period than the majority of products that are sterilized with EO. The facilities installed the recirculating system to decrease the aeration time and the residual EO concentrations in the products.[43] A catalytic oxidation system is used to control the EO emissions and to provide hot air to heat the room.[43]

Another alternative is to replace the large, warehouse-type aeration rooms with smaller (70 m^3 [2,500 ft^3] or less), heated aeration cells and control the emissions from the cell. In this process, instead of storing the sterile products in a warehouse and aerating at normal room temperatures, the products are aerated in heated (>43°C [110°F]) insulated cellular units. The emissions from these cells can be controlled by catalytic oxidation or the gas/solid reactor system. Emissions from the control unit can be recirculated to the aeration cell or vented to the atmosphere. The cells can be filled approximately 40 to 75 percent full and still allow sufficient air space for off-gassing.[29,44] The cell is heated either with supplemental heat or hot air from the control device if

catalytic oxidation is used. Several commercial sterilization facilities, particularly contractors, are aerating at least part of the sterile products in heated, cellular units.[31,38] Structures used for aeration include insulated shipping containers, modified walk-in coolers (which are heated instead of cooled), and manufactured units designed specifically for the heated aeration process.[45-47] Most of these facilities have installed these units to reduce the aeration time or the residual EO concentration in the products. The heated cells are similar to the first technique described above (i.e., the practice of recirculating the aeration room air) in that the EO concentration in the cell will increase due to elevated temperature.

Another strategy for reducing aeration room emissions is modifying the evacuation/air wash phase of the sterilization cycle. Residual EO in the product can be reduced by performing additional sterilization chamber purges. However, this procedure does require additional time in the sterilizer and could affect plant operating schedules. The potential reduction in residual EO with evacuation-phase modifications is product dependent. Results from tests performed at one facility that fumigates spices showed an average reduction in residual EO of 26 percent for four different spices following evacuation-phase modifications.[19] Some facilities aerate in the sterilizer, with or without cycle modifications.[31] Aeration emissions from the sterilizer can be sent to the sterilizer control device. However, the removal efficiencies of the hydrolysis techniques have not been determined for the low inlet concentrations associated with aeration emissions. Also, condensation/reclamation would not be practicable for controlling these low concentrations.

4.1.3.2 Aeration Chambers. Many hospitals and some commercial sterilization facilities use aeration chambers instead of aeration rooms. These chambers are similar in appearance and size (<1 m^3 [40 ft^3]) to the sterilization chambers used at hospitals. However, the flow rate is much lower from the chambers than from aeration rooms. Therefore, catalytic oxidation and the gas/solid reactor are applicable to the control of EO emissions from aeration chambers. Several hospitals and small commercial sterilization facilities use catalytic oxidation or the

gas/solid reactor system to control aeration chamber emissions, and at least one commercial sterilization facility uses an acid-water scrubber to control these emissions.[9,10,31] However, as stated in Section 4.1.3.1, the control efficiencies of these techniques have not been determined for the low concentrations from aeration processes.

4.2 OTHER STERILIZATION PROCESSES

There are no demonstrated EO emission control devices for single-item sterilization processes or for portable fumigation units. The problems associated with controlling EO emissions from these sources are discussed below.

4.2.1 Single-Item Sterilization

Single-item sterilization systems do not use a chamber evacuated with a vacuum pump. (See Section 3.2.2 for a description of single-item sterilization.) Instead, the EO is allowed to diffuse from products while they are inside an aeration room or cabinet. The EO from facilities using single-item sterilization systems is, therefore, emitted from one major source, the aeration room/cabinet vent. Because there is no evacuation phase, the EO concentration in the gas stream from single-item sterilization systems is higher than the concentration of EO in aeration rooms. However, the concentration is sufficiently low such that catalytic oxidation or the gas/solid reactor system may be viable control options.

4.2.2 Fumigation with Portable Units

Because of problems with transporting an emission control device, there are no practical controls of EO emissions from the portable units operated by State departments of agriculture to fumigate beehives. However, one State Department of Agriculture is working on the development of an acid-water scrubber for portable fumigation units.[3]

4.3 ALTERNATIVES TO EO STERILIZATION

In some cases, radiation sterilization can replace EO sterilization. Radiation sterilization is used for about half of the products sterilized in the U.S.[48] However, not all products can be sterilized with radiation; plastics can become broken, discolored, or malodorous, and Teflon® and acetyl delrin are damaged by radiation.[48,49] According to industry representatives, most of the commonly used plastics have been or are in the process of being reformulated to withstand radiation.[50,51] Therefore, the potential use of this alternative will probably increase.

There are several chemical alternatives to EO sterilization (e.g., chlorine dioxide, gas plasma, hydrogen peroxide, and ozone). However, these chemicals do not necessarily offer environmental improvements over EO. Other alternatives include X-ray (a new, developing technology), deep freezing (museum and spice industry), and increased use of disposable medical items in hospitals. However, none of these alternatives can replace the use of EO in all applications.

4.4 RETROFIT CONSIDERATIONS

All of the control devices discussed above can be retrofitted to existing EO bulk sterilization chambers. However, the use of flares in urban areas is prohibited because of safety hazards. There are no retrofit problems associated with the replacement of once-through vacuum pumps with closed-loop recirculating vacuum pumps for control of drain emissions.

4.5 IMPACTS OF A CFC REGULATION ON EO EMISSION CONTROLS

Federal regulations for stratospheric ozone-depleting chlorofluorocarbons (CFC's) have been developed under EPA's Stratospheric Ozone Protection Program (SOPP). The use of CFC's in sterilant gases is one of the source categories subject to these regulations. The most popular sterilant gas mixture, 12/88, contains 88 percent by weight dichlorodifluoromethane (CFC-12), which is an ozone-depleting CFC. Nearly all hospitals and 75 percent of the 203 commercial sterilization facilities represented in the EPA data base use 12/88 at least part of the time.[2,3] The requirements of a CFC regulation would not affect the ability of a sterilization facility to control EO emissions. The explosion-proof condensation/reclamation system discussed above recovers CFC-12 emissions in addition to EO emissions. However, if this control device is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete. Also, a nonexplosion-proof condensation/reclamation system that recovers only CFC-12 could follow the acid-water scrubbing of EO to ethylene glycol.[52] Some facilities may switch to sterilant gases that do not contain CFC-12 (such as 10/90 and pure EO), in which case, the EO control techniques discussed above still would be applicable.

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5. EMISSION CONTROL COSTS

5.1 INTRODUCTION

This chapter presents a summary of the methodology to develop emission control cost estimates. Costs presented in this chapter are in December 1984 dollars. A method for estimating EO emission control costs at commercial sterilization facilities is presented in Section 5.2. Limited cost information has been obtained about emission controls for hospital sterilizers, single-item sterilization systems, and aeration rooms; these costs are discussed in Sections 5.3 through 5.5, respectively.

5.2 CONTROL COSTS FOR COMMERCIAL STERILIZATION FACILITIES

This section describes a method for estimating emission control costs for sterilizer vent(s) and the vacuum pump drain at commercial sterilization facilities. Acid hydrolysis (i.e., acid-water scrubbing) was chosen as the basis for the costing procedure because that control technique currently is practiced at several commercial sterilization facilities and has been demonstrated at both small and large commercial facilities. A detailed review of the available test data indicated that 99.0 percent is the maximum EO removal efficiency that acid hydrolysis techniques can achieve on a continuous basis.[1] Therefore, 99.0 percent was used to calculate the emission reductions.

The costing procedure presented in this section has been used to develop emissions control costs for the 203 commercial sterilization facilities represented in the EPA data base.[2] (See Section 3.1 of this report for a description of how the data base was developed.) The results of this cost analysis for three actual commercial sterilization facilities are presented in Table 5-1. Detailed sample calculations for another commercial sterilization facility are given in Appendix B.

5.2.1 Description of Components Costed

The following components were costed: (1) an acid-water scrubber, (2) a water-sealed vacuum pump with closed-loop recirculation for each sterilizer, (3) piping for manifolding all chambers at a facility to one scrubber, (4) operating materials (i.e., chemicals and chlorine filters), (5) scrubber waste disposal, and (6) labor.

Scrubber prices are listed in Table 5-2. The capital costs of the piping system for manifolding and the installed cost of the vacuum pump are presented in Tables 5-3 and 5-4. The costs of operating materials, as well as the shipping charges used for computing disposal costs for the spent scrubber solution, are presented in Table 5-5.[2]

Costs reported in Tables 5-2 through 5-5 are in fourth quarter 1984 dollars. The prices for the scrubbers, vacuum pump, chlorine filters, and chemicals were obtained from the manufacturer and suppliers and were originally in 1986 dollars. These prices were converted to fourth quarter 1984 dollars using the CE Plant Cost Index (for the equipment) and the Current Business Indicators (for the chemicals) in Chemical Engineering.[3,4] The labor costs were calculated from the Economics Assessment Branch (EAB/EPA) control cost manual and from the CE Plant Cost Index.[4,5] The indices used and the conversion factors obtained are reported in Appendix B.

5.2.2 General Assumptions

Chamber volume was used as the basis for scrubber sizing. The relationship of chamber volume to scrubber size is presented in Table 5-2.[2]

If a facility has three or more sterilization chambers, the scrubber costed was chosen based on the sum of the volumes of the two largest chambers at that facility. This methodology simulates the cost of controlling emissions from a facility if two chambers at that facility were to be evacuated simultaneously. If a facility has two chambers, the scrubber was selected based on the volume of the larger chamber. For facilities with two chambers, it was assumed that the sterilization cycles could be staggered so that the chambers would not be evacuated simultaneously.[2]

For the purposes of this cost analysis, it was assumed that the ethylene glycol would be accepted by a recovery facility on a no cost/no credit basis, except for shipping charges. Therefore, the disposal cost for the aqueous ethylene glycol solution produced by the acid-water scrubbers was computed as the cost to ship the solution, either in 55-gallon drums or in a tank truck, depending on quantity, to a recovery facility. Transportation costs were calculated by assuming that commercial sterilization facilities are within 1,000 miles of one of the three known

recovery facilities.[2] However, these disposal costs may not be applicable to all sterilization facilities. If a recovery facility is not available to accept the liquor, it may be necessary to neutralize the scrubbing liquor and then have it hauled to a landfill or incinerator, which may increase the waste disposal costs.

5.2.3 Capital Costs

The fixed capital costs for a particular facility represent the initial investment and installation charges for control equipment. The cost data presented in Table 5-6 were used to calculate capital cost estimates for each of the facilities.[2]

5.2.4 Annualized Costs

Annualized costs for a particular facility represent direct operating costs such as labor costs, cost of materials, and disposal costs, as well as indirect operating costs such as overhead charges, tax/insurance charges, and capital recovery costs. The cost data presented in Table 5-7 were used to estimate plant-specific annualized costs.[2]

5.3 CONTROL COSTS FOR HOSPITAL STERILIZATION CHAMBERS

Detailed cost estimates have not been developed for EO emission controls at hospitals. Only a small percentage of hospitals control EO emissions to the atmosphere. Emission controls used at hospitals include acid-water hydrolysis, catalytic oxidation, and the gas/solid reactor system discussed in Section 4.1.1.4 of this report.[6-9]

Because only a few control devices are in place at hospitals, the cost data available are limited and, therefore, should be used cautiously. Table 5-8 presents a range of the approximate costs of using catalytic oxidation to control EO emissions from hospitals. The capital costs and annual operating costs for catalytic oxidation were obtained from two hospitals.[10] Additional control cost estimates for hospitals have been obtained from vendors and are given in Appendix C.

5.4 CONTROL COSTS FOR OTHER STERILIZATION SYSTEMS

There are no demonstrated EO emission control devices for single-item sterilization processes or for portable fumigation units. Therefore, emission cost estimates have not been developed for these processes. However, the EO concentration and flow rate from single-item sterilization units is low enough that catalytic oxidation or the gas/solid reactor system

may be viable control options. See Appendix C for vendor-supplied cost estimates for these control devices.

5.5 CONTROL COSTS FOR AERATION ROOMS

The potential control of aeration emissions is being evaluated by EPA, and the preliminary cost analysis should be available by June 1989. Catalytic oxidation and the gas/solid reactor system may be applicable to the control of aeration emissions particularly from aeration chambers and the heated, cellular structures to which some facilities are switching. See Appendix C for vendor-supplied cost estimates for catalytic oxidation and the gas/solid reactor system.

TABLE 5-1. CONTROL COSTS FOR ACID HYDROLYSIS[a] [b]

Model plant	Total sterilizer volume, m^3 (ft^3)	Annual EO use, Mg (lb/1,000)	Capital costs, $	Annualized costs, $	Annual emission reduction, Mg (lb/1,000)[c]
Small[d]	2.8 (100)	0.18 (0.39)	76,000	21,200	0.17 (0.37)
Medium[e]	28 (1,000)	3.9 (8.7)	160,000	40,800	3.7 (8.2)
Large[f]	168 (6,000)	109 (240)	291,000	117,000	102 (226)

[a]These cost estimates are not applicable to hospitals because the acid-water scrubbers costed are not designed for the low flowrates from the vacuum pumps on hospital sterilizers.
[b]See Appendix B for the methodology used to calculate these control costs.
[c]Calculated as (0.99)x(0.95)(EO use). Five percent of the EO use is assumed to be retained in the product after sterilization and emitted from the aeration room, which is assumed to be uncontrolled.
[d]The small model plant has one chamber and uses 12/88 (EO/CFC-12). Therefore, a model 100 scrubber (see Table 5-2) was chosen as the basis for the calculations.
[e]The medium model plant has one chamber and uses 12/88 gas. Therefore, a model 400 scrubber was chosen as the basis for the calculations.
[f]The large model plant has seven chambers and uses 100 percent EO. The sum of the volumes of the two largest chambers is 2,000 ft^3. Therefore, a model 500 scrubber (with explosion-proof valves) was chosen as the basis for the calculations.

TABLE 5-2. COST OF DAMAS SCRUBBER MODELS (F.O.B.)[1]
(4th Quarter 1984 Dollars)

Model No.	Chamber size, m^3 (ft^3)[a]	Conversion capacity of scrubber, kg (lb) of EO	Automated scrubber cost, $	Cost of explosion-proof valves for scrubber, $[b]
100	<11.3 (<400)	908 (2,000)	47,250	12,180
200	11.3 to 17.0 (400 to 600)	1,816 (4,000)	68,250	13,195
300	17.0 to 22.7 (600 to 800)	2,724 (6,000)	89,250	14,210
400	22.7 to 45.3 (800 to 1,600)	3,632 (8,000)	99,750	15,225
500	45.3 to 56.6 (1,600 to 2,000)	4,540 (10,000)	141,750	17,255
600	>56.6 (>2,000)	5,448 (12,000)	157,500	18,270

[a]The size of sterilization chamber that can be served by the model number, assuming the smallest appropriate vacuum pump is used.
[b]Explosion-proof valves are necessary if the sterilization chamber that is vented to the scrubber uses a gas mixture greater than 20 percent by weight EO.

TABLE 5-3. INCREMENTAL CAPITAL COSTS OF MANIFOLDING STERILIZATION CHAMBERS

Item	Cost, 1984 $
Opening in explosion-proof wall[a]	
Adjustable sheetmetal sleeve	2[b]
Labor costs at $18.05/hour	93
Overhead costs at $8.35/hour	43
Drill holes for pipe hangers[c]	
Labor costs at $19.40/hour	146
Overhead costs at $15.06/hour	113
Piping[d]	
100 ft, 2 in. diameter, 40 standard carbon steel pipe	240[b]
90° elbows, 3 at $4.19	13[b]
Tee with full-size outlet	14[b]
Swing check valve	350[b]
Bolts and gaskets, two sets at $6.76	14[b]
Pipe hangers, 1 carton of 50 hangers	140[b]
Labor costs at $20.50/hour	576
Overhead costs at $12.71/hour	357
Total installed cost for piping system	
Total direct costs[e]	1,588
Total indirect costs:	
Overhead costs[f]	513
Administration[g]	159
Taxes[h]	39
Total installed cost[i]	2,299
Total installed cost for recirculating vacuum pump	4,935
TOTAL CAPITAL COST	7,234

[a]Requires 5.15 labor-hours.
[b]Equipment cost.
[c]Requires 7.5 labor-hours.
[d]Requires 28 labor-hours.
[e]Sum of all labor and equipment costs.
[f]Sum of all overhead costs.
[g]Ten percent of total direct costs.
[h]Five percent of total equipment costs.
[i](Total direct costs)+(total indirect costs).

TABLE 5-4. CAPITAL COST OF CHECK VALVE FOR CHAMBER[1]

Cost item	Cost, 1984 $
Swing check valve	350[a]
Installation costs[b]	
Labor costs at $20.50/hour	23
Overhead costs at $12.71/hour	14
Total direct costs[c]	373
Administration: 10 percent of total direct costs	37
Taxes: 5 percent of equipment cost	18
Total indirect costs[d]	69
Total installed cost[e]	442
Annualized capital recovery cost[f]	74

[a]Equipment cost.
[b]Requires 1.1 labor hours to install.
[c]Sum of all labor and equipment costs.
[d]Sum of overhead costs, taxes, and administration.
[e](Total direct costs)+(total indirect costs).
[f]Calculated as 0.16275x(total installed cost), for an interest rate of 10 percent and a 10-year recovery period.

TABLE 5-5. MISCELLANEOUS OPERATING COSTS[1]

Item description	Cost, 1984 $
Operating materials	
1. 50 percent H_2SO_4, electrolyte-grade	0.069/lb
2. 50 percent NaOH, industrial grade:	
<2 drums	0.108/lb
3-9 drums	0.0787/lb
>9 drums	0.0738/lb
3. Chlorine filters:	
Filter housing	41.50 each
Filter	15.00 each
Installation	20.00 each
Shipping charges for waste disposal	
Weight of solution for disposal:	
<42,000 lb (drums)	0.096/lb
≥42,000 lb (bulk)	0.059/lb

TABLE 5-6. DATA USED TO CALCULATE CONTROL EQUIPMENT CAPITAL COSTS[1]
(4th Quarter 1984 Dollars)

Item	Cost factor
Automated scrubber	--[a]
Explosion-proof valves for scrubber	--[a b]
Chlorine filter house	($41.50 each)x(No. of tanks)[c]
Scrubber installation	50 percent of scrubber cost
Chlorine filter installation	($20.00)x(No. of tanks)[c]
Taxes	5 percent of total equipment cost
Freight	5 percent of total equipment cost
Vacuum pump(s)	$4,935 per pump
Manifolding of chambers (includes check valve)	--[d]

[a]Function of chamber size (see Table 5-2).
[b]Explosion-proof valves are necessary if the chamber that is vented to the scrubber uses a gas mixture greater than 20 percent (by weight) EO.
[c]Number of scrubber tanks required = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO).
[d]See Tables 5-3 and 5-4.

TABLE 5-7. DATA USED TO CALCULATE CONTROL DEVICE ANNUALIZED COSTS[1]
(4th Quarter 1984 Dollars)

Item	Cost factor
Direct operating costs	
Labor	\$3,177+(\$11.60)x(16 person-hours)x(No. of scrubber regenerations)[a b]
Materials:	
50 percent H_2SO_4	(\$0.069/lb)x(594 lb/drum)x(No. of drums required)[c d]
50 percent NaOH	(Cost/lb)x(700 lb/drum)x(No. of drums required)[c, e, f]
Chlorine filters	(\$15/filter)x(No. of tank regenerations)[c g]
Taxes	5 percent of materials cost
Freight	5 percent of materials cost
Compressed air	0[h]
Disposal of ethylene glycol	--[i]
Indirect operating costs	
Overhead	(0.8)x(labor costs)
Property tax, insurance, and administration	4 percent of total capital costs
Capital recovery costs	(0.16275)x(total capital costs)[j]

(continued)

TABLE 5-7. (continued)

[a]Number of scrubber regenerations = amount of EO to be treated divided by the conversion capacity of the scrubber (See Table 5-2).
[b]The $3,177 is for visual inspection of the system 15 minutes per shift, 3 shifts per day, 365 days per year at $11.60/person-hour. It was assumed that each regeneration of the scrubber solution would require two people at 8 person-hours each, independent of scrubber size.
[c]Number of scrubber tanks = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO). Number of tank regenerations = number of scrubber regenerations multiplied by the number of scrubber tanks.
[d]Each tank regeneration requires one 55-gallon drum of 50 percent H_2SO_4.
[e]Each tank regeneration requires 250 pounds of NaOH for neutralization.
[f]Cost basis for 50 percent NaOH (350 pounds NaOH per drum):
If No. of drums >9, cost/lb = $0.0738
If No. of drums = 3 to 9, cost/lb = $0.0787
If No. of drums <2, cost/lb = $0.108
[g]Each chlorine filter can dechlorinate approximately 200 gallons (one tank) of H_2O; replace filter at each tank regeneration.
[h]The cost of 10 seconds of in-house compressed air per cycle is considered negligible.
[i]Unit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at regeneration, approximately 4,845 lb (see Example Calculation No. 3 in Appendix B [page B-3]).
If the total weight <42,000 lb, disposal cost = (weight)x($0.096/lb).
If the total weight ≥42,000 lb, disposal cost = (weight)x($0.059/lb).
[j]Assumes an interest rate of 10 percent and a 10-year recovery period.

TABLE 5-8. HOSPITAL EMISSION CONTROL COSTS[10]

Control device	Capital costs, $[a]	Annual operating costs, $[b]
Catalytic oxidation	30,000-50,000	6,000-16,000

[a]Total installed capital costs. (Does not include modifying vacuum pump)
[b]Direct operating cost and annualized catalyst and prefilter replacement.

5.6 REFERENCES FOR CHAPTER 5

1. Memorandum. Srebro, S., MRI, to Markwordt, D., EPA/CPB. Examination of Ethylene Oxide Control Efficiencies. Attachment to Effect on the Maximum Individual Risk from an Increase in the Ethylene Oxide Removal Efficiencies. October 5, 1988.

2. Memorandum. Srebro, S., MRI, to Markwordt, D., EPA/CPB. Capital cost, annualized cost, and cost effectiveness of reducing ethylene oxide emissions at commercial sterilization facilities. March 20, 1987. 80 p.

3. Chemical Engineering. Economic Indicators. February 18, 1985. p. 7.

4. Chemical Engineering. Economic Indicators. June 23, 1986. p. 7.

5. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc. Niles, Illinois. Publication No. EPA-450/5-80-002. December 1978. p. 3-11, 12, 16.

6. Responses to July 1988 EPA information request regarding chamber operating parameters, vacuum pumps, current controls, and aeration rooms.

7. Telecon. Nicholson, R., MRI, with Olson, C., Donaldson Company, Inc. May 12, 1988 and June 13, 1988. Discussion about applicability of catalytic oxidation to large aeration rooms and location of facilities using EtO Abators™.

8. Contact report. Srebro, S., MRI, with Meo, D., DM3, Incorporated. December 9, 1988.

9. Telecon. Nicholson, R., MRI, with Kruse, R., Advanced Air Technologies, Inc. June 14, 1988. Discussion about Safe-Cell™ gas/solid reactor.

10. Ethylene Oxide Control Technology Development for Hospital Sterilizers. Meiners, A., MRI. EPA 600/2-88-028. May 1988.

APPENDIX A.

FEDERAL AGENCY CONTACTS, CONTROL DEVICE VENDORS, AND ETHYLENE GLYCOL RECOVERY COMPANIES

TABLE A-1. CONTACTS AT FEDERAL AGENCIES

Agency name and address	Item of concern	Contact name	Phone
Food and Drug Administration Division of Compliance 8757 Georgia Avenue Silver Spring, Md. 20910	Sterility compliance (e.g., switching sterilants)	Virginia Chamberlain	(301) 427-7194
Occupational Safety and Health Administration 200 Constitution Avenue Washington, D.C. 20210	Worker exposure (e.g., aeration rooms)	Melody Sands	(202) 523-9308
U. S. Environmental Protection Agency	Sterilant registration (e.g., switching sterilants)	John Lee	(703) 557-5339
U. S. Environmental Protection Agency Global Change Program 401 M Street, S.W. Washington, D.C. 20460	Chlorofluorocarbon regulations	Karla Perri	(202) 475-7496
U. S. Environmental Protection Agency Office of Air Quality Planning and Standards Research Triangle Park, N.C. 27711	Economics	Tom Walton	(919) 541-5311
	Emission test method	John Margeson (Office of Research and Development	(919) 541-2848
	Health risk assessment	Nancy Pate	(919) 541-5347
	Standards development (EPA Lead Engineer)	David Markwordt	(919) 541-0837

TABLE A-2. CONTROL DEVICE MANUFACTURERS[a]

Company name and address	Control types	Emission source applicability
Advanced Air Technologies, Inc. 710 S. McMillan Street Owosso, Michigan 48867 (517) 723-2171	Scrubber Gas/solid reactor	Scrubber--vent (small and large chambers) Gas/solid reactor--vent (after scrubbing); aeration chamber or room; sterilizer door; hood; single-item sterilization units
Chemrox, Incorporated 217 Long Hill Crossroads Shelton, Connecticut 06484 (203) 926-9081	Scrubber CFC reclamation system (after EO removed)	Vent
Croll-Reynolds Post Office Box 668 Westfield, New Jersey 07091 (201) 232-4200	Scrubber	Vent
Damas Corporation 8 Romanelli Avenue S. Hackensack, New Jersey 07606 (201) 489-0525	Scrubber	Vent
DM3, Incorporated 1530 E. Edinger Avenue Santa Ana, California 92705 (714) 543-1312	Catalytic oxidation	Vent (low flows, small chambers) Aeration chamber or room Single-item sterilization units
Donaldson Company, Inc. Post Office Box 1299 Minneapolis, Minnesota 55440 (612) 887-3155	Catalytic oxidation	Vent (low flows, small chambers) Aeration chamber or room Single-item sterilization units
John Zink 4401 South Peoria Avenue Post Office Box 702220 Tulsa, Oklahoma 74170 (918) 747-1371	Flare	Vent (large chambers; pure EO)
Environmental Tectonics, Inc. County Line Industrial Park Southampton, Pennsylvania 18966 (215) 355-9100	Scrubber	Vent
Vacudyne, Inc. 375 E. Joe Orr Road Chicago Heights, Illinois 60411 (312) 757-5200	EO reclamation system (for use with 12/88)	Vent (large chambers)

[a]This information is provided for the convenience of the reader and does not imply product endorsement by EPA.

TABLE A-3. ETHYLENE GLYCOL RECOVERY COMPANIES[a]

Mr. Jerry Duvow
Chemstreams
3501 River Road
Matthews, North Carolina 28106
(704) 821-6727

Mr. Keven Dalton
High Valley Chemicals
1151 S. Redwood Road
Suite 105
Salt Lake City, Utah 74104
(801) 973-7966

Mr. John Hoffman
Med-Chem Reclamation, Inc. (formerly B&D Industries)
7900 N. Kolmar
Skokie, Illinois 60076
(312) 673-1441

[a]This information is provided for the convenience of the reader and does not imply product endorsement by EPA.

APPENDIX B.

COST INDICES AND

SAMPLE COST CALCULATIONS

COST INDICES AND CONVERSION FACTORS

The prices for the scrubbers, vacuum pump, chlorine filters, and chemicals were obtained from the manufacturers and suppliers and were originally in 1986 dollars. These prices were converted to 4th quarter 1984 dollars using the following indices from Chemical Engineering:

	February 1986[1]	October 1984[2]	Conversion factor
CE Plant Cost Index			
Scrubber	319.2	335.1	1.05
Vacuum pump	418.6	413.1	0.987
Explosion-proof valves	377.1	382.9	1.015
Chlorine filters	344.1	334.7	0.98
Current Business Indicators			
Industrial chemicals	340.0	334.7	0.98

The labor costs were calculated using the Economics Assessment Branch (OAQPS/EAB) Control Cost Manual and the annual CE Plant Cost Indices in Chemical Engineering:

CE Plant Cost Index[1]	
1978	218.8
1984	322.7
Conversion factor	1.47
EAB Conrol Cost Manual[3]	$7.87/person-hour
Labor for calculations	$11.60/person-hour

EXAMPLE CALCULATIONS FOR CONTROL COSTS[4]

	Sterilization chambers at the facility				
	No. 1	No. 2	No. 3	No. 4	No. 5
Size, ft^3	667	667	1,200	1,334	1,334
Gas type	100	100	12/88	100	100
EO USE, lb	28,000	28,000	1,200	46,000	46,000
EO-EMIT, lb	26,600	26,600	1,140	43,700	43,700
MEO-EMIT, Mg	12.07	12.07	0.52	19.82	19.82
EO-FAC, lb	141,740				
MEO-FAC, Mg	64.30				
EO-TOT, lb	149,200				
MEO-TOT, Mg	67.7				
CON-EM, Mg	0.64				
REDUCE, Mg	63.66				

1. The size, gas type, and EO use are those for an actual commercial sterilization facility represented in the EPA data base. (See Section 3.1 of this report for a description of how this data base was developed.) The other values were calculated using the following assumptions:

a. EO-EMIT (lb) = EO (lb) emitted annually from an individual sterilization chamber to the vacuum pump drain and to the atmosphere. Sterilizer vent emissions and vacuum pump drain emissions were assumed to be 50 percent and 45 percent of EO use (lb), respectively. Residual EO in the sterilized product prior to aeration was assumed to be 5 percent of EO-USE (lb). This 5 percent of the EO use is not included as part of EO-EMIT (lb).

b. MEO-EMIT (Mg EO) = EO-EMIT (lb)/2,204.6

c. EO-FAC (lb) and MEO-FAC (Mg) are the amount of EO released annually by the facility to the vacuum pump drain and to the atmosphere, i.e., the sum of EO-EMIT and the sum of MEO-EMIT, respectively.

d. EO-TOT (lb) is the total amount of EO (lb) used annually by the facility, i.e., the sum of EO use. MEO-TOT (Mg) = EO-TOT (lb)/2,204.6.

e. CON-EM (Mg) is the amount of EO that would be released annually after control, i.e., MEO-TOT*(1-0.99)*0.95. Note that the 5 percent residual EO in the sterilized product, which is later released from the aeration room vent, is excluded from this calculated emission estimate.

f. REDUCE (Mg) is the incremental amount of EO that would be reduced if controls are implemented, i.e., (MEO-FAC)-(CON-EM).

2. For all calculations, a conversion efficiency of 99.0 percent was assumed for the scrubber.

3. Each tank of the scrubber initially holds 198 gal H_2O and 19.8 gal H_2SO_4. The manufacturer recommends that the tank be regenerated (i.e., drained, rinsed, and refilled) after 2,000 lb EO have been treated.

a. 19.8 gal H_2SO_4 = 1.42 kg-mole H_2SO_4 (ρ = 1.834; MW = 98.08) $2NaOH+H_2SO_4 \rightarrow Na_2SO_4+2H_2O$; 1.42 kg-mole H_2SO_4 requires 2.84 kg mole NaOH to neutralize. Neutralization will produce 2.84 kg-moles H_2O and 1.42 kg mole Na_2SO_4. Use 50 percent (w/w) NaOH to neutralize; each 55-gal drum of 50 percent NaOH weighs 700 lb, i.e., 350 lb NaOH (MW = 40); need 2.84 kg-moles or 250 lb NaOH to neutralize.

b. C_2H_4O (EO)$+H_2O \rightarrow C_2H_4(OH)_2$ (ethylene glycol); 2,000 lb EO = 20.51 kg-moles EO (MW = 44.1).

c. At 99 percent conversion, yield is 20.365 kg-moles or 301 gal ethylene glycol (EG) (MW = 62.07; ρ = 1.1088).

d. At 99 percent conversion, 20.365 kg-moles H_2O have reacted. 41.64 kg moles H_2O originally available (MW = 18; ρ = 1); 21.275 kg-moles or 100 gal H_2O remain unreacted.

e. Weight of neutralized solution per tank: 1.42-kg mole Na_2SO_4 = 202 kg Na_2SO_4 (MW = 142.04); 2.84 kg-moles H_2O (from neutralization) = 51 kg H_2O; 250 lb (113 kg) H_2O = from 50 percent NaOH solution; 100 gal unreacted H_2O = 378 kg H_2O; 301 gal EG = 1,264 kg EG; total wt = 2,008 kg = 4,427 lb.

f. Solution is 63 percent (w/w) EG. Add about 50 gal rinse water for each tank = 189 kg; total wt (+rinse H_2O) = 4,844 lb; total gal (+rinse H_2O) = 495 gal = nine 55-gal drums; wt per 55-gal drum = 538 lb.

4. Find scrubber model and cost from Table 5-2, based on the sum of the volumes of the two largest chambers at the facility:

Chambers 4 and 5	2,668 ft^3	Model 600	$157,500

5. Because at least one chamber uses 100 percent EO, explosion-proof valves are necessary.

6. Find number of regenerations of scrubber required per year:

a. Number of scrubber tanks = scrubber model/100 = 6 (scrubber consists of modular tanks).

b. Conversion capacity of scrubber = (no. of tanks)x2,000 lb = 12,000 lb

c. Number of scrubber regenerations = EO-FAC (lb)/12,000, i.e., the amount of EO (lb) to be treated per year divided by the conversion capacity of the scrubber.

141,700/12,000 = 11.81 scrubber regenerations/yr

d. Number of tank regenerations = (No. of scrubber regenerations)x(No. of tanks per scrubber) = (11.81)x(6) = 70.87.

7. Cost of chlorine filter housing = (41.50)x(no. of tanks) = $(41.50)x(6) = $249.

8. Installation costs:

a. Scrubber installation = (0.5)x(cost of scrubber) = $78,750

b. Chlorine filter housing installation = (20)x(no. of tanks) = $120

9. The incremental capital costs of manifolding are presented in Table 5-3 of this report.

10. Vacuum pumps. A closed-loop recirculating water vacuum pump is required on each of the five chambers. The cost of modifying the first vacuum pump is included in the cost of the scrubber; the cost of modifying the other four vacuum pumps is $4,935 each.

11. Calculate direct operating costs:

a. Labor = 3,177+(11.60)x(16)x(no. of regenerations). The $3,177 is for general inspection of the system 15 minutes/shift, 3 shifts/day, 365 days/yr at $11.60/person-hour. For the purposes of these cost analyses, it was assumed that each regeneration of the scrubber would require 2 people at 8 person-hours each, independent of scrubber size. System inspection was also assumed to be independent of scrubber size.

b. Sulfuric acid (50 percent H_2SO_4-electrolyte grade). Assumed: 1 55-gal drum of 50 percent H_2SO_4, i.e., 19.4 gal H_2SO_4, per scrubber tank.

No. of drums required = No. of tank regenerations = (No. of scrubber regenerations)x(No. of tanks per scrubber) = 70.87

Cost of acid = (no. of drums)x(594 lb/drum)x($0.069/lb)

c. Caustic (50 percent NaOH-industrial grade). First, the unit cost of NaOH was calculated.

NaOH required per year = [No. of tank regenerations]x[NaOH (lb) required per tank] = 70.87x250 = 17,718 lb/yr

Total drums/yr required by facility = total NaOH (lb)/350 lb per drum; total drums = 50.6

If total drums >9, cost/lb = 0.0738

If total drums = 3 to 9, cost/lb = 0.0787

If total drums = <2, cost/lb = 0.108

Cost of caustic = (No. of drums)x(cost/lb)x(700 lb/drum)

d. Cost of chlorine filters. Each filter can dechlorinate ~200 gal H_2O (or 1 scrubber tank); replace at each scrubber regeneration.

Cost = (No. of scrubber regenerations)x(No. of tanks)x($15/filter)

e. Disposal. Unit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at the time of regeneration, including rinse water (see 3.f).

Total wt = 70.87x4,844 lb/tank = 343,943 lb/yr

If total wt <42,000 lb, disposal cost = wt (lb)x($0.096/lb)

If total wt ≥42,000 lb, disposal cost = wt (lb)x($0.059/lb)

f. Compressed air. The cost of 10 seconds of in-house air per cycle was considered negligible and was not computed for these cost analyses.

12. The capital and annualized costs are reported in Table B-1.

TABLE B-1. CAPITAL AND ANNUALIZED COSTS OF INSTALLING SCRUBBER[1]
(4th Quarter 1984 Dollars)

Item	Cost
I. CAPITAL COSTS[a]	
Installed equipment costs, 1984, $	
Automated scrubber[b]	158,000
Explosion-proof valves for scrubber[c]	18,300
Chlorine filter house[d]	249
Installation of scrubber[e]	79,000
Installation of chlorine filters	120
Taxes: 5 percent of equipment cost	8,850
Freight: 5 percent of equipment cost	8,850
Vacuum pump[f]	19,700
Manifolding of chambers (includes check valve)[g]	9,560
Total capital costs, 1984, $	303,000
II. ANNUALIZED COSTS[a]	
Direct operating costs, 1984, $	
Labor[h]	5,370
Materials	
50 percent H_2SO_4[i]	2,900
50 percent NaOH[j]	2,620
Chlorine filters[k]	1,060
Taxes: 5 percent of materials cost	329
Freight: 5 percent of materials cost	329
Compressed air[l]	0
Disposal of ethylene glycol[m]	20,300
Indirect operating costs, 1984, $	
Overhead: 0.80 x labor	4,300
Property tax, insurance, and administration[n]	12,100
Capital recovery costs[o]	49,300
TOTAL ANNUALIZED COSTS, 1984, $	98,600
III. COST EFFECTIVENESS	
Reduce, Mg EO yr	63.66
Cost effectiveness, 1984, $/Mg EO	1,500

(continued)

TABLE B-1. (continued)

[a]Costs rounded to three significant figures.
[b]Based on total volume of two largest chambers.
[c]One set per scrubber at $18,300 each.
[d]One per tank; six tanks; $41.50 each.
[e]Fifty percent of scrubber cost.
[f]The cost of the first vacuum pump is included in the installation cost of the scrubber; therefore, cost is for remaining four pumps at $4,935 each.
[g]See Table 5-4 of this report. Manifold four chambers at $2,300 each plus $355 for a check valve for the first chamber.
[h]Labor was calculated for 0.25 person-hours/shift, 3 shifts/day, 365 days/year for system inspection and 16 person-hours for each regeneration of the scrubber at $11.60/person-hour. No. of scrubber regenerations = (annual EO use at facility)÷(2,000)x(No. of tanks in scrubber).
[i]The cost of acid is calculated, (annual EO use at facility)÷(2,000)x(594)x($0.069).
[j]The cost of caustic is calculated, No. drum = (EO use/yr at facility)÷(2,000)x(250)÷(350). No. drum = 50.62; therefore, unit cost = $0.0738. Total cost = (No.drums)x(700)x(0.0738).
[k]Chlorine filter cost is (annual EO use at facility)x(15)÷(2,000).
[l]The cost of 10 seconds of house-supplied compressed air per cycle was considered negligible.
[m]Disposal cost is (annual EO use at facility)÷(2,000)x(4,845)x(0.059).
[n]Calculated as 4 percent of total capital costs.
[o]Calculated as (0.16275)x(total capital costs) for an interest rate of 10 percent and a 10-year recovery period.

REFERENCES FOR APPENDIX B

1. Chemical Engineering. Economic Indicators. June 23, 1986. p. 7.

2. Chemical Engineering. Economic Indicators. February 18, 1985. p. 7.

3. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc. Niles, Illinois. Publication No. EPA-450/5-80-002. December 1978. p. 3-11, 12, 16.

4. Memorandum from Srebro, S., MRI, to Markwordt, D., EPA/CPB. March 20, 1987. Capital cost, annualized cost, and cost effectiveness of reducing ethylene oxide emissions at commercial sterilization facilities.

APPENDIX C.

CONTROL DEVICE COSTS

(CATALYTIC OXIDATION AND GAS/SOLID REACTOR SYSTEM)

TABLE C-1. CATALYTIC OXIDATION[1]

Flow rate, m^3/min^a (ft^3/min)	Cost, $[b c]
1.4 (50)	15,000
3.5 (125)	23,000
14 (500)	37,000
28 (1,000)	60,000
84 (3,000)	97,000
168 (6,000)	140,000
252 (9,000)	192,000
336 (12,000)	240,000

[a]The catalytic oxidation units are modular. The sizes listed are available currently. Larger sizes can be designed.
[b]These costs are for catalytic oxidation systems capable of handling sterilizer and aeration emissions simultaneously. Costs were not provided for a system to handle only aeration emissions.
[c]Cost includes heat exchanger (70 percent heat recovery), preheater, and prewiring. Installation and ducting costs are facility-specific and were not provided.

TABLE C-2. ACID-WATER SCRUBBER AND GAS/SOLID REACTOR SYSTEM[2]

Sterilizer volume	Cost, $[a] [b]
$\leq$0.6 m^3 (20 ft^3)	30,000 to 35,000
0.6 to 1.2 m^3 (20 to 40 ft^3)	40,000 to 45,000
Two 0.8 m^3 (30 ft^3) sterilizers	45,000 to 50,000
One 2 m^3 (72 ft^3) sterilizer	50,000 to 55,000

[a]These are "budget" costs for a complete two-stage system (i.e., acid-water scrubber and the gas/solid reactor). Costs were not provided for the gas/solid reactor separately.
[b]Includes installation costs, wiring, and ductwork.

REFERENCES FOR APPENDIX C

1. Telecon. Nicholson, R., MRI, with Olson, C., Donaldson Company, Inc. May 12, 1988, and June 13, 1988. Discussion regarding the EtO Abator™ catalytic oxidation system.

2. Letter from Kruse, R., Advanced Air Technologies, Inc., to Nicholson, R., MRI. June 13, 1988. Transmitting information about the Safe-Cell™ two-stage system.

TECHNICAL REPORT DATA

Please read Instructions on the reverse before completing)

1. REPORT NO. EPA-450/3-89-007	2.	3. RECIPIENT'S ACCESSION NO.
4. TITLE AND SUBTITLE Alternative Control Technology Document Ethylene Oxide Sterilization/Fumigation Operations		5. REPORT DATE March 1989
		6. PERFORMING ORGANIZATION CODE
7. AUTHOR(S)		8. PERFORMING ORGANIZATION REPORT NO.
9. PERFORMING ORGANIZATION NAME AND ADDRESS Midwest Research Institute 401 Harrison Oaks Boulevard Cary, North Carolina 27513		10. PROGRAM ELEMENT NO.
		11. CONTRACT/GRANT NO. 68-02-4379
12. SPONSORING AGENCY NAME AND ADDRESS U. S. Environmental Protection Agency Emission Standards Division Office of Air Quality Planning and Standards Research Triangle Park, North Carolina 27711		13. TYPE OF REPORT AND PERIOD COVERED
		14. SPONSORING AGENCY CODE

15. SUPPLEMENTARY NOTES

ESD Work Assignment Managers: David Markwordt (MD-13) (919) 541-0837

16. ABSTRACT

This document contains the data and methodology which EPA believes most accurately describes alternative control technologies for ethylene oxide emissions from sterilization facilities.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Ethylene Oxide Ethylene Oxide Sterilization Sterilization Chlorofluorocarbons Volatile Organic Compound (VOC) Emissions		

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Office of Air Quality Planning and Standards Research Triangle Park NC 27711

EPA-453/R-94-084b
November 1994

Air

EPA

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations

Background Information for Final Standards: Summary of Public Comments and Responses

NESHAP

NATIONAL EMISSIONS STANDARDS FOR COMMERCIAL STERILIZATION AND FUMIGATION FACILITIES --

BACKGROUND INFORMATION FOR FINAL STANDARDS

NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR COMMERCIAL STERILIZATION AND FUMIGATION FACILITIES-- BACKGROUND INFORMATION FOR FINAL STANDARDS

Summary of Public Comments and Responses

Emissions Standards Division

U. S. Environmental Protection Agency
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, NC 27711

November 1994

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Publication No. EPA-453/R-94-084b

ENVIRONMENTAL PROTECTION AGENCY

Background Information for Final Standards
Commercial Sterilization/Fumigation Operations

Prepared by:

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U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

11/18/94
(Date)

1. The final national emissions standard limits emissions of ethylene oxide from existing and new commercial sterilization/fumigation operations. The final standards implement Section 112 of the Clean air Act as amended in 1990 and are based on the Administrator's determination of July 16, 1992 (57 FR 31576) that commercial sterilization sources generate a large amount of ethylene oxide, a hazardous air pollutant listed in Section 112(b) of the Act.

2. Copies of this document have been sent to the following Federal Departments: Labor, Health and Human Services, Defense, Transportation, Agriculture, Commerce, Interior, and Energy; the National Science Foundation; the Council on Environmental Quality; members of the State and Territorial Air Pollution Program Administrators; the Association of Local Air Pollution Control Officials; EPA Regional Administrators; Office of Management and Budget; and other interested parties.

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TABLE 2-1. COMMENTS RECEIVED ON THE PROPOSED EO STERILIZATION NESHAP 2-2

1.0 SUMMARY

On March 7, 1994, the Environmental Protection Agency (EPA) proposed national emissions standards for hazardous air pollutants (NESHAP) for commercial sterilization and fumigation operations (59 FR 10591) under authority of § 112 of the amended Clean Air Act (Act). Public comments were requested on the proposal in the Federal Register. There were 19 commenters composed of States, environmental groups, control equipment vendors, trade groups, and commercial sterilizer owners/operators.

The comments that were submitted along with responses to these comments are summarized in this document. The summary of comments and responses serves as the basis for the revisions made to the standards between proposal and promulgation.

1.1 SUMMARY OF IMPACTS OF PROMULGATED ACTION

These standards will reduce nationwide emissions of hazardous air pollutants (HAP) from commercial ethylene oxide sterilization and fumigation operations by 1,030 megagrams (Mg) (1,140 tons), or by 96 percent, in 1997 compared to the emissions that would result in the absence of the standards.[1] The standards for sterilization chamber vent and aeration room vent emissions are unchanged from those in the proposed preamble [950 Mg (1,050 tons) and 48 Mg (53 tons), respectively] [as published in the Federal Register on March 7, 1994, (59 FR 10595)]. The standards for chamber exhaust vent emissions account for a nationwide reduction of 34 Mg (37 tons) in 1997.[1] No significant adverse secondary air impacts, water, solid waste, or energy impacts are anticipated from the promulgation of these standards (59 FR 10595-10596).

Implementation of this regulation is expected to result in nationwide annualized costs for existing ethylene oxide commercial sterilization facilities of about $6.6 million beyond baseline.[2] Capital cost incurred by a typical uncontrolled existing source such as a large commercial sterilization and fumigation operation using 68,000 kilograms per year (kg/yr) [(75 tons per year (tons/yr)] of ethylene oxide would be about $310,000 for controlling the sterilization chamber vent emissions (unchanged since proposal, see 59 FR 10596) and about $290,000 for controlling the aeration room vent and chamber exhaust vent emissions.[2] The annualized cost incurred by this typical source to operate the control devices would be about $100,000 for the sterilization chamber vent (unchanged since proposal, see 59 FR 10596) and about $80,000 for the aeration room vent and chamber exhaust vent.[2] The costing analysis is summarized and can be found in detail in Chapter 7 of the background information for proposed standards[3] and changes to capital and annualized costs since proposal are provided in reference 2.

The economic impact analysis done prior to proposal showed that the economic impacts from the proposed standards would not be significant (59 FR 10596). No changes have been made to the promulgated rule since proposal that would increase the economic impacts to a significant level. The economic impact analysis is summarized in the proposal preamble (59 FR 10596) and a detailed discussion can be found in Chapter 8 of the background information for proposed standards.[3]

1.2 SUMMARY OF CHANGES TO THE MACT FLOOR FOR MAJOR SOURCE CHAMBER EXHAUST VENTS[4]

The only major change to the regulation from its proposal is the reevaluation of the MACT floor for major source chamber exhaust vents. A general discussion of the MACT floor determination is given in the preamble to the proposed rule (59 FR 10592-10593). Information submitted by commenters on the proposed regulation indicated that a controlled MACT floor exists for existing major source chamber exhaust vents. The control of these vents involved the ducting of the emissions from the

chamber exhaust to a control device installed to control aeration room vent emissions. For a source that controls aeration room vent emissions already, the emissions from the chamber exhaust vent are manifolded to this control device. To facilitate combined control of the two emissions points, the air flow rate from the aeration room to the control device is reduced when control of emissions from the chamber exhaust vent is necessary. This combined flow option for use with an existing control device may also be used for manifolding the chamber exhaust vent emissions to the sterilization chamber vent control device.

Because there are approximately 50 major sources contained in the Agency's commercial sterilization data base, the best controlled six facilities (12 percent) comprise the MACT floor. The Agency therefore contacted six facilities that commenters listed as controlling chamber exhaust vent emissions to ascertain their major source status. Each of these six facilities indicated that they were a major source (annual ethylene oxide use of 20,000 pounds or more). While commenters reported emissions reduction information for these sources, the efficiencies reported reflect the efficiency achieved by the control device to which multiple vent emissions are vented; the emissions reductions achieved for the chamber exhaust vent emissions were not verified with actual test data. Therefore, the MACT floor for the chamber exhaust vent at existing major source commercial ethylene oxide sterilization and fumigation operations is control of the chamber exhaust vent. The best controlled similar source controls emissions from the chamber exhaust vent, and the MACT floor for new major sources is therefore control of the chamber exhaust vent emissions. The emissions from the chamber exhaust vent at both new and existing major sources either must be vented (manifolded) to a control device achieving 99 percent emissions reduction that controls the emissions from either the aeration room or sterilization chamber vent control device or must be vented to a dedicated control device that achieves at least 99 percent emissions reduction.

1.3 SUMMARY OF CHANGES SINCE PROPOSAL

Several changes have been made since the proposal of these standards in response to public comments. The majority of the changes have been made to clarify portions of the rule that were unclear to the commenters. Other changes include reassessment of the MACT floor for the chamber exhaust vent, addition of another referenced control technology, allowing alternative monitoring scenarios, and extending the compliance period for all sources. All changes that have been made to the regulation are fully explained in the responses to the comments. A summary of the requirements for each emissions source is outlined below and contains the following information: (1) changes to the requirements since proposal have been identified in the outline along with the section of this background information document (BID) containing the discussion and rationale for the change, and (2) in instances where no changes have been made to the regulation since proposal, a reference has been identified for locating the rationale used in determining the requirements.

OUTLINE-MAJOR CHANGES TO REGULATION SINCE PROPOSAL

I. STERILIZATION CHAMBER VENT

A. Standards for Sterilization Chamber Vents

No change in the level of the standards for major and area sources from proposal on March 7, 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01), pp. 10597-10600 for rationale.]

B. Format of the Standards for Sterilization Chamber Vents

No change in the format of the standards from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10600-10601 for rationale.]

C. Compliance and Performance Testing for Sterilization Chamber Vent

The monitoring parameters for the control devices at both major and area sources have changed from proposal in March 1994 as follows:

1. For acid-water scrubbers, the monitoring requirement has changed from continuously monitoring the ethylene glycol in the

proposed rule to weekly monitoring of either the ethylene glycol concentration or the level of scrubber liquor in the scrubber liquor tank in the final rule. (See Section 2.4.2.)

2. For oxidation units, the monitoring requirement has changed from continuously monitoring the temperature within a specific range (±10°F) in the proposed rule to continuously monitoring a minimum baseline temperature in the final rule. (See Section 2.4.3.)

II. AERATION ROOM VENT

A. Standard for Aeration Room Vent

1. Existing and New Major Sources. No change in the level of the standards from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10597-10598 for rationale.]

2. New Area Sources. No change in the level of the standard from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10598-10599 for rationale.]

3. Existing Area Sources. Information submitted by commenters indicated that existing area sources are controlling emissions from the aeration room vent; there are at least eight (12 percent of 68) facilities known to control aeration room vent emissions. The MACT floor for existing area sources for aeration room vents is control.[5] Just as MACT was rejected and GACT was selected based on cost effectiveness of over $100,000/ton for new area sources, the Administrator explained in the preamble to the proposed rule that if information was submitted indicating a controlled floor for existing area sources, MACT would be rejected and GACT selected for existing area sources. Due to the high cost effectiveness associated with control of existing area source aeration room vents, MACT has been rejected and GACT selected for this source category; GACT for this source category is no control. [See Section 2.2.6 and see 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10599-10600 for rationale.]

B. Format of the Standard for Aeration Room Vent

1. Major Sources. The final rule provides additional flexibility to facilities by allowing sources to comply with either the 1 part per million volume (ppmv) concentration limitation as proposed [see 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10600-10601 for rationale] or a 99 percent emissions reduction (based on commenters' suggestions, see Section 2.2.6).

2. Area Sources. No control; no change from proposal in March 1994.

C. Compliance and Performance Testing for Aeration Room Vents

1. Major Sources. Facilities may demonstrate compliance by continuously monitoring either the ethylene oxide concentration from the aeration room vent after the control device as proposed or by parametrically monitoring the control device achieving 99 percent emissions reduction. The monitoring parameters for demonstrating compliance are as follows [same as listed above in Sterilization Chamber Vent]: for oxidation units, the monitoring requirement has changed from continuously monitoring the temperature within a specific range (±10°F) in the proposed rule to continuously monitoring a minimum baseline temperature in the final rule. (See Section 2.4.3.)

2. Area Sources. No control and therefore no compliance requirements are necessary; no change from proposal in March 1994.

III. CHAMBER EXHAUST VENTS

A. Standard for Chamber Exhaust Vent

1. Major Sources. Based on information submitted by commenters and subsequent followup, there are at least six (12 percent of 50) existing major sources known to control chamber exhaust vent emissions by manifolding emissions to a sterilization chamber vent or aeration room vent control device (see Section 2.2.7). The MACT floor for existing major sources for chamber exhaust vents is control of chamber exhaust vent emissions by a control device. The best controlled source controls emissions from the chamber exhaust vent by venting to a

control device; the MACT floor for new sources is therefore control of chamber exhaust vent emissions.[4] (See § 112(d) of the Act) The standard for chamber exhaust vents specifies that a facility may either manifold the emissions to controls for the sterilization chamber vent or the aeration room vent or may reduce emissions by 99 percent. (See Section 2.2.7.)

2. Area Sources. No control but facilities must demonstrate that the source is under the 5,300 ppmv concentration limit; no change from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10598-10600 for rationale.] Additional flexibility has been added to the standard in that sources may choose to demonstrate control by reducing emissions by 99 percent. (See Section 2.2.7.)

B. Format of the Standard for Chamber Exhaust Vent

1. Major Sources. Sources will comply by venting to a device achieving a 99 percent emissions reduction. The percent emissions reduction is consistent with the data submitted by commenters for control devices the emissions are vented to and as is consistent with the format for both the SCV and the ARV standards (for manifolding purposes). (See Section 2.2.7.)

2. Area Sources. The final rule provides flexibility to facilities by allowing sources to comply with the concentration limit as proposed [see 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10600-10601 for rationale] or with a 99 percent emissions reduction limitation (see Section 2.2.7).

C. Compliance and Performance Testing for Chamber Exhaust Vent

1. Major Sources. Sources that manifold emissions would determine the monitoring parameters based on the initial compliance test and the parameters determined for the sterilization chamber vent or the aeration room vent control device. Sources with dedicated control devices would determine the monitoring parameters based on the control technology used.

The monitoring parameters for dedicated control devices are as follows [same as listed above in SCV]:

- for acid-water scrubbers, the requirement is weekly monitoring of either the ethylene glycol concentration or the level of scrubber liquor in the scrubber liquor tank. (See Section 2.4.2.)

- for oxidation units, the requirement is continuously monitoring a minimum baseline temperature. (See Section 2.4.3.)

2. Area Sources. Facilities must demonstrate that there are no increases in emissions from the chamber exhaust vent by either monitoring the ethylene oxide concentration in the sterilization chamber prior to activation of the chamber exhaust or by controlling the emissions from this vent. A facility may choose to comply with the 5,300 ppmv limitation by manifolding the emissions to a control device for the sterilization chamber vent or controlling the emissions with a dedicated control device. Sources that manifold emissions would determine the monitoring parameters based on the initial compliance test and the parameters determined for the sterilization chamber vent. Sources with dedicated control devices would determine the monitoring parameters based on the control technology used.

The monitoring parameters for the dedicated control devices are as follows [same as listed above sterilization chamber vents]:

- for acid-water scrubbers, the requirement is weekly monitoring of either the ethylene glycol concentration or the level of scrubber liquor in the scrubber liquor tank. (See Section 2.4.2.)

- for oxidation units, the requirement is continuously monitoring a minimum baseline temperature. (See Section 2.4.3.)

IV. IMPACTS FOR THE PROMULGATED REGULATION

A. Air. Additional ethylene oxide emissions reduction is achieved by controlling emissions from major source chamber exhaust vents (see Section 2.2.7); the nationwide emissions reduction increases from 93 percent (1,100 tons) reduction anticipated in the proposed rule [see 59 FR 10591 (EPA Air

Docket A-88-03, Docket Entry III-A-01 and III-A-02), p. 10595 for rationale] to 96 percent (1,140 tons) reduction anticipated in the final rule.[1]

B. Water, Solid Waste, Noise. Minimal change from the impacts discussed in the preamble to the proposed rule. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), p. 10596 for rationale.]

C. Energy. Minimal change from the impacts discussed in the preamble to the proposed rule. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), p. 10596 for rationale.]

D. Cost. The combination of aeration room vent and chamber exhaust vent control costs is approximately $290,000 at a typical source, an increase of $20,000 from the $270,000 average facility cost for controlling only the aeration room vent (increase over proposal costs for the aeration room vent due to duct work for the chamber exhaust vent); total nationwide costs increased from $6.4 million to $6.6 million.[2]

E. Economic. Not a significant regulation per Executive Order 12866 (58 FR 51735); minimal change from proposal. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10604-10605 for rationale.]

V. MISCELLANEOUS

A. The compliance time for all sources has been extended from 2 to 3 years. This extension has been provided to allow sources additional time in complying with these standards. New sources with startup after the 3 year compliance date will be required to comply upon startup of the source.

B. Several commenters requested clarification of General Provisions requirements as they relate to this rule. A table identifying the relationship of the final General Provisions requirements has been added to the final rule. Language similar to that contained in the General Provisions has been added to this regulation in cases where a direct reference to the General Provisions was not appropriate.

C. Reporting of excess emissions is required semiannually, whether the source has experienced excess emissions or not; the Administrator may determine on a case basis that more frequent reporting is necessary.

1.4 REFERENCES

1. U. S. Environmental Protection Agency. Ethylene Oxide Commercial Sterilization Data Base. Research Triangle Park, North Carolina. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-A-01.

2. Memorandum from Schmidtke, K.L., Midwest Research Institute to Markwordt, D.W., EPA/CPB/CMS. October 24, 1994. Costing of Controls for the Chamber Exhaust Vent. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-B-03.

3. U. S. Environmental Protection Agency. Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations, Background Information for Proposed Standards. Draft EIS. October 1992. U. S. Environmental Protection Agency Publication No. EPA-453/D-93-016. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry II-A-22.

4. Memorandum from Hearne, D.G., and Schmidtke, K.L., Midwest Research Institute to Markwordt, D.W., EPA/CPB/CMS. October 24, 1994. Revised Calculation of MACT Floors for Major Source Chamber Exhaust Vents at Ethylene Oxide Commercial Sterilization and Fumigation Operations. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-B-02.

5. Memorandum from Schmidtke, K.L., Midwest Research Institute to Markwordt, D.W., EPA/CPB/CMS. October 27, 1994. Revised Calculation of the MACT Floor for Area Source Aeration Room Vents. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-B-05.

2.0 SUMMARY OF PUBLIC COMMENTS

A total of 18 letters commenting on the proposed rule and the BID for the proposed standards were received during the public comment period. Two comments were received after the close of the comment period and were considered in finalizing the regulation. A list of commenters, their affiliations, and the EPA tracking number assigned to their correspondence is given in Table 2-1.

For the purpose of presentation, the comments have been categorized under the following topics:

1. Selection of Source Categories to be Regulated;
2. Regulatory Approach;
3. Compliance Dates;
4. Monitoring Requirements;
5. Test Methods;
6. Reporting and Recordkeeping Requirements;
7. Wording of the Regulation; and
8. Miscellaneous

2.1 SELECTION OF SOURCE CATEGORIES TO BE REGULATED

2.1.1 Source Type

Comment: One commenter (10) expressed concern that EPA has not addressed ethylene oxide storage areas and the point where the ethylene oxide storage tank is connected to the sterilization unit as possible emissions points. At a minimum, EPA should prevent uncontrolled venting of the unused ethylene oxide from the tank. One commenter (19) stated that the final rule should address equipment leaks and sterilizer door hood exhaust emissions. The commenter indicated that these emissions points are addressed by regulations in California.

TABLE 2-1. COMMENTS RECEIVED ON THE PROPOSED EO STERILIZATION NESHAP

Docket Item[a]	Commenter and Affiliation
IV-D-01	David Driesen Natural Resources Defense Council 1350 New York Avenue, Northwest Washington, DC 20005
IV-D-02	John Walton Tennessee Department of Environment and Conservation Tennessee Air Pollution Control Board 9th Floor, L & C Annex 401 Church Street Nashville, TN 37243-1531
IV-D-03	Margaret Corbin Puget Sound Air Pollution Control Agency 110 Union Street, Suite 500 Seattle, WA 98101-2038
IV-D-04	Ann Baldwin Health Industry Manufacturers Association 1200 G Street, Northwest Suite 400 Washington, DC 20005-3814
IV-D-05	Gary Wilson COBE Laboratories, Inc. Environmental Health and Safety 1185 Oak Street Lakewood, CO 80215
IV-D-06a[b]	Robert Wheeler SIMS Concord/Portex Technical Services 15 Kit Street Keene, NH 03431
IV-D-06b[b]	Allen Ammerman Griffith Micro Science 200 S. Frontage Road, Suite 120 Burr Ridge, IL 60521-6916
IV-D-07	Michael Pucci AT&T Corporate Environment and Safety Engineering Center 131 Morristown Road Basking Ridge, NJ 07920
IV-D-08	Raymond Connor Manufacturers of Emission Controls Association 1707 L Street, Northwest Suite 570 Washington, DC 20036-4201

TABLE 2-1. (continued)

Docket Item[a]	Commenter and Affiliation
IV-D-09	David Mixon McCormick and Company, Inc. 18 Loveton Circle Post Office Box 6000 Sparks, MD 21152-6000
IV-D-10	Thomas Allen New York State Department of Environmental Conservation Division of Air Resources 50 Wolf Road Albany, NY 12233-3254
IV-D-11	Cary Olson Donaldson Company, Inc. Chemical and Catalytic Systems Post Office Box 1299 Minneapolis, MN 55440-1299
IV-D-12	Gerald Messerschmidt C. R. Bard, Inc. Scientific Affairs 730 Central Avenue Murray Hill, NJ 07974
IV-D-13	William O'Sullivan New Jersey Department of Environmental Protection and Energy Air Quality Regulation Program 401 East State Street Trenton, NJ 08625
IV-D-14	Michael Wax Institute of Clean Air Companies 1707 L Street, Northwest Suite 570 Washington, DC 20036-4201
IV-D-15	Barbara Morin Rhode Island Department of Environmental Management Division of Air Resources 291 Promenade Street Providence, RI 02908-5767
IV-D-16	Patricia Leyden South Coast Air Quality Management District (SCAQMD) 21865 E. Copley Drive Diamond Bar, CA 91765-4182

TABLE 2-1. (continued)

Docket Item[a]	Commenter and Affiliation
IV-D-17	Robert Colby Donald Theiler STAPPA/ALAPCO 444 North Capitol Street, Northwest Washington, DC 20001
IV-D-18[c]	Bay Area Air Quality Management District (BAAQMD) 939 Ellis Street San Francisco, CA 94109
IV-D-19[c]	Deborah Sheiman Natural Resources Defense Council 1350 New York Avenue, Northwest Washington, DC 20005

[a]The docket number for the commercial sterilization and fumigation docket is A-88-03.
[b]This designation for internal use only, these comments were assigned identical docket numbers by EPA's Air and Radiation Docket and Information Center.
[c]This designation for internal use only, these comments were received after the close of the comment period and have not been assigned a docket number.

One commenter (17) stated that fugitive leak emissions should be addressed in these standards. One commenter (18) stated that a separate standard based on leak monitoring should be established to address equipment leaks. This commenter and one other (03) recommended that the regulation should address leak detection and repair (LDAR) and prohibit operation of a sterilizer (03, 18) or aerator (03) unless the maximum concentration of ethylene oxide as measured 1 centimeter away from any portion of the equipment, with an FID calibrated with methane or other approved gas (18), is less than 10 ppmv.

Response: The main fugitive emissions point for sterilization and fumigation operations is the sterilization chamber door. The chamber door is opened slightly prior to unloading products from the sterilization chamber, and this opened door is an emissions point that must be properly ventilated in order to meet OSHA standards to reduce worker exposure to ethylene oxide. The OSHA requirement specifies that the level of exposure to workers not exceed 1 ppmv or 1.8 mg/m^3 ethylene oxide over a normal 8-hour (hr) workday and 40-hr workweek. Emissions from the opened chamber door are typically vented automatically by the chamber exhaust vent. Emissions from the other fugitive emissions points listed by the commenters are addressed by the OSHA standards for ethylene oxide sources and are negligible. The Agency believes that the OSHA requirements limiting worker exposure to a maximum of 1 ppmv ethylene oxide should be sufficient to limit these fugitive emissions points and protect employees. Based on additional data submitted by a commenter, the chamber exhaust vent will be controlled at both existing and new major sources (see Section 2.2.7).

In the Agency's experience, venting of ethylene oxide from the storage tanks is not practiced, and the Agency has received no evidence to show that uncontrolled venting occurs. The Agency believes that common practice for handling empty or nearly empty ethylene oxide tanks includes closing the valve at the outlet of the tank, removing the tank from the line to the sterilization

chamber, and returning the tank to the chemical company or supplier for reuse.

Comment: One commenter (10) stated that the standards for the sterilization chamber vent should be written to specifically delineate that the ethylene oxide drain emissions are to be eliminated by use of a closed-loop, recirculating vacuum pump drain and that these emissions are to be included with the sterilization chamber vent emissions and are subject to the 99 percent control requirement. Another commenter (03) also requested that a clear statement that it is unlawful to cause or allow discharge of ethylene oxide to the wastewater stream from the sterilizer exhaust pump working fluid be included in the rule. Another (19) also stated that the final rule should address vacuum pump drain emissions.

One commenter (06b) supported EPA's proposed requirements for the sterilizer vacuum pump.

Response: The background information document for the proposed standards identifies emissions from wastewater associated with the use of once-through vacuum pumps as a component of the sterilization chamber vent emissions stream. Under the proposed rule, the emissions from this entire stream are to be reduced by 99 percent. The proposed regulation therefore provides sources with the flexibility to convert to a closed-loop vacuum pump (a recirculating fluid pump that has no wastewater emissions) or retain the once-through pump and choose to control the wastewater emissions of ethylene oxide by some other method. However, because the definition of sterilization chamber vent includes emissions from any vacuum pump used, the control efficiency of these vacuum pump drain emissions must be included in the overall calculation for 99 percent emissions reduction required for this vent. The Agency does not believe that an equipment-based standard such as the commenter suggests is necessary for the vacuum pump emissions to achieve a 99 percent reduction in emissions.

Comment: Two commenters (04, 07) supported the exemptions for research and laboratory facilities. One of these commenters

(04) stated that the regulation should not apply to research and development vessels located at commercial sterilization facilities, provided they meet the other requirements of § 63.360. The commenter stated that companies should not be penalized for locating small research and development units at a site where commercial sterilization occurs. The commenter added that these units would be exempt from the proposed rule if they were located at different sites. The commenter noted that this is particularly onerous if the research and development units are located in a different part of the site from the commercial scale units and cannot utilize the same control device. Another commenter (18) also requested that EPA clarify the application of § 63.360(e) to include in the exemption research and development installations on the site of manufacturing facilities and for profit facilities that perform contract research (e.g., product testing) as their primary "product."

Two commenters (05, 10) indicated that the regulation should apply to research and laboratory facilities. One commenter (05) stated that the rule should be expanded to include research and development vessels, provided the vessels meet the other requirements of § 63.360. Another commenter (11) stated the rule should include any research or laboratory facility that uses more than the limit established in § 63.360(c). This commenter also stated that these vessels are generally used to validate process parameters for the production and sterilization of medical components and, as such, are part of the manufacturing process, not a true R&D function. This commenter also indicated that the cost to control such equipment, because of its small size and low usage, is minimal. Costs for equipment would range from $15,000 to $65,000 and should not create an economic hardship for a manufacturer even if the sterilizer is located remotely from the main manufacturing unit.

Response: Section 112(c)(7) of the Act requires the Administrator to establish a separate category for research and laboratory facilities. Sources that engage in purely research and development activities are exempt from this regulation,

however, all sterilization chambers located at commercial sterilization facilities that are otherwise an affected source are not exempt from the final rule. Sterilization chambers used to develop pressure, temperature, and humidity settings are considered part of the process procedure and are not considered to be research or laboratory operations as defined in the Act.

Comment: One commenter (07) supported the exemptions for medical services facilities.

Seven commenters (03, 10, 11, 15, 16, 17, 19) suggested that the rule should apply to medical care facilities. One of these commenters (10) indicated that their state is attempting to locate, control, and permit all sources of ethylene oxide. This state controls hospital sources, which typically have low release heights and are located in urban areas, because exposure and the associated effect on health would be great. This commenter also stated that exempting hospital sterilizers would prevent the regulation of a large amount of ethylene oxide which would have a significant effect on health. Another commenter (17) noted that in several states, many significant sources would be exempt from the standards as written. The commenter pointed out that these sources are not only the largest ethylene oxide emitters but are often located in residential areas and are themselves the site of some of the most sensitive receptors in the population. Another of these commenters (15) indicated that hospital sterilizers are controlled in Rhode Island and that modelling of hospitals in their state has shown health impacts considerably higher than acceptable levels. The commenter added that members of the public and sensitive individuals (e.g., persons with compromised health, pregnant women, young children) are often within close proximity to hospital ethylene oxide emissions. Another commenter (03) suggested that exempting hospitals and other sources, which emit significant quantities of ethylene oxide to potentially sensitive populations, is unacceptable.

One commenter (16) stated that ethylene oxide emissions from medical facilities such as hospitals represent approximately 64 percent of the sources and 17 percent of the total ethylene

oxide emissions in California. Another commenter (10) indicated that hospital sterilizers in New York use over one-third of the total ethylene oxide used statewide. One commenter (11) indicated that the source-type exemptions and the ethylene oxide usage cutoffs in § 63.360 exempt approximately 9,000 hospitals and leave close to 600 tons/yr ethylene oxide uncontrolled, not the 15 tons/yr of ethylene oxide left uncontrolled that was presented in the preamble [the 15 tons/yr was calculated as the residual ethylene oxide emissions from commercial sterilizers after the standards].

Two commenters (10, 11) provided information regarding the economic burden of controlling ethylene oxide emissions from hospital sources. One of these commenters (11) indicated that the financial burden to a hospital is minimal as the control equipment for this segment costs between $15,000 and $35,000, depending on sterilizer size. The other commenter (10) indicated that the economic burden associated with controlling the medical services facilities has not resulted in a significant removal of sterilizers from hospitals in their state.

One commenter (17) suggested that because some distinction between hospitals and commercial interests is warranted, EPA could consider reduced administrative requirements for medical facilities. One commenter (18) stated that in the event EPA chooses to regulate hospital sterilizers using less than 1 ton/yr ethylene oxide, an exemption should be provided for sources subject to stringent State/local standards, Title V permits should not be required, and administrative requirements should be limited.

One commenter (19) stated that EPA's actions under § 112(d) should not be treated as a distinct activity wholly separate from work under § 112(k). This commenter stated that EPA should address smaller ethylene oxide sources under these standards rather than under the urban air toxics program. The commenter noted that this would be more protective of human health and the environment and reduce the level of effort required from the Agency. This commenter also stated that the proposed rule

ignores EPA's broader responsibility under the Clean Air Act to establish abatement strategies for sources of air toxics emissions in urban areas, a program that provides additional impetus and legal authority to establish lower applicability cutoffs and to regulate sterilizers located at medical institutions such as hospitals. The commenter also stated that the exempt and excluded facilities under the proposed rule typify area sources of hazardous air pollution that contribute to health risks in urban areas; control of emissions from such sources will be needed to achieve the legislative mandate to reduce cumulative exposures to hazardous air pollutants from many relatively small emissions sources. In addition, the commenter indicated that ethylene oxide is prototypical of the type of pollutant and uses that Congress directed EPA to address under the urban air toxics program and that EPA should address such pollutants and source categories under the § 112(d) standards rather than deferring control to the § 112(k) program, which is running behind schedule.

Two commenters (15, 17) stated that if hospitals are not included in this regulation, then they should be listed as a separate source category for MACT standards; one of these commenters (17) also stated these operations should be subject to later review under § 112(f). Another commenter (19) indicated that if EPA does not address hospital sterilizers under these NESHAP, hospital sterilizers should be added to the list of source categories as soon as possible and EPA should concurrently propose application of the commercial sterilizer standards to hospital sterilizers. This commenter noted that hospital sterilization was initially included on the proposed source category list but was dropped from the final source category list and that the commenter was therefore unaware that this category had been dropped until reading the definition of "commercial sterilizer" in this proposed rule and realizing that it was being defined so as to exclude hospitals. The commenter stated that EPA should broaden the definition of commercial sterilization to include hospital sterilizers. The commenter asserted that there

is no fundamental difference between ethylene oxide sterilization carried out in a commercial sterilizer as defined in the proposed rule and ethylene oxide sterilization in a hospital.

Response: The reference to hospital sterilizers was included in the regulation for clarification purposes in defining commercial sterilizers. It is important to note that sterilization at hospital facilities was not exempted in a true sense but was omitted based on the definition of commercial sterilization. The EPA originally listed "commercial sterilization facilities" and "hospital sterilization facilities" as two separate categories on the proposed source category list. These source categories by definition did not overlap. When it was decided not to include hospital sterilizers on the final source category list, only commercial sterilization facilities remained on the list. Source categories have to be on the source category list to be regulated by EPA under § 112(d) of Title III. The source category list was published on July 16, 1992 (57 FR 31576); the public was given an opportunity to review and comment on the list. Section 112(c) requires EPA to establish a list of source categories of major and area sources that emit these HAP and to promulgate regulations for each of these source categories under § 112(d); this section also specifies that the source category list will be periodically revised in response to public comment or new information. If hospitals are added to the source category list at a future date, hospital sterilizers will be placed in the 10-year promulgation bin. In addition, the majority of hospital sources emit less than 1 ton/yr. If this rule for commercial sterilization had been developed in conjunction with hospital sterilization, the majority of hospital sterilization sources would not be included due to the area source emissions exemption of 1 ton/yr (see Section 2.1.2).

The Agency believes that it is appropriate to address the urban air toxics program of § 112(k) separately from this rulemaking. The urban toxics study will include a large variety of sources; hospital sterilization sources and sources with

emissions less than 1 ton/yr will likely be assessed as part of this under § 112(k).

Because sterilization operations performed at medical facilities are not subject to these NESHAP, consideration of alternative administrative requirements and Title V issues for medical facilities is not necessary. (See Section 2.2.4 for discussion of risk and see Section 2.2.6 for discussion of § 112(f).)

Comment: One commenter (18) stated that the Agency has expanded the source category description to include fumigation operations while limiting the source category to operations that use ethylene oxide as the sterilant/fumigant. The commenter recommended that EPA provide rationale for their decision to restrict the applicability of the rule to ethylene oxide and not cover operations that use other sterilant/fumigant gases (e.g., methyl bromide) and to amend the source category description in the source category list. Another commenter (17) also suggested that other sterilants and fumigants besides ethylene oxide (e.g., methyl bromide) should be regulated under this source category, and if they are not included, then these operations using the other sterilants and fumigants should be listed as a separate source category. Another commenter (06b) questioned whether EPA will regulate manufacturers of ethylene oxide as well.

Response: The Agency would like to point out that fumigation processes have always been a part of this regulation and were not added to the source category; the Agency considers sterilization and fumigation processes to be the same, with the processes being used for eliminating microorganisms and vermin (insects), respectively. As is evident, the only HAP compound regulated in this rule for the commercial sterilization and fumigation source category is ethylene oxide. The category listed on the final source category list (57 FR 31576) for which this rule was developed relates specifically to ethylene oxide commercial sterilization processes. Other categories of sterilization facilities using other HAP as the sterilizing compound were not identified on the source category list and

therefore will not be regulated by EPA at this time. Other types of sterilization processes may be added to the source category list in the future.

While ethylene oxide production is not listed specifically on the source category list, ethylene oxide is one of approximately 400 chemicals listed in the Synthetic Organic Compound Manufacturing Industry NESHAP (SOCMI; also referred to as the Hazardous Organic NESHAP, or the HON). Manufacturers who produce ethylene oxide and emit HAP compounds as a result of this production or who use ethylene oxide as a raw material in the production of another listed SOCMI chemical are subject to the SOCMI NESHAP.

Comment: One commenter (10) noted that some States, by State law, are not able to regulate pollutant emissions more stringently than a Federal regulation. The commenter added that this would prevent these States from regulating facilities exempted in §§ 63.360(b) through (f), such as hospital sterilizers. Another commenter (17) stated that EPA should mandate strong standards on a national scale and not rely on State and local agencies to compensate with stronger measures, since some States will be precluded from going beyond Federal requirements.

One commenter (18) requested that if the sources are regulated under a stringent State or local standard, EPA should continue to exempt hospital sterilizers and small sterilizers (using less than 1 ton/yr ethylene oxide) from any otherwise applicable requirements, including Title V permitting and administrative requirements. This commenter also recommended that EPA require control of the aeration room vents unless they are required to control aeration room vent emissions under a stringent State or local requirement.

Response: There are several State and local regulations that require control of ethylene oxide emissions from commercial sterilization operations. The EPA agrees that there may be instances where the Federal emissions standards could be less stringent than a State or local standard. The NESHAP are

intended to be representative of maximum achievable control on a national basis, and the Agency recognizes that in some areas the standards may not address individual air pollution control needs. While States are prohibited from adopting standards that are less stringent, they may go beyond the Federal requirement and adopt standards that are more stringent. Certain States use Federal rules as a baseline for their own regulations and it is at the State's discretion to go beyond the Federal requirement.

The fact that a State currently regulates a particular source that is also the subject of NESHAP does not predispose those facilities to exemption from the Federal regulation and its requirements. The NESHAP apply to all major and in some instances area sources within the subject source category. However, if a source is currently controlling emissions from commercial sterilization to comply with a State or local rule, they may have sufficient control in place to meet this standard as well. In addition, reporting required for a State rule may also be submitted to fulfill the reporting requirements for the Federal rule given that all of the appropriate information is contained in the State report (i.e., ethylene oxide usage, test data, excess emissions, etc.). States will likely be delegated the authority for implementing rules for Part 63.

2.1.2 Source Size

Comment: Eight commenters (03, 10, 11, 15, 16, 17, 18, 19) requested that EPA reevaluate the emissions cutoff for area sources. These commenters pointed out that several States are requiring lower cutoffs, as low as 2.5 pounds per year (lb/yr), than the 1 ton/yr cutoff found in the proposed rule and indicated that these State regulations should be considered. One of these commenters (16) indicated that facilities with ethylene oxide emissions less than 1 ton/yr represent a large segment of the ethylene oxide emitted in its district. Another commenter (11) suggested that the emissions cutoff should be 100 lb/yr [0.05 ton/yr] for area sources. Another (19) suggested that the emissions cutoff be lowered to include sources using 4 lb/yr or more of ethylene oxide. One commenter (17) indicated that the

applicability threshold should be established to include area sources as well as sources that are considered "major."

One commenter (18) stated that EPA's justification for the 1 ton/yr cutoff (cost-effectiveness data and low emissions contribution) was not sufficient and was counter to the commenter's experience; the commenter requested a better justification for this cutoff. One commenter (19) stated that cost-effectiveness analysis is inappropriate and irrelevant to EPA's selection of an applicability cutoff. The commenter stated that the 1 ton/yr cutoff is arbitrary and inequitable, both for commercial sterilizers and for people living near ethylene oxide facilities. The commenter added that EPA's reliance on cost-effectiveness analysis to establish a regulatory cutoff of one ton is inappropriate because it does not speak to feasibility or to the actual cost to a facility or affordability of controls. The commenter referred to CARB estimates of the costs of compliance with its commercial and hospital ethylene oxide sterilization regulations indicating an annualized cost of $24,000 - costs that most small businesses would be able to absorb without significant adverse impact on their profitability. The commenter stated that the fact that controls are in place for all sterilizers down to the 4 lb/yr use level in California indicates that it is not only achievable, but also affordable, to control ethylene oxide emissions from sources under 1 ton/yr. The commenter stated that local impacts on individuals living near ethylene oxide sources should be the critical issue in determining an applicability cutoff. The commenter asserted that because there is a greater potential for human exposure from thousands of small sources located in commercial and residential areas that vent ethylene oxide directly into the atmosphere than from the few facilities that manufacture the substance, these smaller sources should be controlled under the standards.

Two commenters (10, 16) indicated that the majority of ethylene oxide sterilization and fumigation sources located in their State and district will not be subject to the proposed rule due to the combination of the ethylene oxide usage cutoff and the

source exemptions; another commenter (18) stated that the exemptions of the proposed rule apply to all ethylene oxide sterilizers in their district. One of these commenters (10) stated that, considering the large number of ethylene oxide sources and the high toxicity of this contaminant, the applicability of the final rule should be expanded so that a larger number of facilities would be controlled by this Federal MACT standard.

Two commenters (10, 11) indicated that the emissions cutoff limit for the sterilization chamber vent should be either eliminated or reduced. One of these commenters (11) pointed out that several States require controls for emissions from sterilization chamber vents for sources as low as 25 lb/yr [0.013 ton/yr]. This commenter suggested reducing the emissions cutoff to 100 lb/yr [0.05 ton/yr] for sterilization chamber vents. The other commenter (10) suggested that the emissions cutoff should be eliminated or substantially reduced.

One commenter (11) requested that the emissions cutoff for regulation of exhaust chamber vents be lowered to 5,000 lb/yr [2.5 tons/yr].

Response: The Agency believes the 1 ton/yr emissions cutoff for affected area sources is appropriate for this regulation. The Agency believes low emissions contribution and high cost effectiveness are sufficient reasons for placing the cutoff at 1 ton/yr. The EPA has considered the potential cost (including costs for monitoring, recording, and recordkeeping) to small sources by establishing a cutoff at 1 ton/yr. Emissions cutoffs for area sources are at the discretion of the Agency. The commenters presented no compelling reason to lower the cutoff for commercial sterilization area sources; in addition, the Agency received no information from commenters to support their statements regarding the impacts to the public. Sources emitting less than 1 ton/yr of ethylene oxide will continue to be exempt from requirements for the sterilization chamber, chamber exhaust, and aeration room vents. (See Section 2.2.4 for discussion of risk.)

Comment: One commenter (03) indicated that an applicability statement based on facility-wide usage [of ethylene oxide] would be appropriate and that control requirements should be based on the amount of ethylene oxide emissions; this commenter also stated that the control technology requirements should be based on technical feasibility for a facility emitting a specified amount of the pollutant, regardless of the type of facility. One commenter (17) agreed that the applicability for the rule should be based on actual usage of ethylene oxide rather than on a theoretical maximum potential-to-emit.

Another commenter (05) suggested that the potential-to-emit issue (opened to public comment and separate rulemaking in the final General Provisions) should be fast-tracked or the NESHAP for ethylene oxide should be delayed to avoid confusion and inappropriate characterization of a given source.

Response: Ethylene oxide usage data are used for "applicability" purposes in determining sources subject to the regulation. The applicability of the standards is based on actual annual ethylene oxide usage and is Federally enforceable. The provisions addressing the General Provisions in the final regulation indicate that applicability for these source categories is based on actual emissions rather than potential-to-emit. Control levels are not based on the emissions levels of the source; the control requirements for NESHAP regulation of major and area sources are based on MACT or MACT/GACT determinations. All sources subject to these NESHAP with similar ethylene oxide usage, regardless of the type of facility, are required to control at the same stringency.

2.2 REGULATORY APPROACH

2.2.1 MACT Floor Interpretation

Comment: One commenter in two comment submittals (01 and 19) stated that the Agency should average the emissions limitations achieved by the sources in the top 12 percent of a source category in order to determine the average emissions limitation of the best performing 12 percent of the existing sources. The commenter stated that EPA should not use the

88th percentile to calculate the MACT floor and supplied several instances from the legislative history of the Clean Air Act to support this statement. The commenter agrees with EPA that this matter is of great precedential importance and asserted that an incorrect interpretation of the MACT floor would increase the likelihood of more emissions remaining wholly uncontrolled in spite of MACT standard setting efforts and an increased likelihood of court intervention in determining the legislative intent of the MACT floor language.

The commenter also stated that the fact that the average yields an emissions limitation corresponding to no particular technology should not preclude its use; the MACT floor is a floor. The commenter added that in cases where the actual average does not match the most stringent emissions limitation achievable by any particular technology, EPA may properly set the MACT standard above the median; EPA has the authority to go above the floor but lacks the authority to go below the floor or to manipulate the floor to make it contrary to Congressional intent. The commenter stated that the final rule should use a straight average, not a median; if the final rule uses a median, the Agency must explain why use of a median is appropriate as a matter of statutory interpretation and provide a reasoned explanation for the decision to use the median in this case.

Response: The Agency appreciates the commenter's opinion on the determination of the MACT floor. In a March 9, 1994, Federal Register notice reopening the public comment period for determination of the MACT floor for NESHAP source categories (59 FR 11018), the Agency considered more than one interpretation of the statutory language concerning the MACT floor for existing sources and solicited comment on them. After consideration of the comments received in response to this request, the Agency published a final rule in the Federal Register on June 6, 1994, (59 FR 29196). In this final rule, the Agency determined that the MACT floor would be determined by averaging the best performing 12 percent of sources. This was the method followed in determining the MACT floor in the proposed rule and is the

method being used in determining the MACT floor in the final rule. In this notice, the Agency left open the use of the 94th percentile in cases where the average does not match a control technology.

Regarding the commenter's concern about use of the 94th percentile (median value) for determining the MACT floor, a discussion in Section 2.2.6 of additional data supplied by a commenter for area source aeration room vents indicates the MACT floor for existing area source aeration room vents is controlled. In the final rule, the MACT floor is determined based on a mean rather than a median value.

2.2.2 Technology Neutral MACT

Comment: Several commenters (08, 17 and 18) supported EPA's approach in determining MACT as technology neutral. One of these commenters (18) supported this flexibility because it would provide implementing agencies the authority (through delegation under Subpart E) to approve or deny the selected technology. Another of these commenters (17) stated that it was acceptable to allow sources to select their control methods provided they meet a specified percent reduction, which gives industry flexibility as well as an incentive to develop new control technologies. This commenter added that this flexibility must be accompanied by a mandate to sources to meet a strong performance standard.

One commenter (18) recommended that the language of § 63.362(a) should be revised to require control of ethylene oxide emissions from the sterilization chamber vent with an approved abatement device and then specify the performance of the device.

Response: The Agency appreciates the support for the development of these emissions reduction and emissions limitation standards. The Agency does not believe that it is necessary to require equipment-based standards such as one of the commenters recommends for sterilization chamber vents. The Agency has selected emissions reduction standards that provide the owner or operator the flexibility to choose how to achieve the required emissions reductions.

2.2.3 MACT Considerations for Sterilization Chamber Vents

Comment: Six commenters (10, 11, 13, 15, 18, 19) suggested that more stringent control requirements for the MACT standards are appropriate. One commenter (19) stated that they disagree with EPA's belief that there is little or no practical difference between a 99 percent control requirement and a 99.9 percent control requirement, because either standard would compel use of the same general type of control device and that the device, in actual practice, would achieve whatever reductions it is capable of, regardless of the numeric standard. The commenter asserted that a more stringent standard would lead to better operation and maintenance practices that would enhance the degree of emissions reductions achieved. The commenter stated that EPA has not set the standards based on information available from control device vendors regarding the efficiency of their control devices. The commenter referred to information from vendors indicating greater than 99.9 percent control from catalytic oxidation units. The commenter stated that based on this information and information in the BID, the final standard require 99.9 percent emissions reduction using catalytic oxidation for new sources.

One commenter (11) supplied information for sterilization facilities that indicated an emissions reduction of 99.9 percent from the sterilization chamber vent. The commenter was aware of 29 industrial units operating at this level of efficiency. One commenter (10) identified two major sources and three area sources above 1 ton/yr controlling sterilization chamber emissions by at least 99.8 to 99.9 percent. The commenter suggested that EPA contact these and other manufacturers to validate their claims and consider a higher control efficiency requirement for the sterilizer vent. The commenter stated that all sources in New York with an emissions rate potential greater than or equal to 1.0 lb/hr are required to install 99 percent control or greater or best available control technology (BACT). One commenter (15) stated that the proposed 99 percent control efficiency for sterilization chamber vent emissions is not stringent enough nor is it consistent with the requirements of

new source MACT. One commenter (18) recommended that EPA adopt a 99.9 percent level of control for existing sources subject to the NESHAP as is the case in California. The commenter stated that new source MACT for sterilization chamber vents should be set at 99.99 percent emissions reduction as this level of reduction has been shown in the BAAQMD.

One commenter (13) added that air permits issued recently in New Jersey have required a destruction efficiency of at least 99 percent, however, the annual emissions from some facilities meeting the minimum destruction efficiency requirement may be subject to additional control measures, such as improved dispersion and higher efficiency control, because of the carcinogenic risk of ethylene oxide.

Response: These NESHAP were based on the technological state of achieved emissions control (i.e., MACT for major sources, MACT and GACT for area sources). The Agency appreciates the submittal of data. Regarding the commenters' view on the establishment of the MACT floor at 99 percent emissions reduction for sterilization chamber vents, the Agency notes that the information submitted by commenters was not sufficient to demonstrate that an emissions reduction of 99.9 percent could be achieved on a continuous basis. The Agency therefore does not believe that a reassessment of MACT for the sterilization chamber vent is technically defensible. The Agency believes that the control technologies in use at the facilities the commenter is referring to (i.e., facilities achieving 99.9 percent control) are the same technologies that will be used at facilities required to meet the 99 percent standard.

Comment: One commenter (04) suggested that the use of thermal oxidizers should also be considered MACT for sterilizer chamber vents. The commenter noted that it was aware of several facilities that are using this technology to control chamber vents and that field test data from these units have demonstrated 99 percent removal efficiency as long as a stable flame is present, regardless of stack temperature.

Response: The MACT for sterilization chamber vents is 99 percent reduction of ethylene oxide emissions and is technology neutral; an owner or operator may comply with MACT by use of any technology capable of meeting the 99 percent emisson reduction efficiency. The Agency agrees that thermal oxidizers meet the reduction efficiency and has included compliance provisions for thermal oxidizers in § 63.363. The requirements of this technology are similar to those for the catalytic oxidizers; monitoring requirements are included in Section 2.4.4.

2.2.4 Role of Risk

Comment: Five commenters (10, 13, 15, 17, 19) indicated that the resulting risk from the proposed rule is unacceptable. One of these commenters (19) asserted that more stringent standards would be justified because of the extreme toxicity of ethylene oxide. This commenter also suggested the establishment of a lesser quantity cutoff [i.e., a lower emissions cutoff, because the term lesser quantity cutoff is specific to lowering of the 10 tons major source cutoff] for area sources due to the health evidence for ethylene oxide [below 1 ton/yr]. Another commenter (10) stated that the State of New York regulates all ethylene oxide emissions points under 6NYCRR Part 212 as a high toxicity contaminant. The commenter added that because of the hazardous health effects associated with exposure to small concentrations of a high toxicity contaminant, emissions points that release from 0.1 to 1.0 lb/hr are also required to install controls, and controls may be required for emissions rates less than this. This commenter provided modelling data indicating risk factors and cancer incidences for New York facilities that would result from the proposed rule:

1. For sterilization chamber vent sources with less than 1 ton/yr ethylene oxide emissions, the short-term effect results in an impact over 32,400 μg/m3 and the cancer risk for an uncontrolled 1 ton source of ethylene oxide was estimated to be over 200 in 1 million;

2. The risk factor and cancer incidence resulting from the 5,300 ppmv limit on the chamber exhaust vent are over 144,000 μg/m3 and 1 in 500, respectively;

3. The risk factors and cancer incidences resulting at a 10 tons source from the overall proposed rule include a short-term modelled impact for the three combined emissions points of over 900 μg/m3 and a cancer risk estimated to be 1 in 3,500; and

4. The short-term impacts for a source not covered by the NESHAP range from 650 to 900 μg/m3 and the cancer risk was estimated at 40 in 1 million.

Another commenter (13) stated that the New Jersey Department of Environmental Protection and Energy regulates ethylene oxide emissions as VOC's and further requires that the incremental risk of cancer posed by new and modified equipment is no more than 1 in 10,000 and preferably less than 1 in 1,000,000. This commenter estimated risk factors for EPA's proposed chamber exhaust standards and stated that this would amount to 40 lb/yr (from a facility using the least amount of ethylene oxide addressed by these standards), which for many facilities would pose more than 1 in 1 million increased cancer risk. This commenter suggested that emissions from the chamber exhaust should be controlled at major sources because of the risks posed by the amount of ethylene oxide uncontrolled from this vent. The commenter suggested that a lower concentration of about 1,000 ppmv be considered for the chamber exhaust vent standards.

One commenter (15) stated that the impacts are unacceptable without controls on aeration emissions. This commenter stated that ethylene oxide emissions in excess of 100 lb/yr result in unacceptable impacts and another (17) stated that emissions of ethylene oxide less than 1 ton/yr can pose a substantial health risk.

Response: The Agency has considered the data submitted by commenters regarding the risk of ethylene oxide related to the regulation. While risk may be considered in some determinations related to this rule, such as including area sources on the

source category list, it is important to note that these NESHAP are technology-based standards and are determined by the maximum emissions reduction achieved in practice, not by risk assessment. Therefore, statements requesting that MACT be more stringent due to the risk impacts from ethylene oxide are not appropriate. In addition, the Agency is required to consider MACT for area sources but may elect to require GACT if MACT is unreasonable. Where appropriate, the Agency has considered the health effects of ethylene oxide in conjunction with cost effectiveness. Risk for sources below 1 ton/yr and for aeration room vents at affected area sources greater than 1 ton/yr were calculated by the Agency and were not determined to be significant when considered in conjunction with cost effectiveness. While the Agency appreciates the information submitted by commenters indicating high risk impacts associated with the standards, the EPA is not certain of the methodologies used to calculate the submitted risk information and did not receive sufficient information that supports the commenters' statements regarding risk for each of the emissions points.

The Agency also notes that it is required to focus on the remaining risk from emissions not subject to the NESHAP. After implementation of these NESHAP for the source category, the Agency will examine the residual risk for major sources and area sources subject to MACT for this source category under § 112(f) of the amended Act. The Agency will then promulgate standards if necessary to reduce excessive risks.

2.2.5 Consideration of State and Local Regulations

Comment: Five commenters (10, 16, 17, 18, 19) suggested EPA consider State and local regulations in MACT determinations. One commenter (19) stated that EPA's proposed standards for major and area sources are inadequate because they exempt certain emissions points from control and because the standards for the emissions points that are regulated do not reflect "maximum achievable control technology" as required by the Clean Air Act. The commenter stated that EPA should consider State and local regulations when identifying MACT and the MACT floor. The

commenter added that a consideration of State and local standards would compel EPA to lower applicability levels, increase the stringency of the emissions limits for major and area sources for aeration rooms, sterilizer vents, and to control chamber exhaust vents and other emissions points. This commenter disagrees with EPA's position that standards may not be established without emissions reduction data regardless of State and local regulations.

Several commenters (16, 17 and 19) stated that the best controlled similar sources for ethylene oxide sterilization and fumigation are those facilities in the State of California that are currently meeting the requirements of CARB's ATCM and AQMD's Rule 1405. The commenters suggested that the MACT floor for new and existing sources be revised to reflect a higher destruction efficiency (the commenter submitted a copy of AQMD Rule 1405 and the respective control technologies and emissions cutoffs). One commenter (16) suggested that EPA adopt more stringent levels such as those currently being implemented and enforced in California. The commenter added that this is feasible and cost effective as evidenced by the commenter's experience (the commenter stated that data are available to support this suggestion). One commenter (19) indicated California State and local regulations that require more stringent controls than those required under the proposed regulation. The commenter stated that a review of State and local aeration room vent standards would compel EPA to regulate aeration room emissions from area sources (the commenter noted California State and local regulations). The commenter also referred EPA to SCAQMD for emissions reduction data on chamber exhaust control devices. The commenter recommended that controls be required for chamber exhaust vents at major and area sources because California requires controls of this vent at facilities using more than 600 lb/yr of ethylene oxide. Another commenter (18) stated that because BAAQMD regulations require control of chamber exhaust vents at sources using more than 600 lb/yr of ethylene oxide, the

NESHAP should be revised to include these controls at least for new sources.

One commenter (10) stated that EPA has failed to consider New York's program when determining the MACT standard for ethylene oxide commercial sterilization. The commenter stated that the State of New York maintains a Source Management System (SMS) data base of 79 facilities with ethylene oxide sterilizers; EPA did not evaluate the MACT standard and the 12 percent MACT floor using New York's current data base. The commenter stated that failure to use current data neglects sources located and controls required for ethylene oxide sources in New York in recent years.

Response: The standards for this source category were based on the data available to the Administrator at the time of proposal and on data submitted by commenters after proposal. Section 112(d)(3) of the Act states that MACT emissions limitations are based on the "best performing . . . existing sources . . . for which the Administrator has emissions information." The Agency developed a nationwide commercial sterilization data base that it believes accurately represents commercial ethylene oxide sterilization and fumigation operations on a national basis (commenters submitted additional data regarding control of area source aeration room vents and major source chamber exhaust vents and this information was incorporated into the data base, see Sections 2.2.6 and 2.2.7, respectively). This data base was used in determining MACT floors for the emissions points addressed in the NESHAP and includes information on 13 New York and 19 California commercial ethylene oxide sterilization and fumigation operations. The Agency appreciates notification that a State data base is available.

The EPA did consider State programs in determining these standards. In regard to the emissions reduction required for sources in New York and California, the Agency appreciates the information and believes that it supports the Agency's findings of the level of control at the MACT floor. The statement that

there are 79 facilities with ethylene oxide sterilizers in New York does not necessarily correspond with the Agency's data base because the Agency is uncertain whether this figure represents sterilization units at facilities that are not addressed under these standards (e.g., hospital sterilization facilities). Because the standards in the final rule require the same minimum level of control as the New York State requirements (99 percent emissions control for the sterilization chamber vent, a maximum emissions concentration of 1 ppmv ethylene oxide for the aeration room, and a control requirement or an emissions limit for the chamber exhaust vent), the Agency does not see where its determination of MACT has not considered these facilities. The California control requirements include a 99 or 99.9 percent control efficiency for the sterilization chamber vent depending on the size of the source and a 95 or 99 percent control requirement for the aeration room vent depending on the source size. The Agency has not received sufficient information to demonstrate an emissions reduction of 99.9 percent on a continuous basis. The California regulation also requires combined control of the aeration room vent and the chamber exhaust vent for sources greater than 2.5 tons/yr ethylene oxide usage but does not require source testing to confirm the emissions reduction achieved continuously. The New York and California requirements do apply to commercial ethylene oxide sterilization and fumigation operations using smaller amounts of ethylene oxide, i.e., nonmajor sources, but it is the prerogative of any State to be more stringent than Federal emissions standards.

2.2.6 <u>MACT and GACT Considerations for Aeration Room Vents</u>

<u>Comment</u>: One commenter (18) recommended that sources using at least 20,000 lb/yr [10 tons/yr] of ethylene oxide be required to reduce aeration room vent emissions by 99 percent or to 1 ppmv, whichever is more stringent, and that emissions below the detection limit of the test be considered in compliance. One commenter (17) stated that because the 1 ppmv emissions limit can be circumvented by increasing the air flow through the vent,

sources required to meet the standard should be required to meet a <1 ppmv concentration and 99-percent control requirement, so that the more stringent limit prevails.

One commenter (14) stated that the standard as written would not allow use of one piece of equipment to control both the sterilizer vent and aeration room vent emissions, i.e., if there are simultaneous emissions from both vents, it may not be possible to show that aeration room vent emissions are controlled to less than 1 ppmv. Use of a catalytic oxidizer will give 99 percent control of aeration room vent emissions, which typically are less than 50 ppmv, so that controlled emissions will be under the 1 ppmv limit. However, given that sterilizer vent emissions, which may be several thousand parts per million, are also controlled, total emissions from a combined control system may be greater than 1 ppmv even with overall 99 percent control.

Response: The Agency proposed a 1 ppmv emissions limit for major source aeration room vents because the inlet concentrations from the aeration room vents are typically relatively low and because the outlet concentrations of some of the controlled aeration room vents approach the levels of detection for ethylene oxide and would preclude a demonstration of compliance with an "equivalent" percent reduction standard (i.e., the control device is achieving 99 percent reduction and the outlet concentration is below the detection limit). The commenters' suggestion to require the more stringent limit or reduction for this emissions point is not technically feasible for sources with low ethylene oxide concentration because the outlet may not be detectable.

While the inlet concentration for most aeration room vents alone is typically less than 100 ppmv, the inlet concentration to the control device for some aeration room vents, especially those manifolded with other vents such as the chamber exhaust vent, may be greater than 100 ppmv. If a control device used to control these emissions is operating at 99 percent efficiency, then such a source would not meet the 1 ppmv standard for this emissions point. The final rule therefore provides additional flexibility

for facilities by allowing owners or operators of major sources to control emissions from aeration room vents either to a maximum outlet concentration of 1 ppmv or a 99 percent reduction of the inlet concentration, whichever is less stringent. There has been no change in the level of the standard for major source aeration room vents since proposal; the percent reduction and the concentration limit are equivalent requirements.

Comment: Eleven commenters (03, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19) indicated that control requirements for area sources are not appropriate. One commenter (10) believed that risk should be considered when determining whether to apply MACT or GACT to area sources. Two commenters (16 and 19) suggested that MACT standards be used for new area sources as well as for existing area sources. One of these commenters (16) stated that they have annual source test results to support this recommendation and stated that the availability, feasibility, and cost effectiveness of controls have been demonstrated in the South Coast Air Basin. One commenter (13) stated that the proposed control requirements for area sources (i.e., MACT for existing area sources and GACT for new area sources) [aeration room vents] appear to be applied contrary to the method expected. The commenter added that this leads to the standards for new sources being less stringent than the standards for existing sources, which is the reverse of common practice. The commenter recommended that the same emissions standards be applied to both new and existing area sources. The commenter suggested that MACT be applied to area sources, with less stringent requirements for recordkeeping and reporting than for major sources. One commenter (11) suggested that EPA recalculate the best performing 12 percent MACT floor for area sources.

Four commenters (03, 11, 17, 18) indicated that the regulation for aeration room vents should apply to sources having emissions less than 10 tons/yr. One of these commenters (03) indicated that all facilities should be required to control emissions from the aeration room vent and indicated that some States do require control of this vent. One commenter (15)

suggested that all regulated sources be required to control both aeration and sterilizer exhaust emissions. The commenter stated that such controls have been required in Rhode Island for commercial sterilizers. One commenter (13) suggested that aeration room vent emissions be directed through the sterilizer control device. The commenter stated that the acid-water scrubber should be effective at this low concentration but questioned if catalytic oxidizers would be effective. One commenter (12) constructed an acid-water scrubber for combined control of sterilization chamber and aeration room vents. One commenter (10) indicated that one catalytic oxidizer at a New York facility controls both the sterilizer vents and aerator exhaust.

Another commenter (17) recommended a 1 ton/yr emissions cutoff for regulation of aeration rooms and also indicated that several State and local agencies have adopted this cutoff, proving that such measures are feasible and cost effective. The commenter added that this cut-off would be more protective of public health. This commenter also stated that aeration room vents should be controlled by 95 to 99 percent at new sources using 600 lb/yr [0.3 ton/yr] or more. One commenter (18) recommended that sources using between 600 lb/yr and 5,000 lb/yr [0.3 to 2.5 tons/yr] of ethylene oxide should be required to reduce emissions from the aeration room vent by 95 percent; facilities using more than 5,000 lb/yr [2.5 tons/yr] of ethylene oxide should be required to control aeration room vent emissions by 99 percent.

Two commenters (11, 14) indicated manifolded control for the aeration room vent would be cost-effective. One commenter (11) suggested an emissions cutoff of 5,000 lb/yr [2.5 tons/yr] and indicated that this level has been adopted in several States. This commenter indicated that control of the aeration room vent would be appropriate because one catalytic oxidation unit can control the aeration vent as well as the sterilization chamber vent, and the capital burden to the facility would therefore be minimal. The commenter added that increases in cost would come

in the form of higher operating costs due to the continuous operation of the emissions control equipment. This commenter further stated that if the facility is utilizing heated aeration cells, cost can be further mitigated by reclaiming waste heat for the aeration rooms from the catalytic process. This commenter submitted information on 36 facilities utilizing catalytic oxidation for the control of aeration room emissions to a minimum level of 99 percent reduction. The commenter stated that many of these facilities are below the 20,000 lb/yr [10 tons/yr] ethylene oxide use limit and suggested that EPA correlate emissions levels using their existing data base and reevaluate the aeration room vent MACT floor.

One commenter (14) stated that the total national cost of controlling ethylene oxide emissions would be reduced by the use of manifolded controls for sterilizer and aeration room vents. The commenter stated that the cost of a manifolded control system would be much less than the $600,000 cost estimate made by EPA for separate controls at such a facility. This commenter stated that the proposed standard does not take account of the possibility of using one piece of equipment to control both sterilizer vent and aeration room vent emissions. The commenter added that even though one piece of equipment can control emissions from both points at a lower cost than two separate devices, the standard as written would preclude this alternative which is being offered commercially today. The commenter suggested that the final rule expressly allow the use of manifolded controls in order to provide the opportunity for lower compliance cost and improved cost effectiveness. The commenter stated that such a manifolded device would greatly reduce the costs of control as estimated by EPA in the preamble and background information document.

Response: All sources emitting less than 1 ton/yr of ethylene oxide will continue to be exempt from the emissions limits of this regulation (see Sections 2.1.2 and 2.2.4). For affected area sources, the Administrator stated in the preamble to the proposed rule that if commenters supplied data to indicate

that existing area sources are controlling aeration room vent emissions and that there is a controlled MACT floor, MACT would be rejected and GACT selected based on cost effectiveness, as provided for in § 112(d)(5) of the amended Act. Given that the cost effectiveness is high, rejection of a MACT standard that would require aeration room vent control in favor of a GACT standard with no control would alleviate this cost burden for area sources. The Agency believes that the costs associated with requiring controls on aeration room vents at area sources are prohibitive after consideration of the emissions reduction achieved by such controls.

While the Agency agrees with the commenters regarding the attractiveness of manifolded control devices for some vents, in some cases it may not be possible to manifold an additional emissions vent type. Control devices are typically designed to control a specific vent, such as packed-bed scrubbers for the sterilization chamber vent. The Agency does not believe that combined control for the aeration room vent is feasible at all sources and has not received information demonstrating that the high flow rate and low concentrations typical of aeration room vent emissions may be easily combined with an existing control device. While several of the commenters suggested that combined control for the area source aeration room vents provides lower costs, the EPA does not believe it is appropriate to base its cost estimates on a manifolded system for this vent since this approach may not be an option for all existing sources. In addition, the cost for aeration room vent control includes not only the necessary ducting to a control device if manifolding is feasible but also the cost to construct a new aeration room if the source is not currently controlling these emissions. It has also been suggested by commenters that the aeration room vent emissions be combined with emissions from the chamber exhaust vent, but the MACT floor for chamber exhaust vents at area sources remains at no control (see Section 2.2.7). While the Agency has required control of major source chamber exhaust vents and has received information that emissions from this vent are

commonly combined with emissions from other vents, in general, the only costs for controlling the chamber exhaust vent at major sources are attributable to ducting.

The commenters submitted sufficient data to enable the Agency to reassess the MACT floor for aeration room vents at existing area sources. The MACT floor for existing sources in the final regulation is controlled. However, data received from commenters were not sufficient to allow the Agency to alter its cost-effectiveness calculations associated with controlling emissions from the aeration room vents of existing area sources. Due to this high cost effectiveness, MACT has been rejected and GACT selected for existing aeration room vents in the final rule. The final rule therefore applies GACT to both existing and new area sources and does not require reduction of emissions from aeration room vents. Control of only the sterilization chamber vents (99 percent emissions limitation) is required for area sources.

Comment: One commenter (13) stated that applying GACT rather than MACT may exempt new area sources from operating permit requirements. The commenter stated that if GACT is chosen for new area sources, it should be applied to existing area sources also, to avoid the confusion of some sources in a category being exempt from operating permits on the basis of their construction date. If MACT is chosen then both existing and new area sources could be covered by a model "General Permit," which would streamline the paperwork to obtain an operating permit, along with a 5-year extension of operating permit requirements.

One commenter (18) recommended that EPA exempt area source sterilizers from Title V permits because limited benefits would be expected from the periodic review of these permits for this source category. The commenter added that in the event EPA chooses to regulate sterilizers using less than 1 ton/yr, Title V permits should not be required.

Response: Regarding the application of the Title V operating permit program to area sources, the final rule for the

operating permit program promulgated on July 21, 1992 (57 FR 32250) states that "... any other source, including an area source, subject to a hazardous air pollutant standards under section 112..." is an affected source required to comply with the Part 70 operating permit requirements. The final rule later specifies that the Part 70 permitting program will be used to implement standards for area sources developed using GACT. The Agency therefore believes that no confusion will result from regulation of area sources with either MACT or GACT. In regard to the commenter's request for an extension of the permit requirements, the Agency believes that the 5 year extension for nonmajor sources contained in Title V would be appropriate.

Comment: Four commenters (10, 13, 18, 19) expressed concern regarding the role of § 112(f) in determining the applicability of MACT or GACT to area sources. One commenter (18) stated that area sources should be regulated under MACT because such sources should be subject to later review under § 112(f). Another commenter (13) stated that avoiding the application of § 112(f) (residual risk analysis) should not be a factor in deciding to exempt area sources from MACT because smaller sources can often pose a high risk, especially with a pollutant like ethylene oxide. One commenter (10) stated that § 112(f) should be considered when deciding whether to select MACT or GACT for an area source category. Another commenter (19) also suggested that the residual risk analysis requirements of § 112(f) should be considered when determining whether MACT or GACT should apply to area sources when they asserted that the setting of GACT standards for area sources would weaken protection from ethylene oxide exposure and would remove these sources from consideration under the residual risk analysis required by § 112(f).

Response: The Agency is required to examine the residual risk under § 112(f) of the Act for major sources and for area sources regulated by MACT. The Agency has not attempted to avoid the requirements of § 112(f) in its determinations to apply GACT to area source aeration room vents in this source category, as one commenter suggests. While the Agency is required to examine

area sources regulated by MACT, the Agency notes that it may also choose to examine the residual risk for area sources subject to GACT as well. Therefore, area sources subject to GACT may be included in the residual risk study and § 112(f) standards may be promulgated for these area sources as well as for those subject to MACT.

2.2.7 MACT for Chamber Exhaust Vents

Comment: Nine commenters (03, 06b, 10, 11, 13, 14, 17, 18, 19) suggested controlling emissions from the chamber exhaust vent. One commenter (17) stated that they were aware of facilities that are required to vent the emissions from the chamber exhaust vents to the control device. One commenter (13) suggested that emissions from the chamber exhaust should be controlled at major sources because of the risks posed by the amount of ethylene oxide uncontrolled from this vent. The commenter suggested that a lower concentration of about 1,000 ppmv be considered for the chamber exhaust vent standards. A commenter (19) referred EPA to SCAQMD for emissions reduction data on chamber exhaust control devices. The commenter recommended that controls be required for chamber exhaust vents at major and area sources because California requires controls of this vent at facilities using more than 600 lb/yr of ethylene oxide. Another commenter (18) stated that because BAAQMD regulations require control of chamber exhaust vents at sources using more than 600 lb/yr of ethylene oxide, the NESHAP should be revised to include these controls at least for new sources. A commenter (03) indicated that the Puget Sound has facilities that control emissions when the sterilization chamber door is opened and including small sources where chamber exhaust vents are routed to the control device. One commenter (06b) stated that they already have two catalytic oxidizers in place that utilize the combined feed of aeration and sterilizer vacuum pump [chamber exhaust vent] flows and that combining sterilizer exhaust and aeration exhaust reduces the use of clean-burning natural gas, a nonrenewable energy source. One commenter (10) stated that the chamber exhaust and the aerator exhaust, which are similar in

nature, could be vented to a single control device. This commenter stated that chamber exhaust vent emissions could be combined with aeration exhaust and routed to a single control device even though they are unaware of a facility so-controlled. One commenter (15) suggested that all regulated sources be required to control both aeration and sterilizer exhaust emissions. The commenter stated that such controls have been required in Rhode Island for commercial sterilizers.

One commenter (14) noted that relatively inexpensive control of chamber exhaust vent ethylene oxide emissions should be possible through the use of a single piece of equipment to control the emissions from multiple points. The commenter suggested that the chamber exhaust vent could be manifolded to the control device used to control either sterilization chamber or aeration room vent emissions; use of such systems should provide additional emissions reductions for small marginal increase in total costs and thus with reasonable cost effectiveness. The commenter suggested that EPA reconsider its rejection of regulatory alternative A, which required 99 percent reductions in chamber exhaust vent emissions at major sources.

One commenter (11) supplied information on 32 systems where emissions from the chamber exhaust or door hood were controlled to a minimum level of 99 percent. The commenter suggested that the MACT floor requirements be changed for both major and area sources to control sterilizer chamber exhaust vents to a level of 99 percent by either directing the emissions to the control device or by introducing further cycle/process changes to reduce the in-chamber concentration to below 5,300 ppmv by conducting further sterilizer evacuations which would be controlled by the sterilizer vent emissions control device. This commenter requested that the emissions cutoff for regulation of exhaust chamber vents be lowered to 5,000 lb/yr [2.5 tons/yr]. Another commenter (10) stated that the MACT standard for chamber exhaust vents should include the number of air washes, including the vacuum, residence time, and temperature associated with these air washes, required prior to opening the sterilizer chamber door.

Response: The Agency agrees with the commenters regarding the attractiveness of manifolded control devices for controlling ethylene oxide emissions for some emissions points. The Agency appreciates the commenter's submittal of data indicating that manifolding is practiced for the chamber exhaust vent. The data were sufficient in detail to allow a reassessment of the MACT floor for the chamber exhaust vent at major sources. At least six chamber exhaust vents at major sources are controlled by manifolding the vent to the aeration room vent or sterilization chamber vent control device when a catalytic oxidizer is used. The Agency contacted the commenter for additional information and has incorporated the data into the commercial sterilization data base. The MACT floor for major source chamber exhaust vents in the final regulation is control by ducting this vent to a control device for the sterilization chamber or aeration room vent or venting to a dedicated control device achieving 99 percent emissions reduction. A specific manifolding or venting scenario for control of this vent has not been specified because the Agency believes that the owners or operators of a particular source are best able to determine the most efficient way to comply with the standards.

The MACT floor for area source chamber exhaust vents remains unchanged since proposal at no control. While the level of the standard at area sources has not changed, an addition has been made to the requirements to provide flexibility to facilities. Area sources may comply with the ethylene oxide concentration limit as was proposed or may comply with a 99 percent emissions reduction for chamber exhaust vent emissions that are vented to a control device (either manifolded to a control device for sterilization chamber vent emissions or vented to a dedicated control device).

The Agency is providing additional flexibility to sources in demonstrating compliance with the standards in the final rule and has included language that provides alternative monitoring requirements and compliance provisions for controlled chamber exhaust vents and aeration room vents. The Agency has provided a

mechanism for sources choosing to manifold vents or vent types to demonstrate compliance with the standards but believes that one approach should not be endorsed or preferenced over another. The final rule allows a source to demonstrate compliance for either the chamber exhaust vent or aeration room vent through parametric monitoring of the performance of a control device. Whether the control device is manifolded to other vents or vent types is immaterial to the compliance demonstration, provided that the conditions for demonstrating compliance are met.

2.3 COMPLIANCE DATES

Comment: Three commenters (04, 05, 12) suggested the compliance date should be 3 years after the effective date; one commenter (04) indicated that a compliance date of 3 years was originally stated in the draft proposed rule available on the EPA Technology Transfer Network. Two of these commenters (04, 05) stated that 2 years would not be enough time for many companies to complete material and process evaluations and to obtain regulatory approval associated with investigating and converting to alternative sterilization methodologies. Another of these commenters (12) indicated that 2 years would not be enough time to: (1) design a system for the aeration cells that will comply fully with the new standard, (2) obtain bids, (3) build the necessary control equipment and associated auxiliary systems, (4) install the system in such a way that it minimizes down time, and (5) start up and debug the system. This commenter provided the following schedule: (1) research available technology and systems--6 to 8 months; (2) prepare and submit permitting requirements--3 months; (3) receive approval for construction permit from the State--8 months; and (4) order systems, complete facility modifications, installation, and debugging the system--12 to 15 months. This schedule indicated a total of 29 to 34 months for completion.

One commenter (19) stated that the compliance date should be shortened to 1 year after the effective date. The commenter stated that industry has been provided a great deal of notice that emissions would be regulated, and that industry

representatives indicated during hearings for the California regulation development that controls would be operable within 1 year.

Response: The Agency agrees with several of the commenters that the compliance time frame for ethylene oxide commercial sterilization and fumigation facilities should be extended. The EPA recognizes that some of the facilities within the source category will have to investigate and install control devices at their facility to meet the standards. Also, some sources may wish to investigate alternative sterilization methods. Based on reasons presented by some of the commenters, EPA has extended the compliance date to 3 years after the promulgation date for all sources subject to this rule. The extension of the compliance date is appropriate and should not result in adverse effects on the environment because several large emitters, i.e., major sources, are already well-controlled. At the same time, the extension provides smaller, less well-controlled sources additional time to achieve compliance. The EPA believes that the 3 year timeframe will address these commenters' concerns and still ensure implementation of controls in a timely fashion. New sources with startup after the 3 year compliance date will be required to comply with the emissions standards upon startup of the source.

2.4 MONITORING REQUIREMENTS

2.4.1 Initial Performance Testing

Comment: One commenter (18) stated that the conditions during the initial compliance test for the sterilization chamber vent do not reflect standard operating conditions; this presents problems for both of the referenced control technologies.

Two commenters (17 and 18) stated that EPA should reconsider the determination of a temperature baseline for catalytic oxidizers because there will be significant differences in the temperature responses exhibited during the compliance tests (run on an empty chamber) and actual operation with material present in the sterilization chamber. The commenters recommended that EPA review actual source test data for a variety of different

sterilizers, running with no load and with a full load, to determine the impact these variables are likely to have.

Response: The Agency believes that the conditions specified during the initial compliance test primarily affect the concentration of ethylene oxide being delivered to the control device. Although the concentration of ethylene oxide may be different from standard operating conditions, the differing amount is not expected to preclude the control device from meeting the standard. The conditions for the initial test (i.e., empty chamber) were specified to eliminate interference from product retention of ethylene oxide.

For sterilization chamber vent emissions controlled with oxidation units, two initial compliance tests will be performed on the sterilization chamber vent: one during the first evacuation of the sterilizer chamber to demonstrate that the control device is designed properly and one during the last evacuation to establish the appropriate baseline temperature. During the compliance test for the first evacuation, the owner or operator should deliver the same mass of ethylene oxide to the chamber as would be used for typical operation. Demonstration of the baseline temperature during the last evacuation addresses concerns that a baseline temperature established during the first evacuation would not be sustainable for subsequent evacuations where the ethylene oxide concentration is lower. For an oxidation unit, the temperature will not elevate as significantly with the lower concentration in the last evacuation, and an appropriate baseline temperature will be determined. Because an additional compliance test has been added at the final evacuation where inlet concentration is lower, the final regulation permits sources to demonstrate compliance with the standard during the performance test for the last evacuation if the outlet concentration is below the detection level of ethylene oxide when the inlet concentration is approximately 50 ppmv or lower; the source must be able to demonstrate the inlet concentration.

The initial compliance test for the chamber exhaust vent will be performed with procedures similar to those used for the

performance during the last evacuation of the sterilization chamber. Use of a low ethylene oxide concentration that allows demonstration of the emissions reduction achieved during the performance test will provide a baseline temperature applicable to all chamber exhaust vent cycles. As explained above for the last evacuation for the sterilization chamber, the final regulation permits the source to demonstrate compliance with the standard if the outlet concentration is below the detection limit for ethylene oxide and the inlet concentration is approximately 50 ppmv or lower.

The Agency believes that the revised monitoring requirements in the final rule are not adversely affected by the conditions during the initial compliance test and that these conditions enable correct measurement of the emissions reduction achieved by the control devices and the setting of monitoring parameters to assure future compliance with the standards.

Comment: One commenter (18) stated that requiring the ethylene glycol solution to be maintained at the average concentration recorded during the initial source test is unreasonable and may present practical difficulties for the source. The commenter stated that because sources could perform at a level substantially above the required 99 percent control during the initial test, the actual performance could fall off by as much as two orders of magnitude before the source would be controlled to less than 99 percent, but if parametric monitoring showed departure from the established baseline, the source could be found in violation. The commenter recommended that the baseline for the parameters be set when the source is operating at the compliance level or an appropriate range should be established.

Two commenters (03, 17) stated that the proposed compliance determination and monitoring requirements for acid-water scrubbers would require a facility to determine the maximum concentration of ethylene glycol in the scrubber liquor under a "worst-case" situation. One commenter (17) stated that the sterilization chamber vent monitoring requirements for acid-water

scrubbers may not be appropriate because the baseline established during the initial performance test may be derived when the source is achieving greater control efficiency than is required under the standards. The commenter added that as the equipment ages, a degradation of the control may be experienced such that the monitored parameter may show noncompliance with the standard when in fact, the source is still in compliance. The commenter requested that if parametric monitoring was to be implemented for these controls, the baseline must correspond to the required level of control, not a higher level.

Two commenters (11 and 16) suggested that annual performance testing be required (in addition to the initial performance test) as part of the monitoring requirements for the standards. One commenter (19) stated that the final rule should include more frequent performance testing of control equipment to prevent deterioration of the control equipment.

Response: The Agency has incorporated monitoring requirements into the proposed and final regulations that provide a continuous determination of compliance with the standards. The underlying principles for these monitoring requirements are that the parameters monitored (where parametric monitoring is used) are to be a direct indicator of compliance. Under the final rule, limits for monitored parameters will first be established during an initial performance test and will be monitored thereafter. In the interest of reducing the costs to affected facilities, additional (e.g., annual) compliance tests are not required under the final rule. The Agency believes that an initial performance test of the control device is sufficient to establish the monitoring parameters needed for determining continuous compliance. However, the Agency offers the flexibility to a source to perform additional performance tests and reestablish new limits for monitored parameters at any time. The Agency believes that this flexibility will address the commenter's concerns about a source showing noncompliance with a higher emissions limit than is contained in the standard when the source is in compliance with the actual standard.

The final rule does not require that the ethylene glycol concentration be maintained at an average concentration established during the initial performance test. The ethylene glycol concentration established during the initial compliance test is a concentration not to be exceeded by the source. In determining the monitoring parameters for the acid-water scrubber, it would be advantageous for the owner or operator to do the initial performance test at the end of the liquor cycle when the ethylene glycol concentration is at the highest point that still provides a 99 percent reduction for the acid-water scrubber. Because the baseline parameter has been changed from an average value (e.g., maintain ethylene glycol concentration at the average baseline concentration) to a maximum or minimum value (e.g., maintain temperature below the minimum oxidation temperature), it is not necessary to specify appropriate ranges for these parameters as one commenter suggested.

2.4.2 Monitoring for Acid-Water Scrubbers

Comment: Eight commenters (03, 04, 05, 06a, 06b, 13, 17, 18) provided comments on the monitoring requirements for acid-water scrubbers. Several commenters (04, 05, 06b, 17, 18) stated that continuously measuring ethylene glycol concentration is not feasible, practicable, or necessary. Two commenters (03, 17) stated that the proposed compliance determination and monitoring requirements for acid-water scrubbers would require a facility to determine the maximum concentration of ethylene glycol in the scrubber liquor under a "worst-case" situation. One commenter (17) stated that ethylene glycol monitoring is not the best parameter to monitor to assure compliance with the sterilizer vent standards and that EPA should select a parameter other than ethylene glycol concentration or offer other parameters as alternatives. The commenter suggested that acid concentration is much easier to measure than ethylene glycol concentration and would be a better surrogate for scrubber performance.

One commenter (04) stated that acid-water control units operate on a batch basis with glycol concentration starting near

zero at the beginning of an operating cycle and increasing up to a predetermined maximum, at which time the glycol is removed and neutralized. The commenter added that makeup water is added, pH adjusted, and a new cycle begins. The commenter stated that enough acid is added at the beginning of each cycle to maintain the proper pH through the complete cycle. One commenter (13) stated that the proposed monitoring requirements for acid-water scrubbers (i.e., continuous monitoring of the scrubber liquor ethylene glycol concentration) for sterilization chamber vents seems excessive since the time between changes of the liquor is often several months. The commenter suggested the initial use of frequent monitoring to determine the rate at which the concentration increases in the liquor, followed by less frequent monitoring, especially if the maximum content of ethylene glycol is set safely below the level required to attain the desired level of efficiency. One commenter (05) stated that their facilities typically operate 3.5 months before approaching the manufacturers recommended ethylene glycol concentration limit. One commenter (06b) stated that a new batch of scrubber liquor requires a physical check of the system parameters and that only the ethylene glycol concentration would change gradually and predictably over the time that the batch fills the storage tanks; continuous or even hourly monitoring of glycol concentration would therefore not be needed. The commenter stated that facilities having typical scrubber units would not see changes in the ethylene glycol concentration of even 0.5 percent by weight per day of sterilization. The commenter added that to detect such relatively small changes in glycol concentration would require specific onsite gas chromatographic analysis that would cost over $15,000 and require special instrument training of hourly employees.

Two commenters (04, 05) stated that they knew of no means to continuously monitor acidified ethylene glycol concentration. One commenter (06a) questioned the ability of available technology to continuously monitor the ethylene glycol concentration in the scrubber liquor due to the sample matrix,

which is very acidic and contains other dihydric glycols which can interfere with accurate determinations of ethylene glycol. This commenter indicated that periodic determinations are achievable, providing adequate sample preparations are carried out in a laboratory.

Several commenters (03, 04, 05, 06b, 13, 17, 18) suggested alternate or modified monitoring requirements for acid-water scrubbers. The following alternatives were suggested:

1. Establish a maximum limit on the amount of ethylene oxide used or scrubbed (03, 17, 18), after which the scrubbing liquor must be changed (17);

2. Measure pH (17, 18) periodically or prior to scrubbing a batch of ethylene oxide (18);

3. Measure ethylene glycol concentration (05, 06b, 13) at the end of each week of operation (05) or less than continuously (06b, 13);

4. Monitor the level of the scrubbing liquid in the tank (17, 18) and establish a maximum tank level that correlates to an ethylene glycol concentration after which the liquor must be changed (17); and

5. Monitor all of the following: monitor gas flow rate or tower pressure differential, the liquid flow rate (or liquid height for reaction/detoxification units), and the liquid temperature; measure pH at the start and end of each operating cycle; and measure the ethylene glycol concentration at the end of each operating cycle (04).

One commenter (18) recommended that if ethylene glycol concentration is to be used as a surrogate parameter for scrubber efficiency, an acceptable range be established, based on a correlation between ethylene glycol concentration and scrubber performance. One commenter (03) indicated that monitoring the ethylene oxide usage would be a much easier method for sources and the regulatory community to implement. One commenter (04) stated that their recommendations for monitoring parameters provide more effective process control and assurance of compliance. The commenter also suggested that maximum or minimum

values for each parameter would be established based on manufacturers' recommended limits and verified during initial compliance testing.

Response: The Agency agrees with the commenters that the continuous monitoring requirements proposed for acid-water scrubbers are not necessarily appropriate. The Agency has carefully considered each of the suggested alternative monitoring scenarios submitted by the commenters.

One alternative monitoring parameter suggested by the commenters is tracking of ethylene oxide usage. The owner or operator would correlate the maximum ethylene oxide usage to the maximum ethylene glycol concentration that still provides a 99 percent emissions reduction for the scrubber. Implementing use of this parameter would require: (1) accurate recordkeeping of all ethylene oxide purchases and use, (2) determination of the ethylene oxide emissions split for each emissions point vented to the control device, and (3) determination of ethylene oxide retention properties for each product sterilized. The Agency does not believe this monitoring approach is appropriate due to uncertainty and variability associated with both the emissions split for each vent and the ethylene oxide retention rates of ethylene oxide for products sterilized. Tracking of ethylene oxide usage has not been included in the final regulation as a referenced monitoring parameter.

Several commenters suggested pH as an appropriate monitoring parameter for acid-water scrubbers. Monitoring the pH of the scrubber liquor is not technically feasible because the pH change over the life of the liquor cycle is typically not measurable. Because the Agency has not received sufficient data indicating that pH monitoring is an acceptable parameter for demonstrating continuous compliance, the Agency has not included pH monitoring as a referenced monitoring parameter in the final rule.

Continuous monitoring of ethylene glycol concentration to determine compliance has been refuted by commenters based on the small incremental changes in ethylene glycol concentration expected over the liquor cycle and the cost of analysis equipment

and employee training and time for performing the analysis on a continuous basis. The Agency has determined through contact with vendors and industry that ethylene glycol concentration is commonly used for compliance determination but agrees that continuous monitoring of ethylene glycol concentration is not necessary. Monitoring of the ethylene glycol concentration demonstrates that ethylene oxide from the vent outlets is being removed and converted to ethylene glycol in the scrubber liquor. Based on the slow change in concentration, the final rule requires monitoring of the ethylene glycol concentration once per week. With less frequent monitoring, it is possible for an affected source to sample the liquor and send to a laboratory offsite for analysis to avoid the cost for analysis equipment.

Monitoring of the scrubber liquor level in the tank was also suggested by commenters as an alternative parameter to monitor. The owner or operator would correlate the maximum level of liquor allowed in the tank to a maximum ethylene glycol concentration that still provides a control efficiency of 99 percent for the scrubber. The increase in mass (until total solution is 40 to 60 percent ethylene glycol by weight) and therefore volume in the scrubber liquor storage tank demonstrates that ethylene oxide from the vents is being scrubbed and converted to ethylene glycol in the scrubber liquor. The owner or operator must place liquid level indicators on the liquor storage tank; minimal employee time and training is necessary for monitoring the liquor level in the tank. [This parameter may be used for monitoring systems that continuously collect the liquor (i.e., a batch operation) and purge the system only at the end of the cycle. While the EPA does not believe that common practice for scrubber systems in this source category includes periodic purging of the liquor cycle, systems that do not follow a batch process will not be permitted to use this monitoring parameter.]

Monitoring of the operating parameters (i.e., liquid to gas flow rate ratio and temperature) of the scrubber in addition to beginning and end of cycle pH monitoring and end of cycle ethylene glycol concentration monitoring was suggested by

commenters. As discussed above, the Agency does not believe pH monitoring for the system is technically feasible for this source category, and ethylene glycol monitoring demonstrates that the scrubber system is absorbing ethylene oxide from the inlet gas stream. While the EPA agrees that monitoring operating parameters may add some benefit, the EPA is reluctant to require these parameters as referenced monitoring parameters in the final regulation because the Agency has not received data indicating that the monitoring of these additional parameters contributes to the continuous compliance indication as determined by ethylene glycol monitoring. The EPA believes that ethylene glycol monitoring provides a sufficient demonstration of compliance.

The Agency has subsequently revised the referenced monitoring parameters in the final rule to require either: (1) weekly monitoring of the ethylene glycol concentration in the scrubber liquor, or (2) weekly monitoring of the level of liquor in the scrubber liquor tank. Operating the scrubber with a monitored ethylene glycol concentration above the maximum concentration determined during an initial performance test is a violation of the applicable standard. Operation of the scrubber with a liquor level in the tank above the maximum as determined during an initial performance test is a violation of the applicable standard. The Agency believes that these monitoring alternatives provide an adequate measure of compliance while providing reduced burden to owners and operators of the affected sources. A source may choose an alternative to the monitoring parameters referenced in the final regulation if the alternative monitoring parameter is approved by the regulating Agency, as provided for in § 63.8 of the General Provisions. (See Section 2.4.1 for determining monitoring parameters at "worst-case" operation.)

2.4.3 Monitoring for Catalytic Oxidizers

Comment: Six commenters (04, 06b, 11, 13, 17, 18) suggested modifications to the monitoring requirements for catalytic oxidizers. Several commenters (13, 17, 18) stated that the control of the catalyst bed temperature to ±10°F may not be

practicable. One commenter (13) stated that maintenance of such a temperature range is feasible under steady state conditions but would be difficult under the continuously varying concentrations encountered in the evacuation process for the sterilization vent. This commenter suggested the use of a continuous temperature control monitor and recorder on both the inlet and outlet of the oxidizer. The commenter stated that compliance would be shown by having the inlet temperature above a minimum and the outlet temperature below a maximum; both temperatures would be determined during a compliance test when 99 percent efficiency was achieved.

One commenter (04) suggested that the current requirement of ±10°F be deleted and replaced with manufacturers' recommended maximum/minimum temperatures. The commenter stated that catalytic oxidation units used to control chamber vents would operate at widely varying temperatures, depending on the amount of ethylene oxide in the feed stream(s), and that various field tests on one manufacturer's units have demonstrated 99 percent removal efficiencies as long as the catalyst bed temperature is 280°F or higher. Another commenter (11) stated that it is well proven that catalytic units will work as designed if a minimum operation temperature is maintained for the particular catalyst. This commenter stated that compliance with the standards would be shown by having the catalyst bed temperature fall above a minimum operating temperature ±10°F established during a performance test and below a maximum temperature limit established by the manufacturer of the control device. The commenter added that the upper baseline temperature could change with different feed rates, environmental conditions, and air flows and suggested that this upper limit be set on a baseline standard cycle. The commenter suggested that a temperature variation in excess of 50°F from this monitored temperature would constitute a violation of the standards. Both commenters (04 and 11) suggested that monitoring the catalyst bed temperature coupled with periodic efficiency tests (minimum annually) should be utilized for monitoring compliance.

Another commenter (06b) stated that the control efficiency of catalytic oxidation units is dependent on catalyst temperature. This commenter stated that any catalyst used in catalytic oxidizers has been tested in the lab and in the field to show a reliable profile of temperature versus control efficiency. The commenter added that all methods of oxidizing ethylene oxide in air are more effective when the oxidation temperature is higher and that the limitation of ±10°F from the baseline temperature is unrealistic and penalizes those that operate their equipment with a high knowledge of their control efficiency. The commenter stated that this temperature requirement would disallow the use of ethylene oxide control from the sterilizer vacuum pumps [chamber exhaust vent] to be combined with aeration feed to a catalytic oxidizer. The commenter stated that only catalytic oxidizers controlling emissions from sterilizer vacuum pump exhausts would show marked temperature changes and that these changes would always be greater than the proposed 10°F limitation. The commenter added that they already have two catalytic oxidizers in place that utilize the combined feed of aeration and sterilizer vacuum pump [chamber exhaust vent] flows and that combining sterilizer exhaust and aeration exhaust reduces the use of clean-burning natural gas, a nonrenewable energy source. This commenter noted that in the "aeration only" feed streams of ethylene oxide, there is seldom any temperature rise of even 10°F for any new hot aeration/degassing cycles started because the total feed concentrations to the oxidizer are typically 40 parts per million or less. The commenter stated that all aeration cycles show a higher concentration of ethylene oxide degassing early in the cycle (although not necessarily at the beginning of the aeration cycle), usually declining asymptotically with the heated aeration. Two commenters (04, 11) stated that aeration room compliance for catalytic oxidation systems should be determined by continuously monitoring the lower operational temperature limit for the catalyst bed coupled with periodic efficiency tests (minimum annually).

One commenter (13) stated that calibration of the temperature controller to ±10°F is acceptable but seems difficult under § 63.363(b)(2)(ii), where a source is required to control the temperature of an oxidizer chamber under operating conditions to ±10°F using a temperature monitor accurate to ±10°F. Two commenters (17 and 18) stated that the temperature probe required in §§ 63.363(b)(1)(ii) and (2)(ii) should at least be accurate to within 1°F because, as written, any measurement that is at or below the limit of accuracy would be considered a violation.

One commenter (06b) stated that except for major concentrations of ethylene oxide (above 2,000 parts per million) or of cases where the allowable high temperature limits were exceeded, the catalyst will deactivate slowly over a period of years. The commenter stated that this deactivation is fairly reliable and predictable over the long-term, which is shown by performing the annual source test on all catalytic units. One commenter (11) submitted life data from two systems from major sources showing that the performance of the catalyst after one and 2 years has not changed from the original compliance test. The commenter also referred to life test data previously submitted to EPA performed on a catalytic system. The commenter noted that the catalyst in this system operated for 8 years before the catalyst performance fell below 99 percent destruction and the catalyst was then replaced. The commenter noted that this proved that the catalyst will not fail catastrophically and that catalyst life doesn't dramatically change over long periods of time.

Response: The Agency agrees with the commenters that the monitoring requirements for catalytic oxidizers may not be appropriate; the baseline temperature limit of ±10°F is not practicable in all situations. The Agency has considered the alternatives suggested. The commenters suggested that a more accurate measure of compliance would be a requirement that the temperature remain above a minimum oxidation temperature. The Agency has included compliance provisions in the final rule requiring that the oxidation temperature be above a minimum

baseline temperature determined during an initial performance test for the sterilization chamber vent, the aeration room vent, and the chamber exhaust vent. The Agency has not included a maximum temperature as part of the monitoring requirements as some commenters suggested because temperatures above the minimum temperature do not adversely affect performance of the oxidizer unit.

For the sterilization chamber vent, the final rule requires owners or operators of affected sources to: (1) monitor the oxidation temperature continuously, (2) calculate an average oxidation temperature over each cycle (the length of the cycle is based on the cycle length during the performance test), and (3) calculate a three-cycle average every third cycle; an average monitored oxidation temperature more than 5.6°C (10°F) below the baseline temperature established during the initial performance test at a time when the control device achieves a 99 percent emissions reduction is a violation. Similar requirements have been added to the monitoring requirements for sources that vent chamber exhaust vent emissions to a control device.

For aeration room vents controlled with catalytic oxidizers, the Agency agrees that additional flexibility regarding the monitoring requirements is warranted. The final rule requires owners or operators at major sources to monitor either: (1) the concentration of ethylene oxide emissions from the aeration room vent outlet, or (2) the oxidation temperature. For major aeration room vent sources monitoring the ethylene oxide concentration, the owner or operator will: (1) measure the concentration once per hour, and (2) calculate a 3-hour average every third hour. A 3-hour average ethylene oxide concentration greater than 1 ppmv is a violation of the standard. For major aeration room vent sources monitoring the oxidation temperature, the owner or operator will: (1) monitor the oxidation temperature continuously, (2) calculate an average oxidation temperature over each hour, and (3) calculate a 3-hour average every third hour. An average monitored oxidation temperature more than 10°F below the baseline temperature established during

an initial performance test at a time when the control device achieves either a 99 percent emissions reduction or a maximum outlet ethylene oxide concentration of 1 ppmv or less is a violation of the standard. The purpose of the monitoring requirements is to show "continuous" compliance with the standards, and since these monitoring requirements have been developed with this purpose, there would be no reason to require annual compliance testing. An affected source may perform compliance tests other than the initial compliance tests required by the final rule (see Section 2.4.1).

The Agency agrees with the commenters' concerns regarding the accuracy of the temperature probe used to measure the oxidation temperature. The final rule requires that the temperature probe have the same accuracy (±10°F) but requires the oxidation temperature to be above a minimum temperature established during a performance test (i.e., if the monitored temperature falls below this level, a violation of the applicable standard has occurred).

Comment: One commenter (18) stated that the language of 63.363(b)(2)(ii) (determination of violation for catalytic oxidation) should be clarified to specify that compliance is based on the average temperature.

Response: Section 63.365(f) in the final rule details the method for determining the baseline temperature for oxidizer units. The baseline temperature is determined by averaging temperature readings from three test runs. Monitoring will consist of continuous temperature measurement to be averaged over a period of time (i.e., cycles or hours). Depending on the vent type, the source will then calculate an average over the last three cycles or hours. A monitored temperature average more than 10°F below the baseline temperature is a violation of the standard.

Comment: One commenter (14) suggested semiannual calibration of temperature monitor accuracy for sources using catalytic oxidizers given the relative stability of the thermocouples used. The commenter added that failure of

thermocouple monitors tends to be catastrophic, with results that are immediately obvious to facility owners or operators.

Response: The Agency is aware of the reliability of thermocouples; thus, revised guidance on the calibration and maintenance of thermocouples have been added. The final rule requires semiannual calibration of temperature monitors.

2.4.4 Monitoring for Other Control Equipment

Comment: One commenter (04) recommended that monitoring of thermal oxidizers consist of continuous monitoring of fuel gas pressure, pilot flame presence, combustion air flow, and system temperature.

Response: The Agency has included thermal oxidizers as a referenced control technology in the final rule and has therefore incorporated compliance provisions, monitoring requirements, and recordkeeping and reporting requirements for thermal oxidizers. While the Agency agrees that monitoring of each of the mentioned parameters indicates flame stability, the Enhanced Monitoring Reference Document, September 1993, suggests that the outlet oxidation temperature be monitored. Other NESHAP have also incorporated this monitoring requirement for thermal oxidation units, such as the HON. The Agency believes that monitoring of this temperature parameter is sufficient to indicate continuous compliance for this control device. The compliance provisions for thermal oxidizers are as follows: during three performance test runs when the control device meets the applicable standard, the owner or operator shall establish as an operating parameter a baseline temperature averaged over the three runs; thereafter, operation of the sterilizer with the average oxidation temperature more than 10°F below this baseline temperature shall constitute noncompliance with the standard.

2.4.5 Monitoring Requirements for Sterilization Chamber Vents

Comment: One commenter (19) stated that actual measurement of inlet and outlet concentrations of ethylene oxide for the sterilization chamber vents should be required to demonstrate compliance with the percent reduction requirements.

Response: Direct monitoring of the inlet and outlet concentrations would require installation of an online gas chromatograph system and the appropriate personnel and training for operation of the analysis equipment; the Agency believes that this monitoring option is costly for this source category. The Agency believes that the parametric monitoring requirements contained in the final rule are sufficient to demonstrate compliance with the standards. The monitoring requirements were revised in response to comments received from control device vendors, industry, and State and local environmental regulatory agencies and incorporate monitoring provisions as required by the amended Act.

2.4.6 Monitoring Requirements for Chamber Exhaust Vents

Comment: One commenter (04) suggested that facilities that send chamber exhaust vent discharge to a control device be exempt from the monitoring requirements proposed for chamber exhaust vents. The commenter added that monitoring of the control device under these conditions should assure compliance with the standards.

Several commenters (04, 05, 11, 17, 18) suggested that facilities discharging chamber exhaust vents to the atmosphere should have the option of demonstrating end-of-cycle chamber concentrations of less than 5,300 ppmv by using specific validated cycle parameters and controlling additional cycles with the sterilization chamber vent control device. One commenter (04) suggested that this validation of cycle parameters include key process parameters affecting ethylene oxide removal from the vessel (initial concentration, number and depth of air washes), coupled with actual measurement of chamber concentration for representative cycles. This commenter suggested that compliance could be assured through the initial validation and review of sterilization cycle charts which are part of the permanent batch record. Another commenter (05) stated that bringing of the sterilization chamber to one atmosphere and holding it there while sampling the chamber ethylene oxide concentration before activating the fan would allow ethylene oxide to diffuse from the

chamber and increase employee exposures. This commenter added that multiple chambers cycling in close succession would compound this problem. The commenter suggested validating the operating parameters during the initial performance test and following these parameters as part of the monitoring for the chamber exhaust standard.

Response: The Agency agrees with the commenters' that additional flexibility should be provided to owners or operators of area and major source commercial ethylene oxide sterilization and fumigation operations regarding the demonstration of compliance with the chamber exhaust standards. The final rule contains provisions for the owner or operator of major and area affected sources to demonstrate compliance with the applicable chamber exhaust standards. Major source facilities, which are required to control emissions from the chamber exhaust, must demonstrate compliance by monitoring parameters established during a performance test for the control device that is used to control emissions. Area source facilities must monitor the ethylene oxide concentration in the sterilization chamber prior to operation of the chamber exhaust or may choose to control emissions from the chamber exhaust vent and demonstrate compliance by monitoring parameters established during a performance test for the control device that is used to control these emissions. In general, the monitoring requirements and compliance provisions for devices controlling emissions from the chamber exhaust vents are similar to the monitoring requirements and compliance provisions for devices controlling emissions from sterilization chamber vents.

2.4.7 Monitoring Requirements for Aeration Room Vents

Comment: Seven commenters (04, 05, 06a, 09, 11, 17, 18) provided comments on the monitoring requirements for aeration room vents. Several commenters (04, 05, 06a, and 11) stated that the proposed monitoring requirements for aeration room vents at major sources are unobtainable given that the industry-accepted detection limit for ethylene oxide is 0.5 ppmv based on laboratory quality equipment not used continuously. The

commenters also expressed concern that ethylene oxide monitoring would be inaccurate due to the heated sample stream, moisture present in sample lines, and the presence of other hydrocarbons and trace organics in the sample stream.

One commenter (09) requested clarification on the measurement of the ethylene oxide concentration for the aeration room vent. Specifically, the commenter requested clarification on whether this was a maximum from a single point sample or a maximum average of continuous monitoring of several samples.

One commenter (17) stated that because the 1 ppmv emissions limit can be circumvented by increasing the airflow through the vent, sources required to meet the standard should be required to meet a <1 ppmv concentration and 99-percent control requirement, so that the more stringent limit prevails. The commenter also stated that a concentration measurement that is below the detection limit of 0.2 ppmv should also indicate compliance. One commenter (18) recommended that emissions below the detection limit of the test be considered in compliance.

Response: The Agency recognizes the potential difficulties associated with accurately monitoring the ethylene oxide concentration on a continuous basis. In the final rule, the Agency has provided sources the flexibility to monitor the ethylene oxide concentration or to monitor control device parameters that provide continuous monitoring of compliance. If the source chooses to measure ethylene oxide concentration in its monitoring program, then the ethylene oxide concentration for the aeration room vent shall be measured hourly and averaged over three 1-hour measurements. The aeration room vent standards specify that this concentration shall be 1 ppmv or less for affected sources. Measurements of ethylene oxide below the detection limit are considered to be in compliance.

2.4.8 Monitoring Requirements in General

Comment: Six commenters (05, 06a, 09, 11, 16, 19) provided general remarks regarding monitoring requirements. One commenter (05) stated that each operator of a commercial sterilization facility should be able to demonstrate compliance by establishing

during the initial performance test the operating parameters of their systems (including control technologies) that will achieve compliance, validate those parameters, and then operate to those parameters and use the procedures outlined in § 63.366 to report deviations. The commenter added that if compliance could not be demonstrated in this manner then additional controls (scrubbers, catalytic oxidizers, etc.) would be in order. One commenter (17) recommended that the final rule consider the entire control device as a whole and that appropriate compliance demonstrations and other considerations be determined on a case-by-case basis where new technologies or hybrid systems are employed. One commenter (18) recommended that the owner/operator of a source seeking to demonstrate compliance with some other control scenario be allowed to establish an appropriate range for the parameters, with the approval of the implementing agency; operation precisely at the conditions established during the performance test may not be practical for normal operating conditions.

One commenter (06a) suggested that a facility should be given the opportunity to validate a process and stay within set operating parameters. The commenter's proposal incorporated an early detection set point that would be established for emissions controls which, in turn, would trigger an alarm notifying personnel of the need for corrective action. The commenter added that process validation cycles could be established annually. The commenter stated that reliance on a continuous monitoring system susceptible to delivering erroneous data could ultimately lead to the unnecessary discontinuation of sterilization of critical life saving medical devices and higher overall cost of medical care. Two commenters (17 and 18) requested that facilities employing an interlock system that shuts down the entire system and prevents the sterilizer from being used in the event that the conditions in the catalyst bed are outside of the acceptable range be exempted from the proposed monitoring, recordkeeping, and compliance provision requirements. One of these commenters (17) suggested that such facilities be required

to record incidences of interlock shutdown and recharging of the bed.

One commenter (09) stated that the proposed monitoring requirements would result in at least $100,000 in capital expenditures for one of the commenter's facilities. The commenter estimated that the monitoring and the submittal of reports would result in approximately $50,000 in annual costs. The commenter also stated that because they also rely on contract sterilizers, their product costs would be significantly increased by this regulation.

Response: The Agency has considered allowing interlock systems in lieu of the monitoring requirements presented for catalytic oxidizers. While the EPA wishes to encourage innovative technologies such as interlock systems, the EPA has insufficient information on the variety of designs and applications of interlock systems to specify alternative monitoring, recordkeeping, and compliance procedures that would be appropriate for all such systems. Sources wishing to use interlock devices may apply to the Administrator as described in the General Provisions § 63.8(f) and in § 63.365(g) of the final rule. In regards to establishing a set point that notifies personnel of system malfunctions, the Agency does not believe that it is appropriate to specify requirements for "triggers" in the standards. Rather, the Agency believes that the establishment of any such triggers or set points should be left to the owners or operators of an affected source.

The Agency agrees with the commenters that compliance should be measured during the initial compliance test and that the source should be allowed to show compliance with the emissions standards through a control scenario of the source's choice. The Agency has provided monitoring requirements and compliance provisions for the most commonly used control devices (i.e., the referenced control technologies) but has also incorporated provisions for sources using alternative controls (§ 63.365(g) of the rule and § 63.8(f) of the General Provisions). However, the Agency believes that sources should not be allowed to establish

their own operating parameters and to monitor parameters of their choice unless the source has applied to the Administrator for approval of such plans. The parameters to be monitored under the final rule for the referenced control technologies have been selected by the Agency to assure compliance with the standards and to standardize reporting of noncompliance. In instances where a referenced control technology is used, the parameters detailed in the rule should be used for monitoring. The Agency understands that allowing sources to select parameters to be monitored for compliance provides flexibility to the source; in instances where the control scenario used at the source does not match those referenced in the rule, the source must develop a comparable compliance and monitoring plan and apply to the regulating Agency for approval. However, the Agency believes that the approval process that would ensue from the commenter's suggested compliance program for all facilities would result in a lessor indication of compliance with the standards, additional time expended by sources for developing individual compliance programs, and an additional review step in the regulating Agency's approval process for these compliance plans. The Agency believes that the additional step in the approval process would overwhelm the regulating agencies.

The owner or operator of the commercial ethylene oxide sterilization and fumigation operation seeking to demonstrate compliance with the standards using an alternative control device may submit a monitoring scenario utilizing a range for the monitored parameters, however, any such submittal will be subject to review and possible modification by the Administrator. Regarding the commenter's request that the Agency consider the entire control device as a whole, the Agency asserts that this is how the compliance determinations and monitoring requirements in the proposed rule and final rule were determined. In evaluating any submitted alternative compliance provisions or monitoring requirements, the Agency will attempt to also consider the control device as an entire unit. In regard to the commenter's statement on the practicality of operation of the source at the

precise conditions as were established during the performance test, the Agency is promulgating monitoring requirements in the final rule that show compliance at all times of operation.

The Agency appreciates the information on the cost of compliance submitted by the commenter. In the final rule, the Agency has provided additional flexibility to affected sources that the Agency believes will reduce the costs of compliance without affecting the effectiveness of the monitoring program.

Comment: One commenter (19) agreed with EPA's proposed point-by-point compliance scheme.

Response: The Agency appreciates the commenter's support.

2.5 TEST METHODS

Comment: Three commenters (04, 05, 11) made suggestions regarding the test methods identified in the regulation. These commenters (04, 05, 11) referred to background documents that state high reactivity (04), low concentrations of ethylene oxide, high temperature, and presence of moisture do not provide reproducible, accurate results (04, 05, 11); one commenter (05) stated that Method 18 is not practical for hourly sampling and another commenter (11) stated that continuous monitoring of ethylene oxide is not obtainable. One commenter (05) asked that an alternative to Method 18, Section 7.2, for the aeration room vent standard as specified in § 63.365(c) be identified due to these factors. Another commenter (11) suggested that the requirement in § 63.365(a)(3)(ii)(A)(1) to have sample bags analyzed within 8 hours should be consistent with § 63.365(a)(3)(ii)(B)(1), which requires that samples be analyzed within 24 hours.

Response: The Agency has included alternative compliance provisions and monitoring requirements in the final rule to provide affected sources with additional flexibility to assure compliance with the standards. The Agency agrees that parametric monitoring of the control device used for the aeration room vent and chamber exhaust vent should be allowed as an alternative to direct measurement of the ethylene oxide concentration in the stream with Method 18, Section 7.2. Additional discussion of

this issue and the compliance test procedures is located in Section 2.4. It is assumed that the commenter is referring to §§ 63.365(a)(4)(ii)(A)(1) and 63.365(a)(4)(ii)(B)(1) of the proposed rule (since the sections mentioned did not exist in the proposed rule) [§§ 63.365(b)(1)(iv)(B)(1)(a) and 63.365(b)(1)(iv)(B)(2)(a) in the final rule]. However, the sections mentioned by the commenter each indicate an 8 hour limit on the time allowed before analysis should occur.

Comment: One commenter (17) suggested that under § 63.365(a), the flow rate and concentration be measured at both the inlet and the outlet to the control device to avoid possible errors including air leaks into the sterilization chamber, leaks from the vacuum pump, and errors that could occur if the inlet ethylene oxide concentration is measured directly but the flow is not measured (i.e., the mass of ethylene oxide fed to the abater must be derived, potentially not taking into account the combustion air added to catalytic oxidizer units). Another commenter (18) stated that the method for determining residual mass of ethylene oxide in the sterilization chamber (§ 63.365(a)(2), based on the ideal gas law) does not consider air leaking into the chamber during initial evacuation. This commenter also stated that the total mass of ethylene oxide (Wi) at the inlet to the control device is not measured directly, and is therefore subject to error. The commenter recommended that the concentration and flow rates be measured at the inlet and the outlet.

Response: Section 63.365(b)(1) of the final rule allows the source two options for calculating the total mass of ethylene oxide at the inlet to the control device: (1) calculating the theoretical mass charged to the chamber by utilizing one of several techniques listed; or (2) by measuring the flow rate and concentration of ethylene oxide by utilizing the techniques to be used at the outlet of the control device. The Agency allowed the use of theoretical calculations for inlet mass in order to minimize exposure of the source tester to ethylene oxide.

Comment: One commenter (18) recommended that EPA provide an expedited mechanism via Subpart E to approve alternative test methods and monitoring protocols, or delegate approval of same to State/local agencies for area sources.

Response: The Agency believes that facilities choosing an alternative test method or monitoring method than those specified in the standard should follow the requirements as specified in §§ 63.7 and 63.8, i.e., apply for approval of such plans to the Administrator, of the General Provisions. The Agency believes the requirements as established in the General Provisions are sufficient for approving use of alternative plans for this regulation. Following the implementation of Part 70, the Agency believes that States may be delegated the authority to implement the provisions of Part 63 standards.

2.6 REPORTING AND RECORDKEEPING REQUIREMENTS

2.6.1 General

Comment: One commenter (18) agreed with the limited recordkeeping and administrative requirements for facilities that qualify for the low usage exemption [i.e., sources <1 ton/yr].

Response: The Agency recognizes the burden recordkeeping places on small sources and has therefore limited the requirements for these sources to alleviate this burden. Many of the requirements of the General Provisions are specific for major sources, and some are not appropriate for area sources in this source category. Several of these requirements, such as construction/reconstruction requirements, performance test plan requirements, and performance evaluation test plan requirements for monitoring equipment, have been waived for area sources.

In addition to these exemptions, all sources (both major and area) in this source category have been waived from the requirement to develop a startup, shutdown, and malfunction plan as specified in § 63.6 of the General Provisions. Due to the batch nature of the industry, the Agency does not foresee emissions associated with startup, shutdown, or malfunction periods that would affect the source's compliance status. No emissions are associated with startup of the process (i.e.,

introducing ethylene oxide into the sterilization chamber); emissions associated with shutdown of the process are vented to control equipment and, in the instance of a malfunction of the control equipment, the process may be stopped (i.e., no ethylene oxide emissions) until the malfunction has been corrected. While the Agency has not required sources to develop a plan, a source may choose to voluntarily develop a startup, shutdown, and malfunction plan if they have a concern regarding the source's compliance status due to ethylene oxide being emitted during startups, shutdowns, and malfunctions.

2.6.2 Relationship to the General Provisions

Comment: Two commenters (04, 05) stated that §§ 63.366(b) and (c) should be modified to conform with § 63.9 (Notification Requirements) of the final General Provisions.

One commenter (18) stated that the initial notification should be required no sooner than 120 days after the effective date in order to allow all facilities to receive and comprehend the Federal Register notice containing the final rule.

Response: The General Provisions were finalized on March 16, 1994, following the proposal of these NESHAP. The recording and recordkeeping requirements of the final rule will be made consistent with the General Provisions. A table identifying the applicable, modified, and nonapplicable requirements of the General Provisions has been included in the final rule.

2.6.3 Reporting Frequency

Comment: One commenter (18) recommended that implementing agencies be allowed to determine the frequency of reports based on individual program needs and routine inspection schedules.

One commenter (13) recommended that an excess emissions and monitoring system performance report be submitted every quarter, and if there have been no exceedances, the facility should state this.

Response: The Agency has determined that semiannual reporting is appropriate for this regulation; however, a source may be subject to more frequent reporting if the Administrator

determines it is necessary for a particular source. In addition, excess emissions reports must be submitted semiannually even when no excess emissions have occurred. The EPA recognizes the value of reporting on a regular basis in that the source demonstrates their attention to applicable standards. By requiring sources to report violations on a regular basis, the enforcement authority is able to identify potential violations in a timely manner. Since penalties are calculated per day per violation, the timely identification of violations reduces a source's liability. More importantly, timely identification allows the enforcement authority to ensure that the cause of a violation has been addressed, thereby reducing potential health effects of the emissions. In addition, companies that have facilities in several States could possibly be subject to numerous different and confusing reporting schedules.

2.7 WORDING OF THE REGULATION

Comment: Three commenters made suggestions regarding the wording of the regulation. One commenter (13) suggested that the definition for the term "baseline ethylene glycol concentration" be amended as follows: "baseline ethylene glycol concentration means the maximum concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device beyond which the scrubber achieves less than 99 percent control of ethylene oxide emissions." This commenter also suggested that § 63.363(a), Compliance and Performance Testing, be reworded as follows: "The emissions limits of this subpart apply at all times except that, during periods of malfunction which might increase emissions, no ethylene oxide shall be charged to the affected sterilization chamber during the malfunction." Another commenter (14) stated that the regulation should avoid confusion between the terms "baseline temperature," "combustion temperature," and "temperature of catalyst bed." An appropriate definition of "baseline temperature" would be as follows: "baseline temperature" means the temperature at the inlet of the catalyst bed in a catalytic oxidation unit control device at which the unit achieves at least 99 percent control of ethylene

oxide emissions. Another commenter (18) stated that the definition for the term "chamber exhaust vent" should only refer to a physical emissions point, not a time period during which that point meets the definition. The standard for the chamber exhaust vent could include the time-frame during which the standard applies.

Response: The definitions for baseline ethylene glycol concentration and baseline temperature have been revised in the final rule. The definition for chamber exhaust vent has not been revised because reference to both the physical point and the time period are significant in defining this term. Interchangeable use of the different temperature terms has been eliminated and the term baseline temperature is used consistently in the final rule. Changes to the wording of § 63.363 for applicability during malfunctions have been incorporated.

Comment: One commenter (18) suggested several clarifications for § 63.360: (1) eliminate § 63.360(a); (2) eliminate § 63.360(b) and include the language of this exemption in the aeration room vent standard; and (3) rephrase § 63.360(c) to refer to sources that are subject to the standard rather than those that are not. Another commenter (17) indicated that a separate applicability threshold for aeration room vents should be included in § 63.362(b), as follows: "Aeration room vent. Each owner or operator of an existing or new sterilization facility that uses 9,070 kilograms (kg) (10 tons) of ethylene oxide within any consecutive 12-month period, shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent . . . ."

Response: Section 63.360 of the final rule identifies the applicability of the regulation to specific commercial sterilization and fumigation sources. Language has also been added as suggested to the standards in § 63.362 of the final rule to identify those sources that are subject to a specific standard. The Agency believes that the applicability section and the emissions standards in the final rule have been written clearly.

2.8 MISCELLANEOUS

Comment: Two commenters (07, 13) questioned why the proposed regulation was not included along with the preamble in the Federal Register. One of these commenters (07) also questioned whether this form of notice satisfies EPA's obligations for informed notice and comment for rulemaking. The other commenter (13) stated that omission of the text of the proposed regulation is not a good policy. This commenter explained that requesting a copy of the rule from EPA through the mail would take time out of the already limited comment period and explained that downloading from the TTN requires access to a computer, modem, and appropriate software. The commenter stated that these methods of obtaining the actual text of the proposed regulation could be difficult for some facilities, especially small facilities, and added that it is critical that facilities know when the proposal date occurs since the regulations will apply to new sources from this date onward. This commenter also suggested that until EPA revises this policy, the fact that the actual proposed regulation is not included in the Federal Register notice should be made very clear, and an EPA contact person, their telephone number, and the TTN telephone number should be included. One commenter (07) indicated that the text of the proposed regulation is equally, if not more, important than the preamble, and the other (13) stated that it makes more sense to leave out the preamble and to print the regulation.

Response: The Agency has reviewed its responsibility to adequately inform the affected public of proposed actions. The decision to reduce the amount of printed material in the Federal Register and assure that the material, including the proposed regulatory text of the proposed rule, is accessible for public comment and judicial review does not conflict with the statutory requirements of the Administrative Procedures Act (APA), the Federal Register Act (FRA), nor the requirements of the Clean Air Act Amendments of 1990. Access to material that is used as the basis of the proposed rule (officially located in the

Air Docket created by the CAAA) is identified in the preamble to the proposals and promulgations of rules. Specifically, the Agency clearly established and will continue to look for additional connections and will include directions for obtaining the text of information not printed in the Federal Register. Currently, this information may be obtained through one of the following sources: (1) the TTN's "Recently Signed Rule" bulletin board; (2) directly from the Air and Radiation Docket and Information Center; (3) distribution to trade associations; (4) plaintiffs in court ordered regulatory actions; (5) contact with small business ombudsman system in each State; and (6) if necessary, through the contact person at the Agency. The response to this approach has been positive as the process has aged.

The proposal date is the date that the notice of the Agency's action is signed by the Administrator and published in the Federal Register. This has always been the case with the Agency's rulemakings. The printing of the regulatory text does not depend on the effective date of applicability as determined by the date of Federal Register publication.

The Agency believes that all information that is developed in the course of the development of a proposed and final rule is important, however, EPA believes they have realistically and responsibly addressed the need to publish information in the Federal Register. The Agency will continue to review the issue of extensive publishing in the Federal Register along with its responsibility to adequately inform affected parties of our proposed and final actions.

Comment: One commenter (03) suggested that the rule include the standards in the form of a table.

Response: The Agency agrees that providing the requirements of the standards in tabular format is a convenient summary method. Tables similar to those presented in the preamble to the proposed rule have been included in the final rule to supplement the regulatory text.

Comment: One commenter (02) requested that EPA promulgate the final rule for this source category by November 15, 1994; promulgation by the scheduled date is important to the States who have the obligation of implementing and enforcing the NESHAP standards and requirements.

Response: As a result of a Clean Air Act litigation suit, Sierra Club v. Browner, the proposal and promulgation dates for several NESHAP were agreed upon in a consent decree. The commercial sterilization and fumigation facilities source category was included in this consent decree and the court-ordered deadline for promulgation of this NESHAP is November 23, 1994. The EPA will promulgate this project on schedule.

Comment: One commenter (10) stated that emissions averaging does not address the possible health effects from exposure to high concentrations of an extremely toxic substance for a short time period.

Response: The EPA does not believe emissions averaging can be used practically for commercial sterilization facilities and has not included emissions averaging in the final regulation. The Agency could not develop a credible averaging scheme and requested comment in the preamble to the proposed rule on the feasibility of emissions averaging for this industry and also requested submittal of potential emissions averaging schemes from commenters. None of the commenters submitted an averaging scheme to the Agency.

Comment: One commenter (08) indicated support for the stated positions of commenter 11.

Response: The Agency appreciates this commenter's support for statements made by commenter 11.

Comment: One commenter (06b) noted that CFC's and HCFC's that are used as a diluent with ethylene oxide in commercial sterilization inhibit the efficiency and can cause permanent damage to catalyst in catalytic oxidizers. The commenter added that there is typically a much higher proportion of CFC/HCFC's relative to ethylene oxide in the sterilant gas. The commenter

also noted that the CFC/HCFC's will produce toxic byproducts including phosgene at oxidation temperatures above 400°F.

Two commenters (17 and 18) stated that EPA should consider the existence of multiple control units on a single vent. The commenters were aware of a number of sources that have installed membranes or condenser/compressor units (whose performance can vary considerably) between the sterilization chamber and the abatement device to collect ethylene oxide and CFC's. The commenters specifically noted these devices as they relate to varying ethylene oxide concentrations and hence temperature responses when catalytic oxidation is used for abatement.

One commenter (19) stated that EPA should address the implications of CFC phase out as it relates to potential increased ethylene oxide emissions, especially from sources falling below the proposed 1 ton/yr ethylene oxide use cutoff.

Response: The Agency is aware of the use of CFC's and HCFC's as dilutants for ethylene oxide in commercial sterilization and the potential impacts associated with catalytic oxidation of CFC-EO mixtures. As noted in the Background Information Document for these proposed standards, the Agency does not believe that toxic CFC byproducts would be emitted following catalytic oxidation because the CFC's do not react at the temperatures typically occurring during catalytic oxidation (150° to 180°C [300° to 350°F]). The Agency has also been made aware that the use of EO-CFC gas mixtures has significantly decreased in response to increased regulation of CFC's. The Health Industry Manufacturer's Association (HIMA) has informed EPA that none of their members are currently using EO-CFC gas mixtures.

Use of multiple controls, ex. installing membranes or condensers prior to the control device, is at the source's discretion as long as the control efficiency achieved by the multiple control units is consistent with the applicable standard. A source, however, would be required to apply to the Administrator for approval of the monitoring plan for the control scenario.

The EPA would like to point out that increased emissions of ethylene oxide should not result from CFC phase out. Because the sterilization process must be performed using a specified concentration of ethylene oxide, the same amount of ethylene oxide is used for a sterilization process whether pure ethylene oxide or 12/88 is used. The Agency believes these NESHAP are sufficient to control ethylene oxide emissions from all affected area and major sources.

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16. ABSTRACT

National emissions standards to control emissions of ethylene oxide from new and existing sterilization/fumigation operations are being promulgated under Section 112 of the Clean Air Act. This document contains information on the background and authority, a summary of public comments and Agency responses, and a summary of changes to the regulation following proposal and the resulting environmental and economic impacts.

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Sampling/Analytical Method Evaluation for Ethylene Oxide Emission and Control Unit Efficiency Determinations

April 5, 1988

RADIAN
CORPORATION

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FINAL REPORT

SAMPLING/ANALYTICAL METHOD EVALUATION FOR ETHYLENE OXIDE EMISSION AND CONTROL UNIT EFFICIENCY DETERMINATIONS

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ABSTRACT

Radian Corporation, assisting the Environmental Monitoring Systems Laboratory, Environmental Protection Agency, Research Triangle Park, North Carolina, performed a field evaluation of a method for sampling and analyzing ethylene oxide (EO) in the vent stream from a sterilization chamber and a dilute acid scrubber. The utility of the sampling method for measuring the efficiency of the control unit was also evaluated.

The evaluated sampling and analysis procedure used semi-continuous direct sampling with on-line gas chromatographic analysis. Laboratory studies of the sampling method previous to the field test showed that semi-continuous direct sampling was capable of measuring EO emissions to within 11% of the expected value with a between-trial precision of 5 percent.

Analysis of samples taken from the vent of a dilute acid hydrolytic scrubber indicated that a column that retained dichlorodifluoromethane (CFC-12) longer than EO would be desirable because low part per million by volume levels of EO were difficult to detect in the presence of percent levels of CFC-12. Studies of several types of columns indicated that a stainless steel 10 foot (3 meter) by 1/8 inch (3 millimeter) outer diameter, 5% Flurocol on 60/80 mesh Carbopack B column, provided the best conditions for separation of EO from CFC-12.

Additional studies performed showed that under the field test conditions used, adequate control unit efficiency measurements were obtained using chambers filled with product and assuming that all of the EO charged to the chamber entered the control unit. The field test conditions used included a sterilization chamber/control unit system that was a closed system (i.e. leak-free), and a control unit that had a normal operating efficiency >99.6 percent.

This report contains conclusions and recommendations based on the field test results; descriptions of the properties of EO, the sterilization industry, previously used sterilizer test methods, and the semi-continuous

direct sampling method; results of the laboratory and field evaluation of the method as well as results of related laboratory studies which were performed; and references used to prepare this report.

This report was submitted in partial fulfillment of EPA Contract No. 68-02-4119 by Radian Corporation under the sponsorship of the U.S. Environmental Protection Agency. This report covers a period from July 1986 to December 1987.

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SAMPLING/ANALYTICAL METHOD EVALUATION FOR ETHYLENE OXIDE EMISSION AND CONTROL UNIT EFFICIENCY DETERMINATIONS

SECTION 1

INTRODUCTION

The Source Branch of the Environmental Protection Agency's (EPA) Environmental Monitoring Systems Laboratory (EMSL) at Research Triangle Park, North Carolina, has a program to develop stationary source test methods of known precision and accuracy for use in determining compliance with EPA standards. While participating in this program, Radian Corporation performed a field evaluation of a method for sampling and analyzing ethylene oxide (EO) in the vent stream from a chamber and a dilute acid scrubber of a commercial sterilizer. The usefulness of the sampling and analytical method for measuring the efficiency of the control unit was also evaluated.

Because EPA has listed EO as a possible hazardous air pollutant, a standardized sampling and analytical method is needed for determining control equipment efficiency. The evaluated sampling and analysis procedure used semi-continuous direct sampling with on-line gas chromatographic analysis.

The semi-continuous direct sampling method with on-line gas chromatographic analysis was tested because this method should provide accurate emissions data regardless of the EO concentration profile of the exhaust stream. The sampling/analytical method was tested at the inlet and outlet of the control unit. At the inlet the EO concentration was in the percent range and the temperature was above ambient (120-140°F, 49-60°C) while EO concentrations were in the ppmv range and at ambient temperatures at the outlet.

The measurement of the emissions were used to calculate the EO control unit efficiency. Two calculational methods were evaluated. The first method calculated a through-put efficiency using the EO emissions measured at the inlet and outlet of the control unit. This method calculated a true-efficiency because the EO actually entering the control unit was used in

the efficiency calculation. However, there was a greater possibility of error because of the necessity of accurately measuring the inlet flow rate, which entered into the calculation. Measuring the inlet flow rate was complicated by the high EO concentrations and the low flow rates at the inlet.

Measurement of the inlet flow rate was not required using the second calculational method which calculated a recovery that was equated to the control unit efficiency. The recovery was calculated from the amount (weight) of EO charged into the chamber and the measured EO emissions at the outlet of the control unit.

The purposes of the field evaluation were:

- To field test the proposed sampling method on an operating sterilizer with a dilute acid scrubber;
- To evaluate the suitability of the proposed sampling method for determining EO emissions and control unit efficiency; and
- To evaluate the applicability of the measured EO recovery as an estimator of control unit efficiency.

Section 2 reports the conclusions and recommendations based on the test results. Section 3.0 describes the properties of EO and provides a basic description of the sterilization process, the sterilization industry, and previously used test methods. Section 4 describes the method tested. Section 5 contains the results of laboratory evaluations of the method and related laboratory studies. Section 6 contains field test results. Section 7 lists references.

SECTION 2

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Six conclusions were based on the field test results. First, the sampling/analytical method adequately determined EO emissions at the outlet of the uncontrolled sterilizer (i.e. the EO mass flow rate into the control unit).

Second, the sampling/analytical method adequately determined EO emissions at the outlet of the dilute acid scrubber, but identification of the EO peak in the chromatogram was complicated by EO retention times that shifted as the EO concentration decreased. The EO retention time shift was magnified due to the large range in the EO concentrations. The bias in the sampling/analytical method averaged 7.4% for EO and -2.4% for CFC-12. .

Third, the sampling/analytical method adequately determined the efficiency of the dilute acid scrubber. Measured efficiency calculated by the throughput method for empty chamber tests ranged from 99.82 to 99.98% and averaged 99.94 percent.

Fourth, the recovery method of determining control unit efficiency was comparable to the throughput method at this site. Efficiencies calculated for empty chamber tests by the throughput method ranged from 99.82 to 99.98% and averaged 99.94 percent. Efficiencies calculated for empty chamber tests by the recovery method ranged from 99.90 to 99.97% and averaged 99.95 percent. A one-way analysis of variance (ANOVA) performed on the data for the empty chamber tests showed that the methods were not different. The sterilizer chamber/control unit tested was a closed system (i.e. leak-free) so this conclusion may not be valid at an older facility where more EO may be lost from the system as fugitive emissions.

Fifth, the presence of product in the chamber did not affect the scrubber efficiency measurement. The efficiencies calculated for empty chamber tests by the throughput method ranged from 99.82 to 99.98% and averaged 99.94 percent. The efficiencies calculated for full chamber tests by the throughput method ranged from 99.92 to 99.98% and averaged 99.96 percent.

Sixth, EO emissions and control unit efficiencies calculated using flow rates based on orifice plate data did not differ significantly for EO emissions and control unit efficiencies calculated using estimates based on chamber temperatures and pressures. Ethylene oxide emissions for empty chamber tests based on orifice plate data ranged from 0.011 to 0.043 lb and averaged 0.024 lb. Estimated EO emissions for the same tests ranged from 0.006 to 0.036 lb and averaged 0.017 lb. Throughput efficiencies based on the orifice plate data ranged from 99.82 to 99.98% and averaged 99.93 percent. Throughput efficiencies based on estimated flows for the same tests ranged from 99.85 to 99.99% and averaged 99.95 percent. Again, the sterilizer chamber/control unit tested was a closed system so this conclusion may not be valid at an older facility where more EO may be lost from the system as fugitive emissions.

RECOMMENDATIONS

Six modifications based on the field test results are recommended. These include:

1. For efficiency determinations, sampling at the control unit inlet should not be required when the sterilizer chamber/control unit is a closed system. Sampling at this location is unnecessary because efficiencies calculated by the Recovery Method were comparable to efficiencies calculated by the Throughput Method. The Recovery Method used initial chamber charge and total EO emissions from the control unit outlet to calculate the efficiency.

2. For on-line analysis on a system using EO/CFC-12 sterilant gas, the analysis at the outlet should be modified by using two separate channels, one to quantitate the EO and the other to quantitate the CFC-12. Quantitation of the CFC-12 is needed to calculate the molecular weight of the vent stream. Separate analyses would eliminate the need to program the detector range and the added difficulties produced by detector range programming.

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3. A minimum of six samples should be taken during each evacuation: two during the first two minutes, two between the second and ninth minute, and two between the tenth minute and the end of the evacuation. During the first two minutes of the evacuation the EO and CFC-12 concentrations should be the same as they were at the end of the previous exhaust and should be fairly constant. During the next five to seven minutes the EO and CFC-12 concentrations should change rapidly as the old chamber gas is swept out of the stack and the remaining chamber gas is diluted by the new chamber gas entering the scrubber. After 10 minutes the EO and CFC-12 concentrations should remain fairly constant at a level lower than the initial level.

4. The use of orifice plates should not be required when testing a closed chamber/control unit equipped with chamber temperature and pressure monitors. Field test data showed that the efficiencies calculated using estimated flow data were similar to efficiencies calculated using flow data based on orifice plate measurements.

5. If possible, sampling should be performed offline. Offline sampling would allow more samples to be collected because the number of samples would not be limited by the analysis time. Offline sampling would allow greater flexibility in the analytical method and improve the reliability of the identification and quantification of the components.

6. For offline sampling, 15-second grab samples should be acquired at one-minute intervals during the first two evacuations when the EO concentration is changing rapidly with time. Grab sampling should be performed during the later evacuations at two- or three-minute intervals. Grab samples could be obtained in syringes equipped with valves, small Tedlar bags or Vacusampler® cans.

SECTION 3

BACKGROUND

PROPERTIES OF ETHYLENE OXIDE

The chemical and physical properties of EO are discussed in References 1, 2 and 3. Only a brief summary is included here. Ethylene oxide, an epoxide, is also called oxirane (the International Union of Pure and Applied Chemistry name).[1] Other synonyms include: dihydrooxirene, dimethylene oxide, 1,2-epoxylethane, oxacyclopropane, oxane, oxidoethane, and α,β-oxidoethane.[1] It is usually handled as a liquid under pressure. At room temperature and pressure, EO is a gas that has a pungent, irritating, ether-like odor.[1] At 10 degrees Celsius (^{o}C) [50 degrees Fahrenheit (^{o}F)] it condenses to a colorless liquid.[1,2,3] It is completely miscible with water and with organic solvents.[1,2] The reactive and volatile properties of EO make it highly flammable and potentially explosive.[1,2] It has a flash point of <-18°C (0.4^{o}F) and is flammable in air at concentrations ranging from 3 to 100 volume percent (% [v]).[1,2] It is currently regulated by the Occupational Safety and Health Administration (OSHA) for occupational exposure of 1 part per million (ppm) over 8 hours (hr).[4] Because EO is a known reproductive hazard[2,5] and a suspected carcinogen[5], these last considerations, coupled with the fact that there is no upper explosive limit, require that special safety precautions be taken when handling and storing EO.

GENERALIZED DESCRIPTION OF THE BULK STERILIZATION PROCESS

Detailed descriptions of the sterilization process are contained in References 1 and 6. The bulk sterilization process, used by the majority of the commercial sterilization industry is described here in general terms. Hospital and medical products to be sterilized are preconditioned with steam in a separate chamber prior to sterilization. An air-tight sterilization chamber is loaded with the preconditioned products. Air inside the chamber is evacuated using steam ejectors to decrease the chamber pressure. Once the

desired vacuum level is achieved, the air inside the chamber is humidified to a predetermined value by adding steam. The sterilant is pressurized into the chamber to a predetermined level. The chamber is held at a constant pressure for a specified period, during which the products are sterilized by EO. When sterilization is complete, the sterilizer gas mixture is exhausted from the chamber until the chamber pressure is decreased to a predetermined level. Filtered air is introduced into the chamber to flush the sterilant gases from the chamber and product. These air washes may be repeated several times. After the last air wash, the door is opened and the chamber unloaded.

The gas in an EO sterilization chamber does not vent at a constant rate for two reasons. First the initial maximum venting rate is determined by the size of the chamber vacuum pump. As the chamber empties, the vent gas flow rate decreases. Second, the evacuation of the chamber is controlled by a solenoid valve which cuts on and off at regular intervals to prevent the chamber from evacuating too rapidly and damaging the products. This changing and pulsing flow rate makes sampling the gas stream more difficult for two reasons. First, calculating the total flow through the vent is an integration rather than a multiplication process and requires continuous monitoring of the flow. Second, calculating the total emissions requires taking many grab samples over the sampling period or collecting a representative sample using special techniques.

There are two models for the EO concentration profile in the chamber exhaust. In one model the chamber is considered to be a closed system at equilibrium. For this model, the EO concentration in the exhaust gas remains constant and only the vent stream flow rate varies. In the other model, the chamber is considered to be a dynamic system. For this model, both the EO concentration and flow rate of the exhaust gas change with time. If the sterilization chamber does not contain product, the exhaust stream will be characterized best by the first (static) model because equilibrium will occur quickly between evacuations. Any product present in the chamber will offgas, releasing ethylene oxide, during chamber evacuations and air washes. With a product-containing chamber, the exhaust stream will be characterized best by the second (dynamic) model.

HOSPITAL SUPPLY STERILIZATION INDUSTRY

Throughout the United States and Puerto Rico approximately two hundred facilities use EO for sterilizing heat- or moisture-sensitive products or for fumigating microorganisms and insects.[6,7] Chambers range in volume from less than 2 cubic meters (m^3) [60 cubic feet (ft^3)] to 170 m^3 (6000 ft^3).[7] Throughout the industry 76% of the chambers are charged with a mixture of 12 weight percent (% [w]) EO and 88% (w) of dichlorodifluoromethane (CFC-12).[7] Pure EO is used in 68% of the chambers and mixtures of carbon dioxide and EO are used in 10%.[7] (Some chambers are used with more than one type of sterilant gas.)

The vent streams from 17% of the EO sterilization facilities have some type of control unit, ranging from a neutral-water scrubber to an incinerator.[7] Forty-four percent of the control units chemically hydrolize the EO to ethylene glycol using dilute acid solutions, 3% use catalytic oxidation to convert the EO to carbon dioxide and water, and 19% of the control units are condensation/reclamation systems.[7] Commercial vendors of EO control units include Chemrox Incorporated, Damas Corporation, Mine Safety Appliances (MSA), and Croll Reynolds. A significant segment of the industry has custom-designed control units. Control units have been tested by the manufacturers and the industry as described below. Ethylene oxide removal efficiencies greater than 99% have been measured.[8,9,10,11]

EO CONTROL UNIT EFFICIENCY MEASUREMENTS

Several methods are currently being used in the EO sterilization industry to measure the efficiency of EO control units.[8,9,10,11] In general, the efficiency of an EO control unit is determined on a weight basis over the entire post-sterilization cycle. The post-sterilization cycle includes the initial chamber evacuation and all subsequent air washes. The units tested and reported include:

- A Chemrox unit in Pennsylvania,[12]
- A Chemrox unit in New York,[10]
- A Damas unit,[9] and
- An MSA unit.[13]

The Chemrox unit in Pennsylvania was tested using EO recovery to estimate control unit efficiency. The empty sterilization chamber was charged with a

known amount of the EO/CFC-12 sterilant gas and then vented. Grab samples of the vent gas were taken in Vacusampler® cans every 5 min and analyzed in the laboratory. After the air wash portion of the sterilization cycle was completed, an air sample was removed from the chamber. The EO input to the control unit was calculated from the difference of the amount charged to the chamber initially and the amount remaining in the chamber at the completion of the evacuation cycle. The amount of EO emitted from the control unit was calculated from the concentration of EO in the outlet grab samples, the exhaust temperature, and outlet flow rate of the vent gas.

The Chemrox unit in New York was tested using a method whereby direct semi-continuous sampling was performed at both the inlet and outlet of the control unit. Samples were directed through heat-traced lines into the gas sampling valve of a gas chromatograph (GC) at 1 min intervals. The weights of EO at the inlet and outlet of the control unit were calculated from the concentration of EO measured by the GC and the measured temperature and flow rate of the vent gas.

The Damas unit was also tested by taking inlet and outlet samples. The inlet samples were collected in six-layered aluminized bags and the outlet samples were collected on charcoal tubes. A series of inlet and outlet samples were collected at a constant sampling rate over 5 min intervals during the entire post-evacuation cycle. The charcoal tubes were desorbed using carbon disulfide. The bag samples from the inlet and the charcoal tube extracts from the outlet were then analyzed by GC. Again, the weights of EO at the inlet and outlet of the control unit were calculated from the measured EO concentrations, vent gas temperature, and vent gas flow rate during each sampling period.

The MSA unit was also tested using both inlet and outlet measurements. The samples were collected in 10 milliliter (mL) syringes at 1 min intervals. Stream flow rates and temperatures were recorded at the time of sample collection. The entire sample in the syringe was injected directly onto a GC column for analysis. The amounts of EO at the inlet and outlet of the control system were calculated from the measured EO concentrations and stream flow rates.

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SECTION 4

SEMI-CONTINUOUS DIRECT SAMPLING AND ANALYTICAL METHOD DESCRIPTION

APPLICABILITY AND PRINCIPLE

Applicability

This method applies to the measurement of EO emissions from sterilization chambers. It is applicable to emissions from sterilization chambers and sterilization control units which use acid hydrolysis to remove the EO. The analytical method is capable of measuring from 0.03 parts per million by volume (ppmv) to 27.7% (v).[14]

Principle

Samples are collected from the sterilization chamber or control unit using a semi-continuous direct sampling technique and are analyzed on-line by gas chromatography with flame ionization detection (GC/FID). The total weight in pounds or kilograms of EO is calculated using the measured EO concentrations and the measured temperatures, flow rates, and pressures of the sampled stream.

APPARATUS

The following equipment is required for performing semi-continuous direct sampling with on-line GC/FID analysis.

Heat-traced Teflon® Line

A heat-traced Teflon line is used to transport the sample from the vent stream to the gas sampling valve of the GC. The line is heated to a temperature slightly higher than the temperature of the vent gas in order to prevent condensation. The length of line required depends upon the proximity of the GC to the sampling port.

Pumps

Two vacuum pumps are required. One pump, capable of pumping 1 liter per minute (L/min) [0.035 cubic feet per minute (cfm)] with a leak-free, Teflon-coated diaphragm, is used to continuously withdraw sample from the sampling port and to pump sample to the gas sampling valve of the GC. The other pump, capable of pumping 100 milliliters per minute (mL/min) [0.0035 cfm] is used to flush the sample loop.

Acid Scrubbers

Two 500 mL Erlenmeyer flasks with two-hole stoppers containing dilute sulfuric acid at a pH of 1 are used to remove EO from the sampling stream and the GC slip stream before venting them to the atmosphere. The acid scrubbers may not be required when sampling controlled emissions if the exhaust lines are vented in a well-ventilated area void of personnel.

Thermocouples

Two thermocouples are needed to monitor the temperature of the vent stream. One should be wrapped in moist material to measure the wet bulb temperature. The accompanying temperature readout devices should be capable of measuring from ambient temperature up to 200°F (93°C).

Restricted Orifice Plates and Flanges

Restricted orifice plates sized to the vent are needed to monitor the flow rate of the vent stream. Standard orifice flange plates and flanges with standard pressure taps are recommended. If CFC-12 is used in the sterilant gas, two orifice plates are required.

Vane Anemometer

A vane anemometer is needed to measure gas stream linear velocites between 20 and 150 ft/min (6-45 m/min). A digital vane anemometer capable of measuring velocity at 10-sec intervals and with an ouput jack for a strip chart recorder is recommended.

Gas Chromatograph with Flame Ionization Detectector(FID) and Heated Gas Sampling Valve

A GC with a sampling valve, column, and detector is needed for the semi-continuous analysis of the vent sample. Other detectors (Thermal

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Conductivity Detector or Photoionization Detector) may be substituted for the FID if they are shown to give equivalent results.

Chromatographic Column

A stainless steel, 10 foot (ft) [3 meter (m)] x 1/8 inch (in) [3 millimeter (mm)] outside diameter (O.D.), column containing 5% Fluorcol on 60/80 mesh Carbopack B is used to separate the EO from the CFC-12 and other materials present in the vent gas. Other columns (Chromosorb 102, Porapak® Q or R, Carbowax 20M) may be used, provided that the precision and accuracy of the standards analysis are not impaired. Information confirming that adequate resolution of the EO peak must be presented. Adequate resolution is defined as an area overlap of not more than 10% of the EO peak by an interferent peak.

Recorder/Integrator

A recorder/integrator is needed to record results.

Flow Meter

A flow meter is needed to accurately monitor sample loop flow rate of 100 mL/min.

Regulators

The following regulators are required for the GC support gases and the EO standards.

CGA 580--

One regulator is needed for the nitrogen carrier gas. A second regulator may be required for the standard manifold purge if the carrier gas line cannot be tapped.

CGA 590--

One regulator is needed for the air for the FID.

CGA 350--

Five regulators are needed; one regulator for the hydrogen on the FID and four regulators for the EO and CFC-12 standards. Two regulators with stainless steel diaphragms and Teflon seats and seals are required for the low concentration standards; one should be reserved for standards under 20 ppmv EO and the other for standards between 20 and 800 ppmv EO. The other two

standard regulators must be stainless steel; one should be reserved for standards between 800 ppmv and 2.5% (v) and the other for standards above 2.5% (v).

Teflon Tubing

Teflon tubing is needed to connect the gas cylinders to the GC, the sample loop to the sampling line and standard cylinders, the sampling line to the exhaust area, and for other miscellaneous connections. The diameter and length of the tubing depend upon the requirements of the system used. A recommended amount and diameter of tubing would be 10-20 ft (3-6 m) of 1/4 inch O.D. tubing. Each standard regulator should be equipped with 4-5 ft (1-2 m) of 1/8 in O.D. Tefon tubing.

Fittings

An assortment of Swagelock® fittings is desirable to plumb the GC to the gas cylinders and the sampling line to ensure leak-tight fittings. The size and type of fittings needed depend upon the type of tubing used and the type of fittings required by the GC and the cylinder regulators. Some recommendations are:

Caps and Front and Back Ferrules--

Teflon caps and ferrules (1/4 in) are needed to plumb in the glass flask. Stainless steel caps and ferrules (1/4 in and 1/8 in) are used on the ends of the Teflon tubing.

Unions--

Teflon (1/4 in) and stainless steel (1/4 in and 1/8 in) unions are used to connect tubing to impingers, sampling valves, etc.

Reducing Unions--

Stainless steel reducing unions (3/8 in to 1/4 in and 1/4 in to 1/8 in) are needed to connect cylinders to the GC and the sampling line to the gas sampling valve.

Soap Film Flow Meter

A soap film flow meter is used to measure GC carrier and support gas flow rates. It is also needed to calibrate any rotameters, dry gas meters, and mass flow meters used.

Two- or Three-way Radio

A two- or three-way radio is helpful to simplify communications between personnel at the sampling port, in the analytical area, and in the sterilizer control room.

REAGENTS

Unless otherwise indicated, it is intended that all reagents conform to the specifications established by the Committee on Analytical Reagents of the American Chemical Society where such specifications are available; otherwise, use the best available grade.

Nitrogen Gas

A grade of nitrogen which is 99.995 percent pure is required for use as the chromatographic carrier gas and as the system blank. If lower grades of nitrogen are used, purify the gas using hydrocarbon, water, and oxygen traps.

Hydrogen Gas

A grade of hydrogen which is 99.995 percent pure is required as a support gas for the FID. If lower grades of hydrogen are used, purify the gas using a hydrocarbon trap.

Air

A grade of air which is 99.9999 percent pure is required as a support gas for the FID. If lower grades of air are used, purify the gas using a hydrocarbon trap containing activated carbon.

Ethylene Oxide Standard Cylinders

Ethylene oxide and CFC-12 standards prepared in nitrogen which are certified through direct analysis are recommended for system calibration. The following concentrations balanced in nitrogen are suggested:

- 30% (v) EO and 5% (v) CFC-12,
- 3% (v) EO and 4000 ppmv CFC-12,
- 0.3% (v) EO and 300 ppmv CFC-12,
- 400 ppmv EO and 70% (v) CFC-12,
- 40 ppmv EO and 5% (v) CFC-12,
- 5 ppmv EO and 4000 ppmv CFC-12,
- 0.5 ppmv EO and 300 ppmv CFC-12.

If testing is performed on a controlled outlet only, the percent level EO standards are not needed.

1 N Sulfuric Acid Solution

A scrubbing solution consisting of 1 N H_2SO_4 with a pH between 1 and 2 is required for removing EO from the sampling stream before venting to the atmosphere. To prepare add 30 mL of concentrated sulfuric acid to 1 L of distilled water. Mix well. A minimum of 500 mL of scrubbing solution is needed.

Quality Assurance Audit Samples

Audit samples as described in Appendix C, Procedure 2: "Procedure for Field Auditing GC Analysis," 40 CFR, Part 61 are required.

PROCEDURE

Sampling Considerations

The sampling period begins with the start of the initial chamber evacuation and ends at the completion of the final air wash. The sampling line is continuously flushed with sample during the sampling period. The number of GC injections is based on the resolution time of the chromatographic column and the length of the evacuation interval.

Flow Rate Determination--

Restricted orifice plates are used as the basis for determining the stack gas velocity and the volumetric flow rate of the sample stream at linear velocities above 150 ft/min (45 m/min). This method calls for the use of orifice plates sized to the vent and fitted in flange holders with standard pipe taps. In cases where the gas density varies significantly two orifice plates may be required. At linear velocities between 20 and 150 ft/min (6-45 m/min) the method calls for the use of a vane anemometer.

Temperature--

Record temperature every 2 min with a type-K thermocouple or equivalent.

Moisture Content--

Determine the moisture content of the vent stream using the wet bulb/dry bulb technique.

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Semi-continuous Direct Sampling Procedure

In this procedure, sample is continuously withdrawn from the vent stream using a vacuum pump. A slip stream of gas is channeled into the gas sampling valve and injected into the chromatograph at 4 min intervals.

Assemble the sampling system as shown in Figure 1. Adjust the needle valves to yield a flow rate of 1 L/min to the manifold and 100 mL/min to the GC gas sampling valve. Leak check the assembly to prevent sample dilution and to protect personnel from fugitive EO emissions.

Place the probe at the centroid of the stack. Start the vacuum pumps and heat the sample transfer lines to prevent condensation.

When evacuation of the chamber begins, record the vane anemometer reading and the temperature of the vent gas at 2 min intervals. During the first and second evacuations measure oxygen content at 1 min intervals during the first 7 min of the evacuation. Measure oxygen content at least once during any subsequent evacuations. Take at least one wet bulb reading during each evacuation.

Analytical Procedure

A slipstream of the sample stream is drawn through a gas sampling loop and injected into a GC at 4 min intervals.

Gas Chromatographic Conditions--

The chromatographic conditions listed in Table 1 will resolve EO from CFC-12 and other interferences common to EO sterilization chamber vents. It may be necessary to change these conditions to resolve other interferences that are present in samples collected from different EO sources.

Calibration--

Calibrate the GC before the start and at the end of the test using the gas standards. A minimum of four points (four different standard concentrations) are needed to construct a calibration curve. For analysis of samples from an uncontrolled chamber, the GC needs to be calibrated with 400 ppmv to 30% (v) EO standards. For analysis of samples from a controlled chamber, the GC requires calibration with 0.5 ppmv to 400 ppmv EO standards. Use the same injection method and the same volume of sample for the calibration standards and the samples.

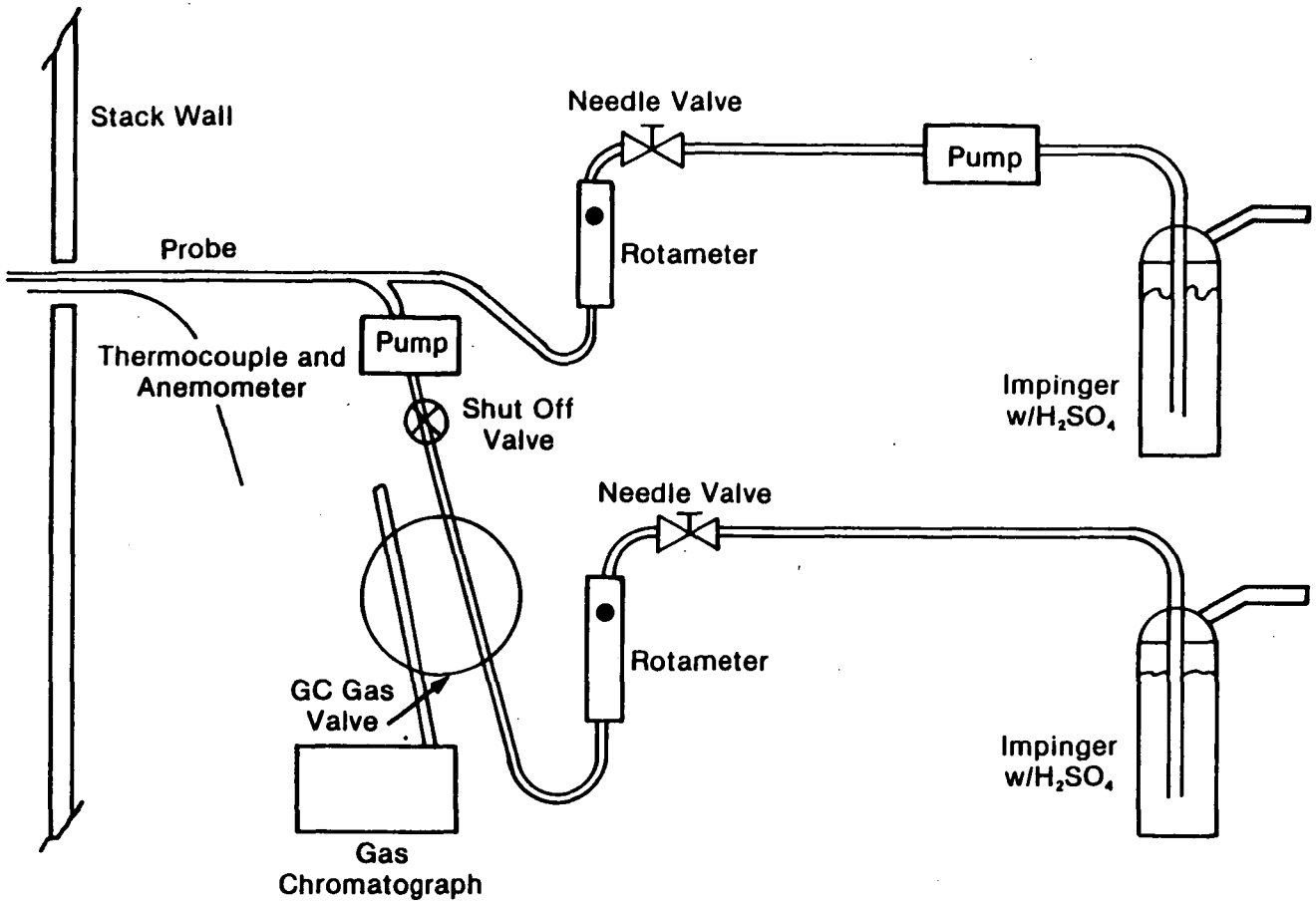

Figure 1. Semi-Continuous Direct Sampling System Assembly

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TABLE 1. GAS CHROMATOGRAPHIC CONDITIONS

Parameter	Recommendation
Column	5 percent Fluorcol on 60/80 Mesh Carbopack B, 10 ft (3 m) x 1/8 in (3 mm), stainless steel
Column Temperature	55°C, isothermal for percent level analyses; 65°C, isothermal for ppmv level analyses
Injector Temperature	200°C
Detector Temperature	250°C
Gas Flow Rates	Follow manufacturer's recommendations
Valve	6-port heated to 150°C
Sample Loop Size	0.5 or 1 mL

Sample Analysis--

After the chamber evacuation begins, prepare to acquire the first sample. Before making the initial injection, allow sufficient time (3-4 min) for the residual air to purge from the line and for the sample to reach the manifold. (The time required will vary depending upon the amount of line used and the distance between the sampling port and the chromatograph. Determine sample line residence time prior to the test period.) Purge the sample loop for a minimum of 20 sec, simultaneously close the sampling valve and disconnect the vacuum pump, allow the sample loop to reach atmospheric pressure and make the initial injection. After the initial injection, make subsequent injections at 4 min intervals until the chamber evacuation ends.

Documentation--

Document each chromatogram by listing the sample location, injection volume, and injection time.

Audit Analysis

Immediately after the preparation of the calibration curve and prior to the sample analyses, perform the analysis audit described in Appendix C, Procedure 2: "Procedure for Field Auditing GC Analysis." 40 CFR, Part 61.

CALIBRATION

Rotameter

Calibrate the rotameter at three different flows before and after each test.

Probe Temperature Gauge and Thermocouple

Calibrate using ice water and boiling water (ASTM-E1 #63C or 63F specifications) before the test.

Restricted Orifice Plates and Pressure Transducers

The restricted orifice plates should be purchased calibrated in the range of expected use. The pressure transducers should be calibrated for the expected range before use in the field.

Vane Anemometer

Provide factory calibration (or equivalent) of the vane anemometer in the range of expected use.

Gas Chromatograph

Calibrate the GC at the start and at the end of each test day using prepared or purchased gas standards. Follow the calibration procedure described earlier. Use the chromatographic data (peak height or area) and standard concentration to prepare a least squares calibration curve.

Certified Standard Cylinders

Verify the certified concentrations of the purchased standard cylinders using an independent standard (one purchased from a second supplier or prepared in the laboratory using pure EO and CFC-12 diluted with nitrogen). Using the independent standard, prepare four-point calibration curves. From the calibration curves, calculate the measured concentrations of the certified standards. If the measured concentrations differ from the certified concentrations by more than ±10%, do not use the standards.

CALCULATIONS

Perform the following calculations, retaining at least one figure more than the required number of significant figures. Round off to the correct number of significant figures after making the final calculation.

Ethylene Oxide Concentration

Determine the EO concentration at each measured point by comparing the peak area obtained for each sample with those derived from the least squares calibration curve obtained as described earlier. Plot EO concentration versus elapsed time.

Inert Gas Concentration

Determine the inert gas concentration at each measured point based on GC data. If no CFC-12 is present in the sample, assume the gas which is not EO is air. Plot the inert gas concentration versus elapsed time.

Moisture Content

Calculate the moisture content (C_a) in the exhaust gas using the following formula:

$$C_a = (VP \times RH)/P_{bar} \qquad \text{(Equation 1)}$$

where:

C_a = Water vapor in the gas stream, mole fraction

P_{bar} = Barometric pressure, mm (inches) Hg

VP = Saturated vapor pressure of water at stack temperature, mm (inches) Hg

RH = Relative humidity determined by wet bulb/dry bulb method

The relative humidity using the wet bulb/dry bulb method and the saturated vapor pressure of water at stack temperature can be obtained from standard tables.[15, 16]

Molecular Weight of the Gas

Determine the molecular weight of the gas at each measured point using the following formula:

$$MW_{av} = P_{EO} \times 44.05 + P_F \times 120.91 + P_A \times 28.975 + P_W \times 18.02 \qquad \text{(Equation 2)}$$

where:

MW_{av} = Average molecular weight, g/g-mole (lb/lb-mole)

P_{EO} = Volume Percent EO

P_F = Volume Percent CFC-12

P_A = Volume Percent air

P_W = Volume Percent water

Total Gas Flow Rate

Calculate the total flow of gas emitted in terms of pounds per second (lb/sec [kilograms per second (kg/sec)]) at each measured point using the following equation:[17]

$$w = KYA \ (2g_c(p_1-p_2)\rho)^{1/2} \qquad \text{(Equation 3)}$$

where:

A = cross-sectional area of the orifice throat, ft^2,

w = mass rate of flow, lb/sec,

$K = C/(1-B^4)^{1/2}$, dimensionless,

C = coefficient of discharge, dimensionless,

B = ratio of throat diameter to pipe diameter, D_2/D_1, dimensionless,

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D_2 = orifice throat diameter, in,

D_1 = pipe diameter, in,

Y = expansion factor, dimensionless,

g_c = dimensional constant = 32.174 (lb ft)/(lb force sec^2),

p_1, p_2 = pressure at upstream and downstream static pressure taps respectively, lb/ft^2, and

ρ = density at upstream pressure and temperature, lb/ft^3.

Values for C may be obtained from Reference 17. Determine the expansion factor, Y using the equation:[17]

$$Y = \{r^{2k}[k/(k-1)][(1-r^{(k-1)/k})/(1-r)][(1-B^4)/(1-B^4 r^{2/k})]\} \qquad \text{(Equation 4)}$$

where:

$r = p_2/p_1$,

k = specific heat ratio, C_p/C_v.

Values for k may be obtained from the appropriate figures in Reference 18. Plot a graph of total gas flow rate versus elapsed time.

Ethylene Oxide Mass Flow Rate

Select a number of points at equal time intervals during the evacuation. At each selected point combine total gas flow rate, vent gas molecular weight, and EO concentration at that point using the following equation:

$$m = 60 \times w \times (P_{EO} \times MW_{EO})/MW_{av} \qquad \text{(Equation 5)}$$

where:

m = mass flow rate of EO, lb/min,

w = total gas flow rate, lb/s,

P_{EO} = EO concentration, percent by volume = $ppmv/10^6$,

MW_{av} = molecular weight of the vent gas, and

MW_{EO} = molecular weight of EO.

Plot a graph of EO mass flow rate versus elapsed time.

Total Mass of Ethylene Oxide

Integrate the curve obtained above to determine the total weight of EO exhausted to the atmosphere during the post-sterilization period. Add the weights determined for the individual evacuations to obtain the total weight

of EO emitted over the entire exhaust cycle using the following equation:

$$\sum_{i=1}^{k} \overline{M_i} \; t = \text{total mass} \qquad \text{(Equation 6)}$$

where:

i = The equally spaced time interval

k = Number of time intervals

$\overline{M_i} = (M_{i-1} + M_i)/2$

M_i = Mass flow rate, lb/min

t = Time interval, min

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SECTION 5

LABORATORY METHOD EVALUATION AND OTHER EXPERIMENTS

SUMMARY OF LABORATORY STUDIES

The following tasks were performed in the laboratory and are reported below:

- A semi-continuous direct sampling method and a canister sampling method were tested on an artificially generated vent stream;
- The stability of EO standards in Summa® canisters was determined and a method of removing residual EO from the canisters was evaluated;
- A sample of vent gas taken during the pretest survey at the chosen facility was analyzed in the laboratory;
- Different packed columns were evaluated to determine their suitability to separate EO and CFC-12;
- Adsorption of EO on the sample loop and other surfaces was determined;
- The retention time shift of the EO peak on the column of choice was studied; and
- A sample of vent gas was analyzed by gas chromatography with mass spectral detection (GC/MS) and with flame ionization detection (GC/FID).

VENT STREAM TESTING

A pseudo-EO chamber vent stream was produced and the necessary sampling equipment was assembled in the laboratory. The testing system performance was checked for reproducibility. A semi-continuous direct and a canister sampling method were tested for accuracy using the assembled system.

The semi-continuous direct sampling method with on-line gas chromatographic analysis was tested because of its rigor. This method should provide accurate emissions data regardless of the EO concentration profile of the exhaust stream. However, this method has several disadvantages. First, it requires on-site analysis. Second, each sample can only be analyzed one

time since sampling and analysis are performed on-line. Finally, the number of samples acquired is limited by the analysis time of the sample on the column.

Using grab sampling or integrated grab sampling eliminates some of these disadvantages. The collection of integrated grab samples in canisters has the advantages that collected samples can be shipped to a laboratory for later analysis and that multiple injections can be obtained for each sample. The major problem with canister sampling is that it is a time-integrated method and will only provide accurate emission measurements if the EO concentration profile of the exhaust stream is static.

Canisters were chosen instead of Tedlar® bags as the collection container for integrated samples because canisters are sturdy containers which have a lower potential for leaking. Ethylene oxide has the potential to cause chromosomal damage at levels of 50 ppmv and to increase the risk of leukemia at levels of 20-30 ppmv.[5] Using canisters would help to minimize worker exposure to EO.

Description of the Testing System and Sampling Setup

Several simulated EO chamber vent and sampling configurations were tested. The final configuration is shown in Figure 2. The dry gas meter was placed after the sampling port so that it would not interfere with concentration determinations. The EO chamber vent was simulated using a cylinder of 50 ppmv EO standard in nitrogen, a nitrogen cylinder, and calibrated Tylan flow controllers. The sampling system consisted of a needle valve, Thomas pump, and either a gas sampling loop or a Summa canister.

Both the flow rate and concentration of the vent stream were adjusted to simulate a reduced, yet similar, flow and concentration pattern which would occur from a large (1000 ft^3 [28 m^3]) sterilizer. Two different flow and concentration patterns were used, one to simulate an initial chamber evacuation and the other to simulate a subsequent evacuation.

Testing System Reproducibility

The EO and nitrogen flow rates were varied at 30-second (sec) intervals. The set flow rates were recorded after every adjustment or 30-sec interval. Using the recorded set flow rates, the total weight of EO emitted from the simulated vent was calculated. The relative standard deviation in total

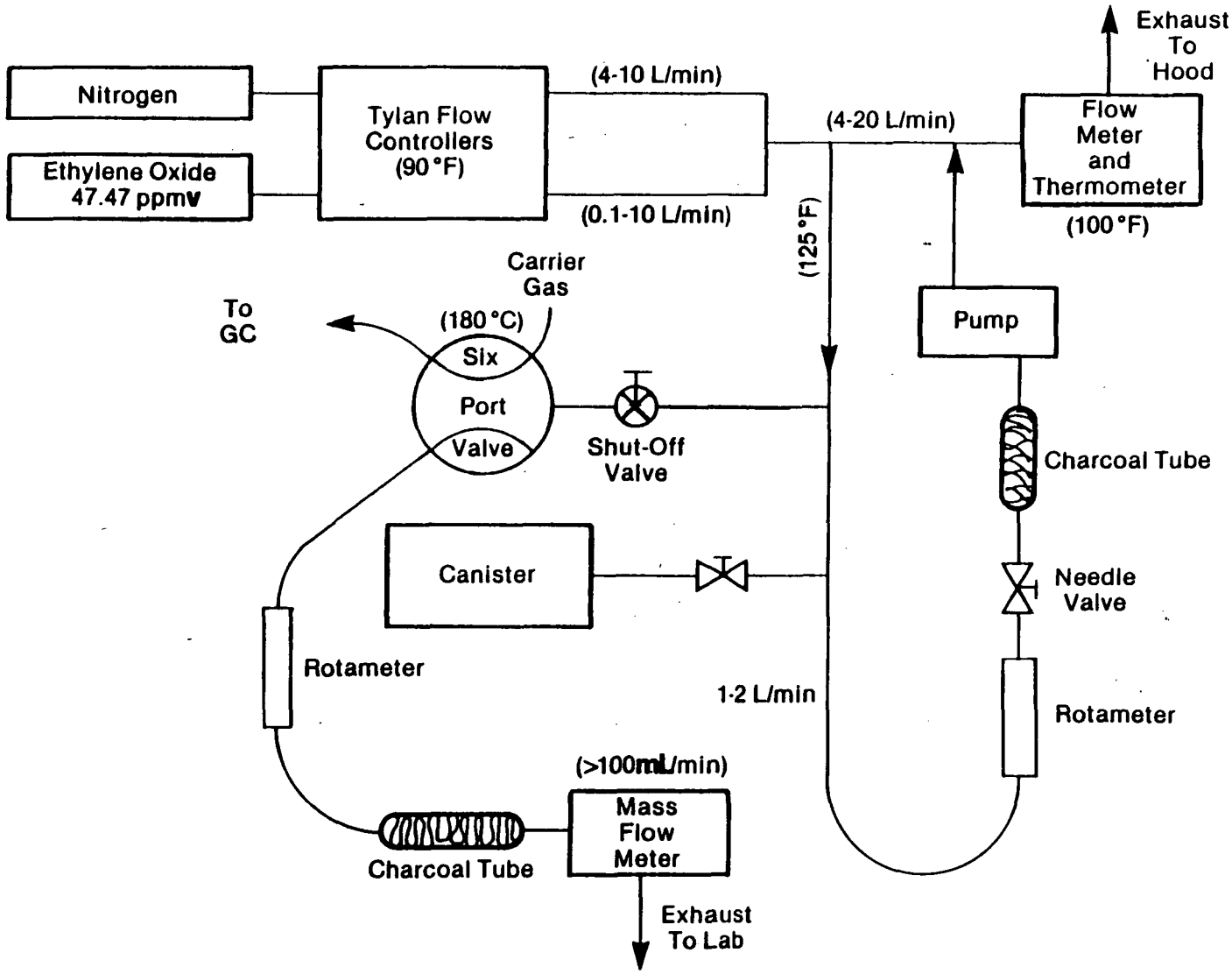

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Figure 2. Laboratory Test System

milligrams of EO emitted between simulations was <1 percent. Thus, the vent simulator generated reproducible variable flow and variable concentration patterns for evaluating both sampling methods.

Results of the Semi-continuous Direct Sampling Method

Semi-continuous direct sampling was evaluated in the laboratory as a method of measuring EO emissions from a variable flow and variable concentration vent. The vent flow rate was recorded every 30 sec. Initially, the gas sampling valve was flushed for a minimum of 30 sec. Samples were injected into the gas chromatograph when the pressure within the loop reached atmospheric pressure. After the initial sample injection, samples were taken every 1.5 to 2 min by closing the gas sampling shut-off valve.

Three trials using semi-continuous direct sampling were conducted. Each trial consisted of an initial evacuation and an air wash simulation. In all three trials the measured emitted mass of EO was within 11% of the expected value. The between-trial precision, as measured by relative standard deviation, was 5 percent.

Results of the Canister Sampling Method

Canister sampling was evaluated in the laboratory as another method of measuring EO emissions from a variable flow and variable concentration vent. The vent flow rate was recorded every 30 sec. The canisters were filled at a constant rate of 500 mL/min (0.0018 cfm). The canister samples were injected into the gas chromatograph at the completion of the vent simulation.

Two trials using canister sampling were conducted. No additional trials were performed because the results of the method were reproducible. Each trial consisted of an initial evacuation and an air wash simulation. In both trials the total measured emitted mass of EO was within 15% of the expected value. The relative difference (given by the difference in the two values divided by the mean) between the two trials was <5 percent.

CANISTER STUDIES

In order to propose a viable canister field sampling method in the future, both the stability of EO in the canisters and a method of removing residual EO from the canisters were determined.

Stability Studies of EO in Summa Canisters

The stability of EO in nitrogen in 6 liter (L) [0.2 ft^3] Summa canisters was studied over a two-month period. Two canisters were used for the study. One canister was filled with a 98.05 ppmv EO standard in nitrogen and the other canister was filled with a 4.454 ppmv EO standard in nitrogen. Both EO standards were certified to within ± 2 percent.

The standards in the two canisters were analyzed throughout a two month period using GC/FID. The response of the standards in the canisters was compared to the response of the standards in the original aluminum cylinders. The results are shown graphically in Figure 3. The graph was prepared by taking the difference between the response of the sample in the canister and the response of the standard, dividing it by the response of the standard and multiplying it by 100. Numbers closer to zero indicate greater stability.

No degradation or loss of EO was observed during the first 24 hours. After three days (72 hours), the 4.454 ppmv EO standard showed a loss of approximately 7 percent. A maximum loss of 40% occurred within a one month (29 day) period. No additional loss in the low concentration standard was observed after one month (between 29 and 65 days). The 98.05 ppmv EO standard showed a 2.5% loss over the two-month (65 day) period.

The loss of EO in the Summa canisters was attributed to adsorption of the EO onto the surface of the canisters. The amount of EO adsorbed on the surface of the canisters was equivalent to approximately 2.5 ppmv. This value was obtained from the loss of approximately 50% of the 4.454 ppmv standard and approximately 2.5% of the 98.05 ppmv standard. A 0.5 ppmv EO standard was prepared in a canister that had been previously exposed to EO. Its response on the GC/FID was compared to the response of the certified 4.454 ppmv standard. After one week, the response ratio of the two standards had not changed. From this limited study of three canister samples, the following recommendations can be made:

- If possible, all EO samples collected in Summa canisters should be analyzed within one week of collection.
- Summa canisters, used to collect EO samples which are expected to be 2.5 ppmv or less, should be pre-exposed to EO before sampling.
- Additional studies regarding the stability of EO samples from actual sources in Summa canisters should be conducted.

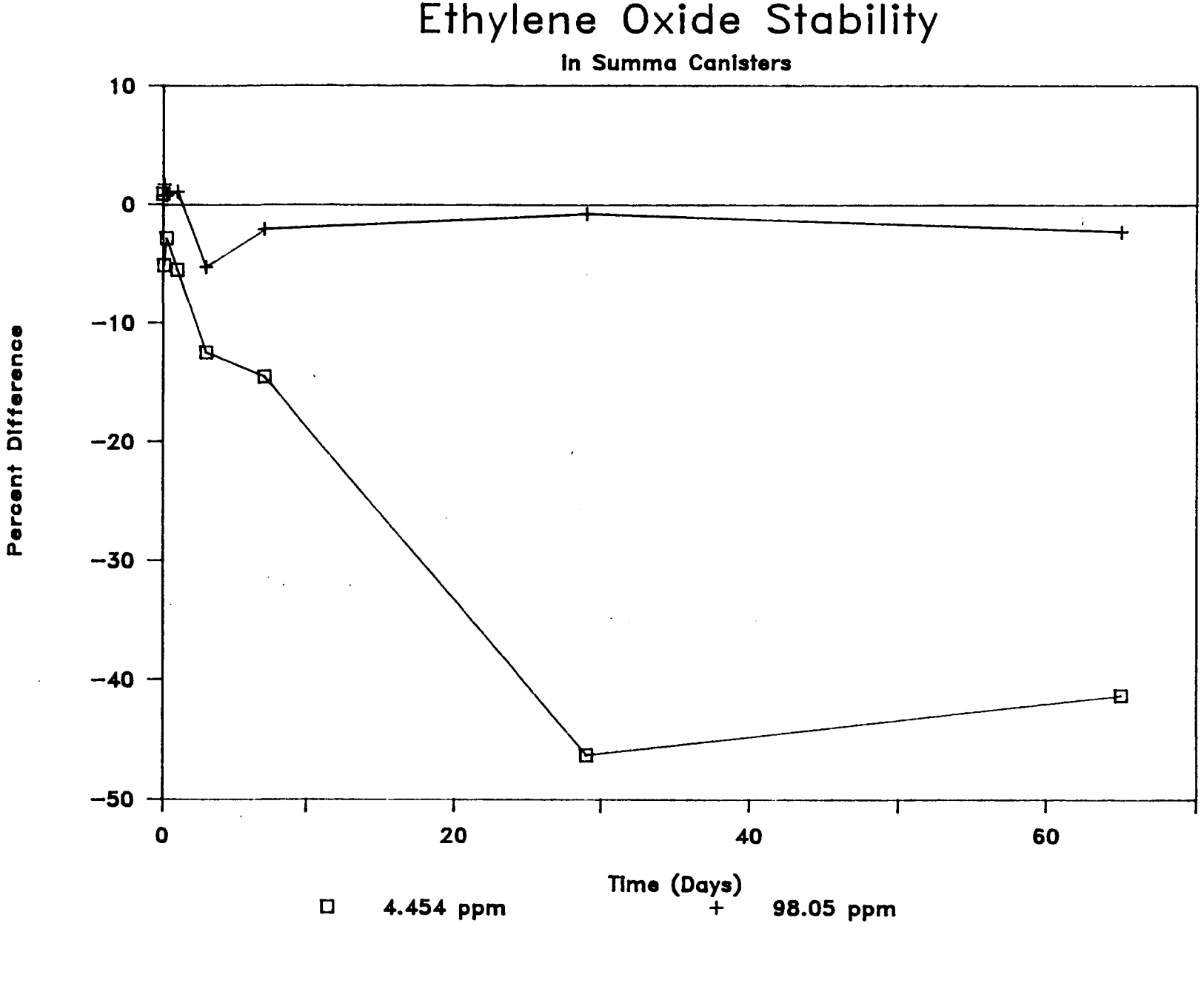

Figure 3. Ethylene Oxide Stability In Canisters

Residual Canister Cleanup

A method for cleaning the canisters in the field was developed and tested in the laboratory. Filling the canisters with clean nitrogen three times was found to be inadequate to remove the residual EO. As much as a third of the original EO remained in the canister. However, when the canister was evacuated with a vacuum pump between each of the three nitrogen purges, all of the residual EO was removed.

ANALYSIS OF PRESURVEY SAMPLE

In September 1986, Burron Medical in Allentown, Pennsylvania was selected as a field test site for evaluation of the semi-continuous direct sampling and analytical method. A pretest site survey was performed to verify the suitability of the site for the method evaluation.

During the survey, eight grab samples were obtained from the control unit stack, six in Vacusampler® cans and two in stainless steel bombs. Five of the samples (three cans and both bombs) were returned to Radian for analysis and three were analyzed by the facility. The samples were obtained during the first chamber evacuation of a normal product sterilization cycle.

The samples returned to Radian were analyzed by GC/FID using both a Porapak® R column and a 1% SP-1000 on Carbopack B column. Both were 6 ft (3 m) by 1/8 in (3 mm) O.D. stainless steel columns. On the Porapak R column the EO eluted after 4 min and the CFC-12 eluted at 2.7 min at a column temperature of 100°C. On the SP-1000 column the EO eluted at 1 min and the CFC-12 eluted at 1.9 min at a column temperature of 60°C.

The EO on the Porapak R column was well resolved from the CFC-12 when moderate amounts of CFC-12 were present; however, when the sample consisted of primarily CFC-12, the EO was lost in the CFC-12 tail. Quantitation of the EO in any of the samples was difficult on the Porapak R column.

The SP-1000 column easily resolved the EO from the CFC-12 and the EO was easily quantitated for all of the samples. The measured EO concentration in the five samples ranged from 0.2 ppmv to 2.3 ppmv.

The plant analyzed their three samples on a glass column packed with 0.8% Tetrahydroxyethylenediamine (THEED) on Carbopack C. The samples were found to contain from 1.6 to 220 ppmv EO.[19]

Analysis of the presurvey samples indicated that replicate samples analyzed using different analytical systems in different laboratories may vary greatly in analyzed concentration. Also, the presurvey sample analysis indicated that a column that eluted EO before CFC-12 would be preferable in the analysis of ppmv levels of EO in the presence of percent levels of CFC-12.

COLUMN EVALUATION

Several columns were evaluated by the EPA Project Officer in order to find a column on which EO eluted before CFC-12.

Columns Evaluated

The columns evaluated by the EPA Project Officer may be divided into three categories, those that did not resolve EO and CFC-12, those in which the CFC-12 eluted before the EO, and those in which the EO eluted before the CFC-12. The columns which failed to resolve EO and CFC-12 included a 6 ft (1.8 m) by 1/8 inch (0.3 cm) stainless steel column containing 10% SP-1000 on 80/100 mesh Supelcoport tested at 50°C and 100°C, a 5 ft (1.5 m) by 1/8 inch (0.3 cm) stainless steel column containing 3.8% OV®-1 on Chromosorb® W HP tested at 70°C, a 10 ft (3 m) by 1/8 inch (0.3 cm) stainless steel 10% Dibutyl maleate on 60/80 mesh Chromosorb P and a 6 ft (1.8 m) by 1/8 inch (0.3 cm) column containing 7% Squalene on Chromosorb 750 tested at 40°C and 70°C.[20]

The columns which eluted CFC-12 before EO can be divided into two categories, those with a liquid phase and those without. The columns without a liquid phase included a 6 ft (1.8 m) by 1/8 inch (0.3 cm) stainless steel column containing 100/120 mesh Porapak R tested at 100°C, a 6 ft (1.8 m) by 1/8 inch (0.3 cm) stainless steel column containing 60/80 mesh Chromosorb 101 tested at 40°C and 100°C, a 6 ft (1.8 m) by 1/8 inch (0.3 cm) stainless steel column containing 60/80 mesh Chromosorb 102 tested at 100°C, and a 10 ft (3 m) by 1/8 inch (0.3 cm) stainless steel column containing 80/100 mesh Porapak QS tested at 100°C.[20] Resolution data of EO from CFC-12 for most of these columns are presented in Table 2.

Columns which contained a liquid phase and in which CFC-12 eluted before EO included a 10 ft (3 m) by 1/8 inch (0.3 cm) stainless steel 10% SP-2401 on 100/120 mesh Supelcoport tested at 30 and 50°C and a 2 ft (0.6 m) by 1/8 inch (0.3 cm) stainless steel column containing 20% Dibutyl maleate on 40/60 mesh

TABLE 2. RESOLUTION OF EO FROM CFC-12[20]

Column[a] Description	Length (ft) [m]	Temperature (°C)	Resolution (R)	Retention Time (min) EO	Retention Time (min) CFC-12
Porapak R	6 [1.8]	100	2.5	4.5	
Chromosorb 101	6 [1.8]	100	1.8	2.7	
Chromosorb 101	6 [1.8]	40	1.8	26	
Chromosorb 102	6 [1.8]	100	3.2	4.4	
Porapak QS	10 [3]	100		7.9	4.6
10% SP-2401	10 [3]	50		1.6	1.0
10% SP-2401	10 [3]	30		2.3	1.0
C_4 Maleate	2 [0.6]			2.1	0.4
Carbopack B HT	6 [1.8]	60	0.5[b]	2.3	
Carbopack B HT	10 [3]	70	c	3.6	4.5
Carbopack B HT	16 [4.8]			5.6	9.6
5% Fluorcol	10 [3]	30	3.1	3.3	6.8
5% Fluorcol	10 [3]	40	2.4	2.6	4.9

[a]All columns were of premium grade stainless steel with outer diameters of 1/8 inch (0.3 cm).

[b]Almost baseline resolution. The R value is misleading because of the large width of the CFC-12 peak.

[c]Baseline resolution.

Chromosorb P.[20] Retention times for EO and CFC-12 on these columns are reported in Table 2.

Columns which resolved the EO from the CFC-12 and eluted EO before CFC-12 included 6 ft (1.8 m), 10 ft (3 m) and 16 ft (4.8 m), by 1/8 inch (0.3 cm) O.D. stainless steel columns containing 60/80 mesh Carbopack B HT and a 10 ft (3 m) by 1.8 inch (0.3 cm) O.D. stainless steel column containing 5% Fluorcol on 60/80 mesh Carbopack B.[20] Resolution and retention data for these columns is presented in Table 2. The Fluorcol column was determined to be the best of these four columns because the linear range of the EO calibration curve spanned the greatest magnitude and the Fluorcol column had the larger number of plates, 2560 plates compared to 1940 plates for the Carbopack B HT columns.[20]

Further Evaluation of the Column of Choice

The 10 ft (3 m) by 1/8 inch (3 mm) O.D. 5% Fluorcol on 60/80 Carbopack B stainless steel column was further evaluated by the EPA Project Officer to determine the optimal GC/FID conditions for the separation of EO from CFC-12 and the limit of detection (LOD) for EO.

Optimization of Instrumental Conditions--

A column temperature of 55°C was required for baseline resolution of percent level mixtures of EO (4-30% [v]) and CFC-12 (96-70% [v]).[14] For ppmv level EO concentrations baseline resolution was achieved at a column temperature of 65°C.[14] A van Deemter plot indicated an optimum flow rate of 30 mL/min.[14]

Sample loops of 0.5 and 1.0 mL and samples of EO/CFC-12 mixtures with no air present were used to determine the linearity of the FID response. Ethylene oxide response was linear up to 30% (v) EO at both sample volumes.[14] The CFC-12 response was linear from 70-100% (v) with the 0.5 mL sample loop, but with the 1.0 mL loop nonlinearity occurred above 90% (v) CFC-12.[14]

Detection Limit Determination--

The LOD was estimated using a procedure developed by Knoll[21] and by taking twice the noise level. Using the optimum conditions determined above for low levels of EO, the LODs were 0.03 and 0.07 ppmv for 1.0 and 0.5 mL sample loops, respectively.[14] Both methods of determinating LOD gave the same results.

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Retention Time Shifts--

The EO retention time was observed to be a function of the EO concentration. With a nitrogen carrier gas flow rate of 30 mL/min and a column oven temperature of 65°C, the retention time was 1.7 min for percent level samples versus 2.1 min for a 1.1 ppmv sample.[14]

ADSORPTION STUDIES

During the column evaluation performed by the EPA Project Officer, some of the EO adsorbed onto the sample loop. Also, a study reported in the literature,[22] indicated that adsorption of EO was greatly reduced by replacing stainless steel sampling loops with Teflon sampling loops. Since heated stainless steel sampling loops would be used in the field, laboratory studies were performed to determine if EO adsorption occurred on heated stainless steel loops. Additional studies were also conducted to determine if adsorption occurred in the heated Teflon lines that would be used as sampling lines to transport sample from the sampling ports to the GC.

Procedure

The heated gas sampling valve was flushed for 0.5 min with nitrogen or standard flowing at 100 mL/min. Samples were injected when the rotameter indicated that there was no flow through the loop.

Initially, the system was blanked with ultra high purity nitrogen. Then the standard was injected until three peaks with reproducible area (within 10%) were obtained. Next nitrogen was injected either until the peak was very small or had totally disappeared.

Three system configurations were tested. In the first system, the shut-off valve and metering valve were connected before the sampling valve by a length of stainless steel tubing. The cylinder regulator was connected to the shut-off valve by a length of 1/4 inch O.D. Teflon tubing. To switch from nitrogen to standard to nitrogen, the Teflon tubing was switched between the nitrogen regulator and the standard regulator.

In the second configuration, the shut-off valve and metering valve were connected after the sampling valve. The cylinder regulator was connected directly to the sampling valve using a length of 1/8 inch O.D. Teflon tubing.

Again, to switch from nitrogen to standard to nitrogen, the Teflon tubing was switched between the nitrogen regulator and the standard regulator.

The third configuration was the same as the second configuration except that two 1/8 inch O.D. lengths of Teflon tubing were used, one between the nitrogen regulator and sampling valve and the other between the standard regulator and sampling valve.

A 5.005% (v) EO standard was used in all three configurations. In the third configuration, a 4.454 ppmv EO standard was also tested.

A 100 ft (30 m) heat-traced line heated to >100°C was tested for adsorption of EO by purging the line with 4.454 ppmv EO standard and comparing the peak area measured to the peak area measured when the same standard was analyzed directly.

Calculations

The amount of adsorption occurring in the system was calculated by the ratio of the area of the EO peak for the first nitrogen injection to the average area of the three standard peaks.

Results

The results of the sample loop adsorption studies are reported in Table 3. In Configuration 3 the adsorption measured was the adsorption occurring on the loop only. The amount of this adsorption was small compared to the adsorption measured in the other two configurations. For the high EO standard, the amount of adsorption was equivalent to 4.24 ppmv and for the low EO standard the amount of adsorption was equivalent to 0.1112 ppmv.

The amount of adsorption occurring on the Teflon line and in the loop was measured using Configuration 2. Approximately 4% of this adsorption could be attributed to the loop, so the amount of adsorption occurring on the surface of the Teflon line was equivalent to 99.4 ppmv.

The EO adsorption study on the heat-traced line was repeated twice. The absolute difference between the EO peak area obtained when standard was purged through the heat-traced line and the EO peak area when standard was analyzed directly ranged from -8.9 to 7.1 percent.

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TABLE 3. RESULTS OF ETHYLENE OXIDE SAMPLE LOOP ADSORPTION STUDIES

Configuration	Standard Concentration	Amount of Ethylene Oxide Adsorbed (In Terms of % of Average Standard Injection)		
		1 Purge	2 Purges	3 Purges
1	5.005% (v)	2.046%	0.569%	0.257%
2	5.005% (v)	0.207%	0.059%	0.032%
3	5.005% (v)	0.00847%	0.00428%	NA
3	4.454 ppmv	2.497%	1.411%	0%

Conclusions

The amount of adsorption occurring on the loop will not significantly affect concentration values for high concentration (>100 ppmv) EO samples. The effect of EO adsorbing on the loop will have a minimal effect on EO samples with concentrations between 10 and 100 ppmv. Sample loop adsorption effects will not become significant unless samples have concentrations below 1 ppmv; therefore, such designs are applicable for streams containing EO concentrations from 1 ppmv to 30 volume percent.

Some adsorption occurs in the Teflon lines between the standard cylinders and the sampling valve. To minimize any effect from EO adsorption on these surfaces, specific Teflon lines should be assigned to each regulator for use with that regulator only. Preferably each standard should have its own regulator or regulators should be used only on standards within a similar concentration range. Also, if possible, no metering valve or shut-off valve should be placed between the regulator and the sampling valve.

Adsorption losses of EO do not occur in the heat-traced sampling lines used to transport the sample from the sampling ports to the GC; therefore, such designs are applicable for streams containing EO concentrations from 1 ppmv to 30 volume percent.

RETENTION SHIFT STUDIES

In the initial study of the column, the EO retention time was observed to vary with the EO concentration. In the field, using a dual column instrument with one column dedicated for analyzing inlet samples and the other for outlet samples, the retention time was observed to shift on one of the columns but not on the other. Retention time shifts occurred when the carrier gas flow rate was less than 30 mL/min and the sample size was 2 mL. A carrier gas flow rate of about 60 mL/min and a 0.25 mL sample size caused minimal retention time shifts. To determine if the retention time shifts were a function of sample size or carrier gas flow rate, additional laboratory studies were performed.

Procedure

Ten standard samples, prepared gravimetrically in aluminum cylinders, were analyzed on the two 5% Fluorcol columns. Standard concentrations ranged

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from less than 1 ppmv to 12.5% (v). The carrier gas flow rates were maintained at less than 30 mL/min on one column (Column B) and about 60 mL/min on the other column (Column A). Two sample volumes, 2 mL and 0.25 mL, were injected on both of the columns. The column oven temperature was maintained at 100°C throughout the experiment.

Results

Each standard was injected twice under the four test conditions. Standard deviations from the two injections are reported in parentheses. At a high carrier flow rate and large sample volume the EO retention time shifted from 1.4 min (0.01) for a 4.5 ppmv standard to 0.9 min (.003) for a 12.5% (v) standard and the CFC-12 retention time shifted from 1.36 min (0) for a 1,200 ppmv standard to 1.14 min (0.004) for a 62.5% (v) standard. When the sample volume was decreased, the EO retention time shifted from 1.2 min (0.007) for a 9.1 ppmv standard to 0.8 min (0.01) for a 12.5% (v) standard and the CFC-12 retention time shifted from 1.21 min (0.02) for a 1,200 ppmv standard to 1.14 min for a 62.5% (v) standard.

A low carrier flow rate and large sample volume resulted in EO retention time shifts of from 2.6 min (0.04) for a 0.9 ppmv standard to 1.3 min (0.01) for a 12.5% (v) standard and CFC-12 retention time shifts of from 2.0 min (0.01) for a 1,200 ppmv to 1.6 min (0.01) for a 62.5% (v) standard. A decreased sample volume yielded EO retention time shifts of from 2.4 min (one injection only) for the 0.9 ppmv standard to 1.3 min (0.002) for the 12.5% (v) standard and CFC-12 retention time shifts of from 2.0 min (0.001) for the 1,200 ppmv standard to 1.8 min (0.003) for the 62.5% (v) standard.

For both compounds and both sample sizes the magnitude of the retention time shift is greater when the lower flow rate is used. There is no noticeable effect on the EO retention time shift due to sample size; however, the magnitude of the retention time shift increases with sample volume for CFC-12.

Retention Order Change and Coelution Possibilities

The shifting retention times raises a question regarding the conditions required for the compounds to coelute or change their relative retention characteristics. Figure 4 shows the EO and CFC-12 data plotted on the same

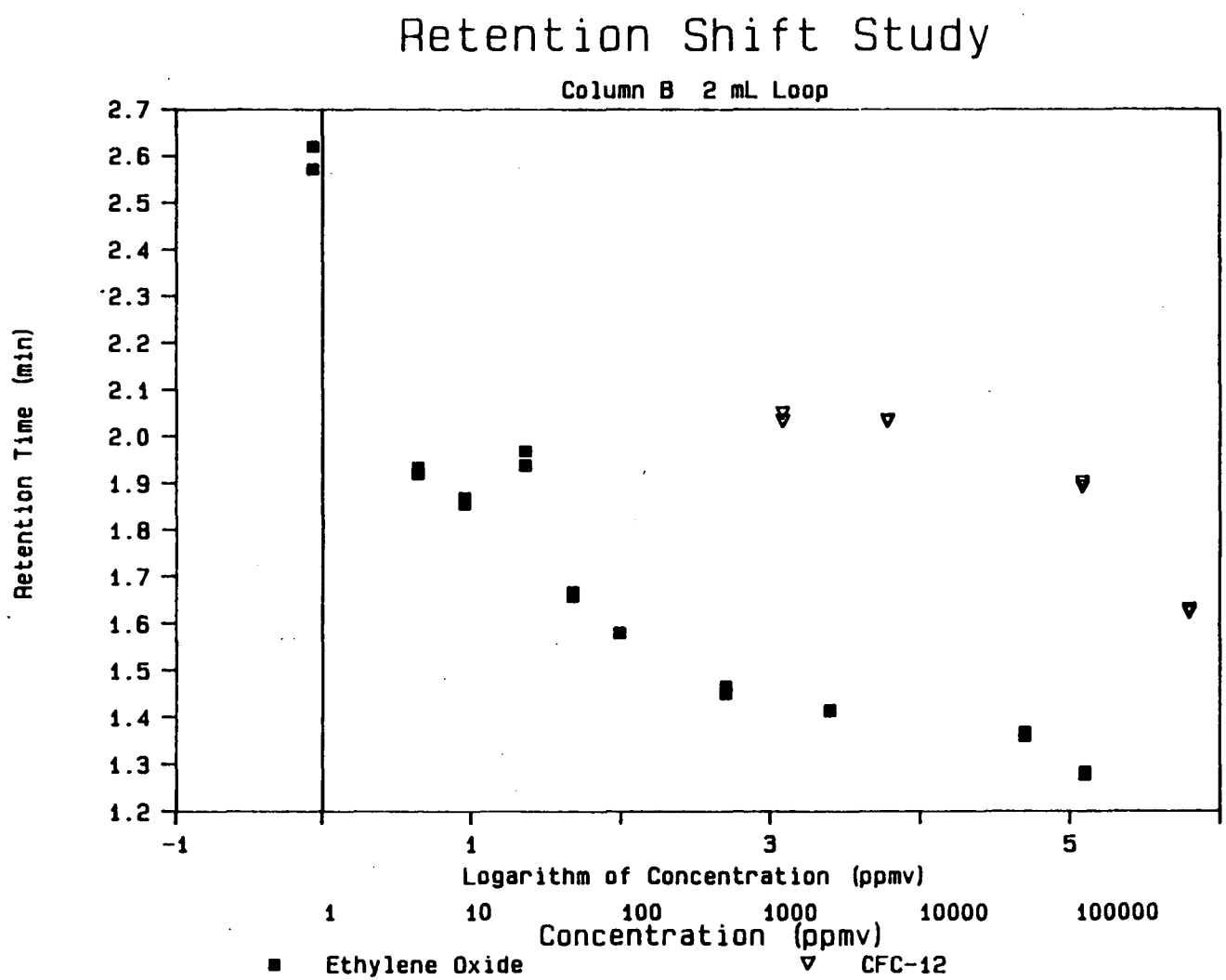

Figure 4. Retention Time Versus Logarithm of Concentration

graph at low carrier gas flow and with a large sample volume. The natural logarithm of the concentration was used for plotting to allow all of the data to be plotted legibly on one graph. From this figure it is apparent that the CFC-12 retention time remains constant until the column is overloaded with sample. The EO retention time changes continually with concentration.

The plot also shows that there are many conditions under which the compounds would be expected to coelute. For example, in samples containing less than 10 ppmv of EO and less than 1% (v) of CFC-12, it is likely that the two components would coelute. Also, in a sample containing less than 100 ppmv of EO and more than 1% (v) CFC-12, it is possible that the order of elution would be reversed. These predictions are derived from the experimental data and need to be substantiated by experimentation to verify that there are no other parameters, such as column temperature or compound interactions, that affect the elution time and order.

Conclusions

The CFC-12 retention time probably remains constant until column overload begins at a concentration of approximately 1 volume percent. The EO retention time continually decreases with increasing concentration. For both compounds, the retention time shift with changing concentration is greater when the carrier gas flow rate is slower. A larger sample size does not increase the magnitude of the EO retention time shift but does increase the magnitude of the CFC-12 retention time shift.

The larger shift in EO retention times compared with the shift in CFC-12 retention times was due to the larger range in EO concentrations which were sampled. Also, the retention time shift was exacerbated relative for the laboratory results because of the higher column temperature used to obtain the needed number of samples.

ANALYSIS OF A VENT GAS SAMPLE IN THE LABORATORY

To verify the presence of EO in the scrubber outlet vent gas and to determine what other compounds are present in the scrubber outlet vent gas, a sample taken during Test 12, Evacuation 6, was analyzed by GC/MS and by GC/FID.

Analysis of Vent Gas Sample by GC/MS

The vent gas sample was analyzed by GC/MS to verify that EO was present in the vent gas during the later evacuations and to identify the other compounds in the vent gas which were interfering with the analysis.

Procedure--

One coil of a 30 meter (m) wide-bore fused silica capillary column (DB-5) was frozen with liquid nitrogen. A 1 mL gas sample was injected through the GC injection port which was heated to 50 degrees Celsius (^{o}C). Injection was made with the GC column oven door open. The door was closed, and the column oven was heated to $35^{o}C$. After a two minute hold at $35^{o}C$, the column oven was heated to $150^{o}C$ at $8^{o}C$ per minute. Both a 5 ppmv EO standard and the sample were analyzed.

Results--

Analysis of the 5 ppmv EO standard showed that the EO elutes at 2.47 min and yields a mass spectrum with a parent peak at mass 44 and a major peak at 29 due to the loss of a methyl group.

The sample chromatogram is shown in Figure 5. There are three peaks: a large one at 2.39 min, a small one at 3.12 min, and a medium one at 3.56 min. The mass spectra identify the first peak as CFC-12, the second peak as carbon disulfide (CS_2), and the third peak as 1,2-epoxybutane (ethyloxirane).

No EO was identified by this analysis. This was not unexpected, however. The estimated detection limit for the method was 1-2 ppmv, and the estimated concentration expected in the sample was 0.5-1 ppmv.

There is no explanation for the presence of the CS_2. The 1,2-epoxybutane may be a reasonable reaction product of the EO although its presence was not expected. At this time it is not known whether these products were materials actually present in the stack or whether they are artifacts formed when the sample contacted the sample container.

Conclusion--

By the sixth evacuation, the major component of the stack gas, other than air, is CFC-12. The concentration of EO has decreased to less than 2 ppmv. Other components present in the stack gas may include CS_2 and 1,2-epoxybutane (ethyloxirane).

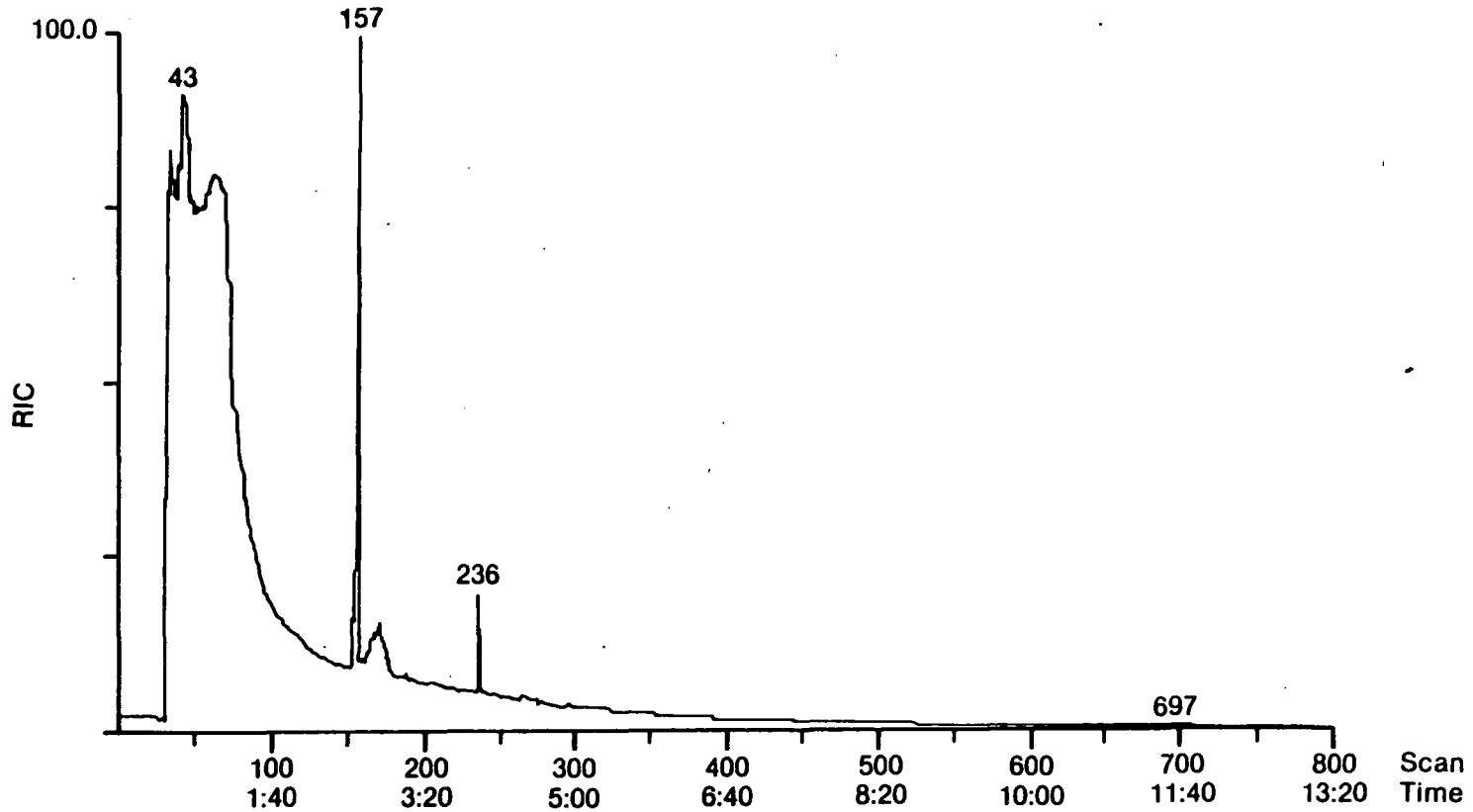

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Figure 5. Total Ion Chromatogram of Vent Sample

Vent Gas Analysis by GC/FID

The vent gas sample taken during Test 12, Evacuation 6, was analyzed by GC/FID using conditions similar to field conditions. Quantitative and qualitative comparisons were made to a standard containing EO, CFC-12, CS_2, and 1,2-epoxybutane.

Procedure--

A 2-L static dilution bulb was purged with 4.454 ppmv EO standard for 2 min. Using a syringe, 0.1 mL of CFC-12, 31.66 mg of CS_2 and 20.94 mg of 1,2-epoxybutane were added to the purged bulb. The bulb was stored in an oven at 60°C. This resulted in concentrations of 4.454 ppmv EO, 50 ppmv CFC-12, 5,000 ppmv CS_2, and 3,600 ppmv 1,2-epoxybutane.

The sample prepared in the static dilution bulb, the 4.454 ppmv EO standard, and headspace samples of CS_2 and 1,2-epoxybutane were injected using a 0.5 mL gas-tight syringe on a 10 ft (3 m) by 1/8 in (3 mm) O.D. column containing 5% Fluorcol on 60/80 mesh Carbopack B. A Varian 3400 GC with a Vista 401 Data System was used. The column temperature was maintained isothermally at 100°C; the injector block was heated to 175°C, and the detector oven was maintained at 225°C. A nitrogen carrier gas flow rate of 30 mL/min was used. Support gas flow rates were set at the manufacturer's recommendations of 30 mL/min for hydrogen and 300 mL/min for air.

Results--

Analysis of the individual components yielded retention times of 1.9 min for CFC-12, 2.2 min for EO, 4.8 min for CS_2, and 5.3 min for 1,2-epoxybutane. Using the sample prepared in the static dilution bulb, the limits of quantitation (LOQs) were estimated to be 1 ppmv for CFC-12, 1.5 ppmv for EO, and 10 ppmv for 1,2-epoxybutane. No LOQ was estimated for CS_2 because the 5,000 ppmv CS_2 in the static dilution bulb was not detected by the FID. No effort was made to determine a CS_2 detection limit.

Analysis of the vent gas sample yielded a chromatogram with one peak at 1.9 min. This peak was identified as CFC-12 and was estimated to be present at a concentration of approximately 500 ppmv. The presence of EO and CS_2

could not be determined. Epoxybutane was estimated to be present at levels below the estimated LOQ of 0.01 ppmv.

Conclusions--

In a mixture containing 50 ppmv of CFC-12 and 5 ppmv of EO, the relative retention times of the two materials were reversed. Figures 6 and 7 show chromatograms taken during the field test at the inlet and outlet of the control unit, respectively. For the analysis of the inlet samples the carrier gas flow rate was faster and the sample volume was smaller. The late eluting component of the vent gas observed in the field at the scrubber outlet was probably 1,2-epoxybutane. This vent gas component required the analysis time to be lengthened on the outlet channel and decreased the number of samples which could be analyzed during each evacuation. Other unidentified components of the outlet vent stream elute before the CFC-12, possibly interfering with the EO analysis.

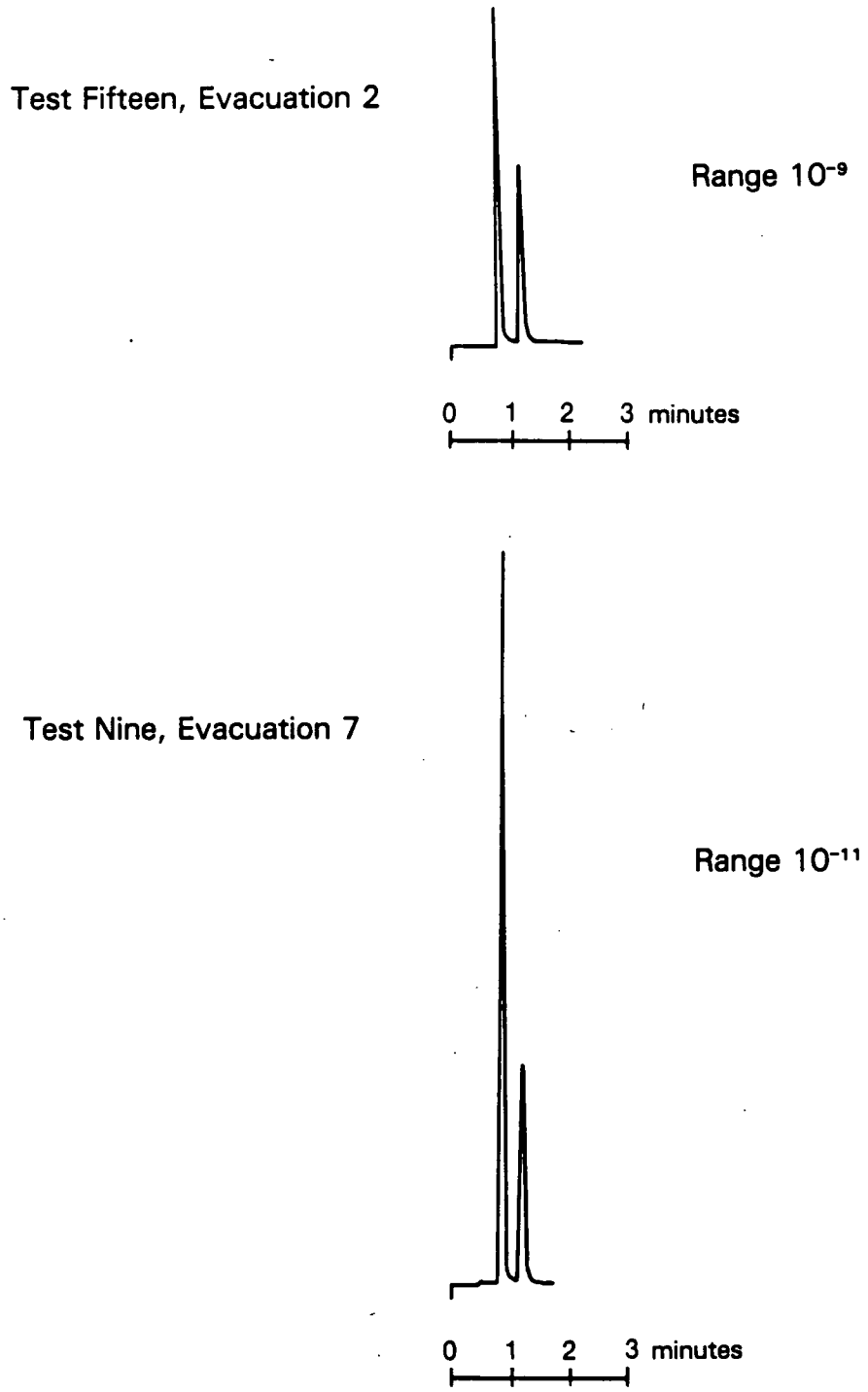

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Figure 6. Chromatograms of Vent Gas at Scrubber Inlet

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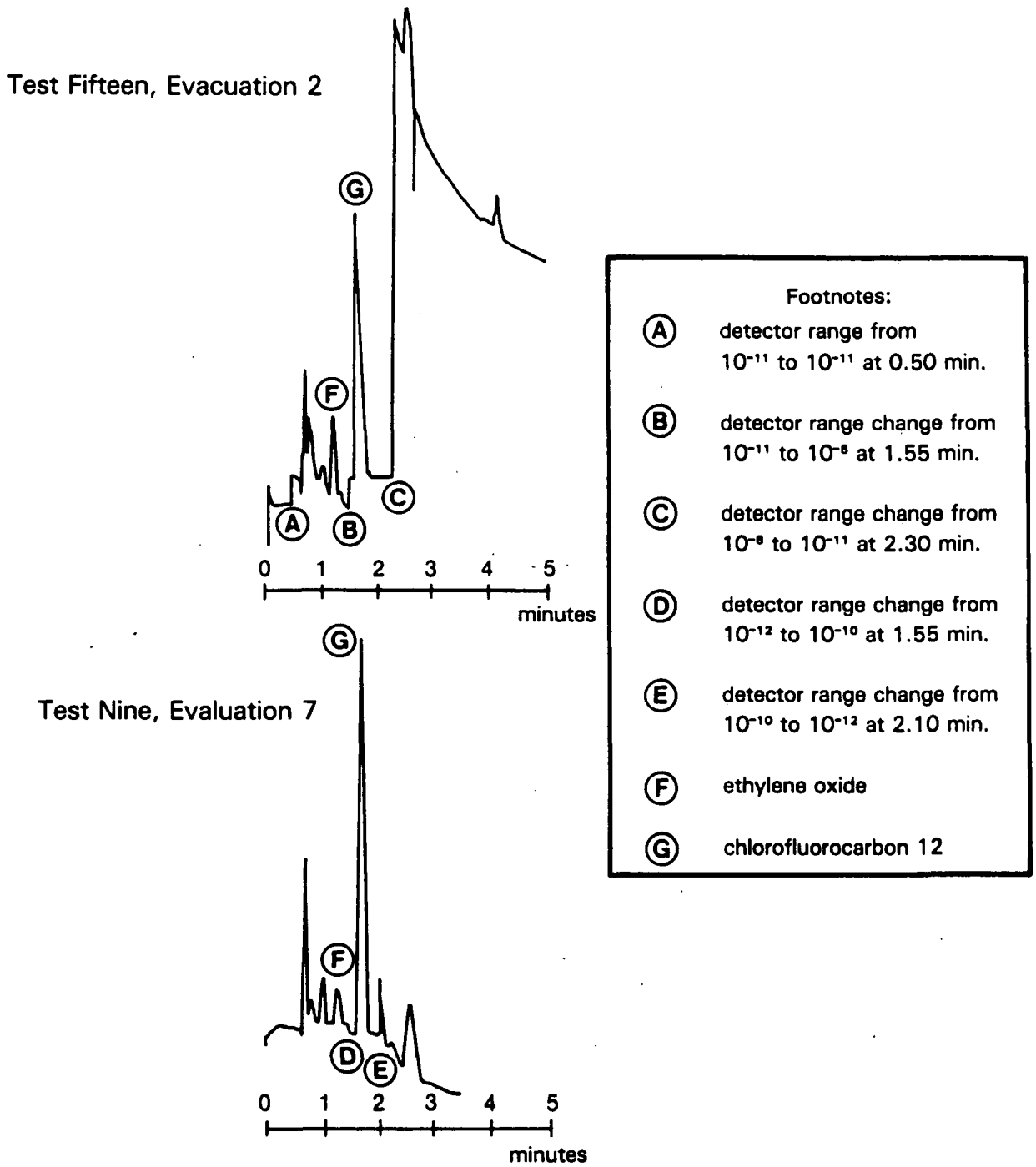

Figure 7. Chromatograms of Vent Gas at Scrubber Outlet

SECTION 6

FIELD EVALUATION

FACILITY DESCRIPTION

The field evaluation was conducted at Burron Medical, a medical supply sterilization facility, located in Allentown, Pennsylvania. The facility has three 1000 ft^3 (28 m^3) sterilizers which use a 12/88 (w/w) EO and CFC-12 gas mixture. The gas is supplied from a common header serving all four units and is controlled by a liquid flow meter.

A sterilization cycle typically uses 38 gallons (140 L) of 12/88 gas mixture. On a weight basis, a sterilization charge consumes 368 lbs (167 Kg) of gas, of which approximately 44 lbs (20 Kg) are EO. The initial charge of EO to the chamber was calculated using the weight of the supply cylinders before and after charging the chamber. The scale measured the supply cylinders to ± 1 lb (0.5 Kg).

The exhaust from the sterilizers is controlled by a DEOXX™ system. The DEOXX system is a dilute acid scrubber manufactured by Chemrox, which hydrolyzes the EO to ethylene glycol. At the time of the test the scrubber contained a mixture of dilute phosphoric and sulfuric acid. The control system has a reported control efficiency of 99.99% based on tests conducted at the facility in April 1986 by the vendor.[12]

Each chamber is equipped with a total recirculating pump manufactured by either CIHI or Intervac. The pumps are equipped with gas/liquid separators which emit the gas to the DEOXX system and recirculate the liquid to the pump inlet. Chambers #1 and #2 are equipped with oil-sealed pumps. Chamber #3 is equipped with a water-sealed pump. All of the tests were conducted using the chambers (#1 and #2) equipped with oil-sealed pumps for the following reasons:

- The use of water-sealed pumps is more likely to affect EO emissions and efficiency calculations because of the infinite solubility of EO in water; and

- The anticipated regulatory development will most likely require the use of oil-sealed pumps.

The sterilization cycle is automatically controlled by a programmable microprocessor system. The control system has the capability to control and record the parameters of the sterilization cycle including chamber temperature, chamber pressure, and elapsed time from the start of the cycle.

The sterilization process begins with a humidification step which takes place in a separate room. After the humidification step, each load to be sterilized is transferred to the sterilization chamber. The sterilization cycle is a batch process which takes 4-6 hr. A sterilizer load begun during the morning shift exhausts at about 2:00 p.m. In a typical plant operating mode seven post-sterilization evacuations occur over a 3 hr period. After the chamber repressurizes following the seventh evacuation, the product is removed from the chamber and allowed to off-gas. Because the control system is designed to handle the exhaust from two sterilizers venting simultaneously, the tested sterilization cycles were scheduled so that only one sterilizer vented at a time.

Three different sterilization programs were used for testing, one for the empty chamber tests, one for the full chamber tests, and one for the last full chamber test (Test 13). Before the start of every test (except Test 13), the chamber was evacuated to 2 pounds per square inch absolute (psia) and then pressurized to 3.1 psia with steam. The humidity dwell at 3.1 psia was maintained for 1 hr for the loaded chamber tests, but was shortened to 5 min for the empty chamber tests. At the completion of the humidity dwell the chamber was charged to 23.9 psia with 12/88 gas. The exposure at 23.9 psia was maintained for 4 hrs for the loaded chamber tests, but was shortened to 5 min for the empty chamber tests. During the last full chamber test (Test 13), the chamber was evacuated to 7 psia and pressurized to 32.9 psia.

Each program contained seven post-sterilization evacuations, the initial chamber evacuation and pump down and six air in-bleeds and subsequent evacuations, followed by a final air in-bleed. Except in Test 13, the chamber was evacuated to 2 psia and pressurized with air to 13.9 psia during each evacuation and air in-bleed cycle. The initial chamber evacuation and pump down lasted 26-27 min. The subsequent evacuations lasted 12-14 min and

the air in-bleeds required 12-14 min. During Test 13 the chamber was evacuated to 7.0 psia, which reduced each evacuation and air in-bleed time by 7 min.

Seventeen tests were performed, five with product in the chamber and 12 without product. Data from ten of these tests were reduced and used to prepare this report. Table 4 summarizes the 10 tests that were used.

SAMPLING LOCATIONS

Samples were acquired at two locations, before and after the control unit. At the scrubber inlet the EO and CFC-12 concentrations were at percent levels and the sample temperatures were 40-50°C (100-120°F). At the scrubber outlet the EO concentrations were at the low ppmv level, CFC-12 concentrations were at the percent levels, and sample temperatures ranged from 30-70°F (0-20°C) depending on the ambient temperature at the time of the test.

Scrubber Inlet Sampling Location

The scrubber inlet sampling location, shown schematically in Figure 8, was used to obtain a continuous sample of sterilizer chamber exhaust. The exhaust was transferred from the chamber outlet to the scrubber inlet via a 6-inch diameter polyvinyl chloride (PVC) duct. Samples were taken from the midpoint between the sterilizer outlet and the scrubber inlet. Sample, acquired with a 3/16-inch Teflon probe, was transported to the GC through 50 ft 0.5 m) of 1/4-inch O.D. heated Teflon sample line. No direct flow measurements were made at this location because the installation of orifice plates in the existing PVC pipe was not considered to be cost-effective.

Scrubber Outlet Sampling Location

A continuous sample of scrubber exhaust was obtained and volumetric flow measurements were made at the scrubber outlet sampling location. Exhaust exited the scrubber vertically through a 6-inch diameter PVC ductwork that exhausted 5 ft (1.5 m) above roof level. To measure volumetric flow, the stack was modified by the installation of:

- additional 6-inch diameter PVC ductwork to allow for diversion of the scrubber exhaust through one of two parallel ducts,

TABLE 4. TEST SUMMARY

Test Number	Product Present	Chamber Number	Weight 12/88 Used	Test Date	Test Start Time	Test End Time
6[a]	Yes	2	368 lb	87/10/06	21:39	00:38
7[b]	No	1	365 lb	87/10/07	10:19	14:04
8[a]	Yes	2	388 lb	87/10/07	15:10	18:11
9[b]	No	1	346 lb	87/10/08	09:25	12:42
10[b]	No	1	353 lb	87/10/08	14:41	17:48
11[a]	Yes	2	392 lb	87/10/08	18:00	21:01
12[b]	No	1	346 lb	87/10/09	12:44	15:53
13[c]	Yes	2	442 lb	87/10/09	16:16	18:03
14[b]	No	1	350 lb	87/10/10	08:54	12:01
15[b]	No	1	343 lb	87/10/10	13:35	16:43

[a]The chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidity dwell lasted 1 hr and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 4 hr. Post-sterilization chamber pressure cycled between 2 psia and 13.9 psia.

[b]The chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidity dwell lasted 5 min and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 5 min. Post-sterilization chamber pressure cycled between 2 psia and 13.9 psia.

[c]The chamber was evacuated to 7 psia before being pressurized with steam to 8 psia. Humidity dwell lasted 1 hr and then the chamber was charged to 32.9 psia with 12/88. Exposure lasted 5 hr. Post-sterilization chamber pressure cycled between 7 psia and 13.5 psia.

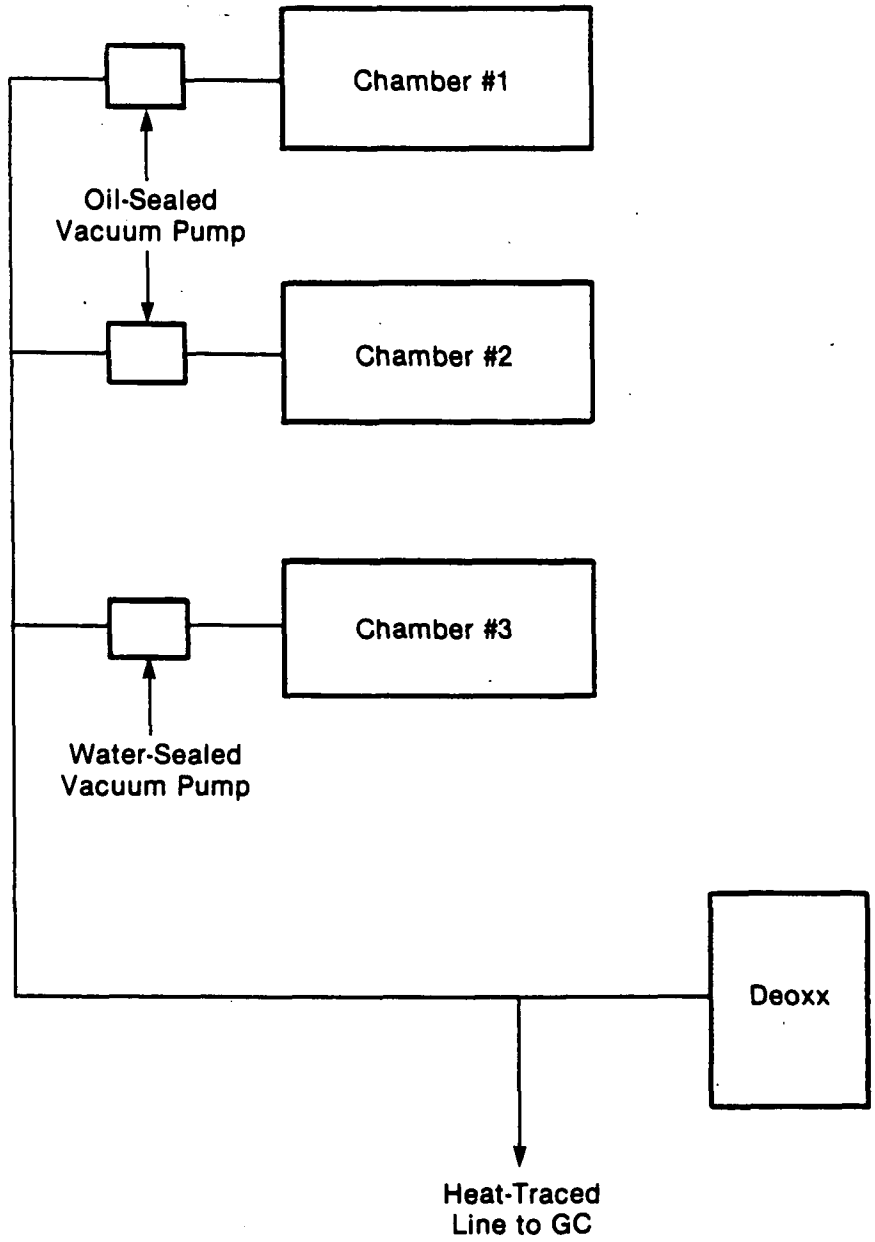

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Figure 8. Inlet Sample Location

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- a vane anemometer in the center of the duct 26 ft (7.9 m [52 duct diameters]) downstream of the the scrubber outlet and 1.3 ft (40 cm [2.7 duct diameters]) upstream of the first 90 degree (^{0}) bend in the stack addition,
- a 3/16-inch (48-mm) sampling probe,
- two butterfly valves to divert the scrubber exhaust through one of the two parallel ducts,
- two orifice plates in parallel, 6.3 ft (1.9 m [12.7 duct diameters]) downstream of their respective butterfly valves, and 1.3 ft (40 cm [2.7 duct diameters]) upstream of their respective 90^{0} bends, and
- wet and dry bulb temperature probes.

These modifications are diagrammed in Figure 9 and can be seen in the photographs shown in Figures 10-13. Descriptions and operational procedures are contained in the Sampling Procedures Subsection.

SAMPLING PROCEDURES

The semi-continuous direct sampling method was used at both sampling locations. The method is described in detail in Section 4.

Ethylene Oxide Sampling

The EO sampling equipment is shown in Figure 14. Samples were taken simultaneously from both sampling locations using the equipment and procedures described below.

Ethylene Oxide Sampling Equipment--

Sample was withdrawn into heated, 1/4-inch (64-mm), Teflon lines using Teflon-lined diaphragm pumps. A 50-ft (15-m) line was used on the inlet port and a 100-ft (30-m) line was used on the outlet port. Stainless steel, 1/4-inch (64-mm) tees were used prior to the pumps to remove slipstreams from the main sampling lines. The slipstreams were routed through heated, 6-port, gas sampling valves that were used to introduce the samples onto the GC columns. Prior to the 6-port valves were pumps with Teflon-lined diaphragms and stainless steel, 1/4-inch (64-mm), toggle operated shut-off valves. Stainless steel fine metering valves and rotameters were used after the 6-port valves to control the flow rates of the slipstreams. Before

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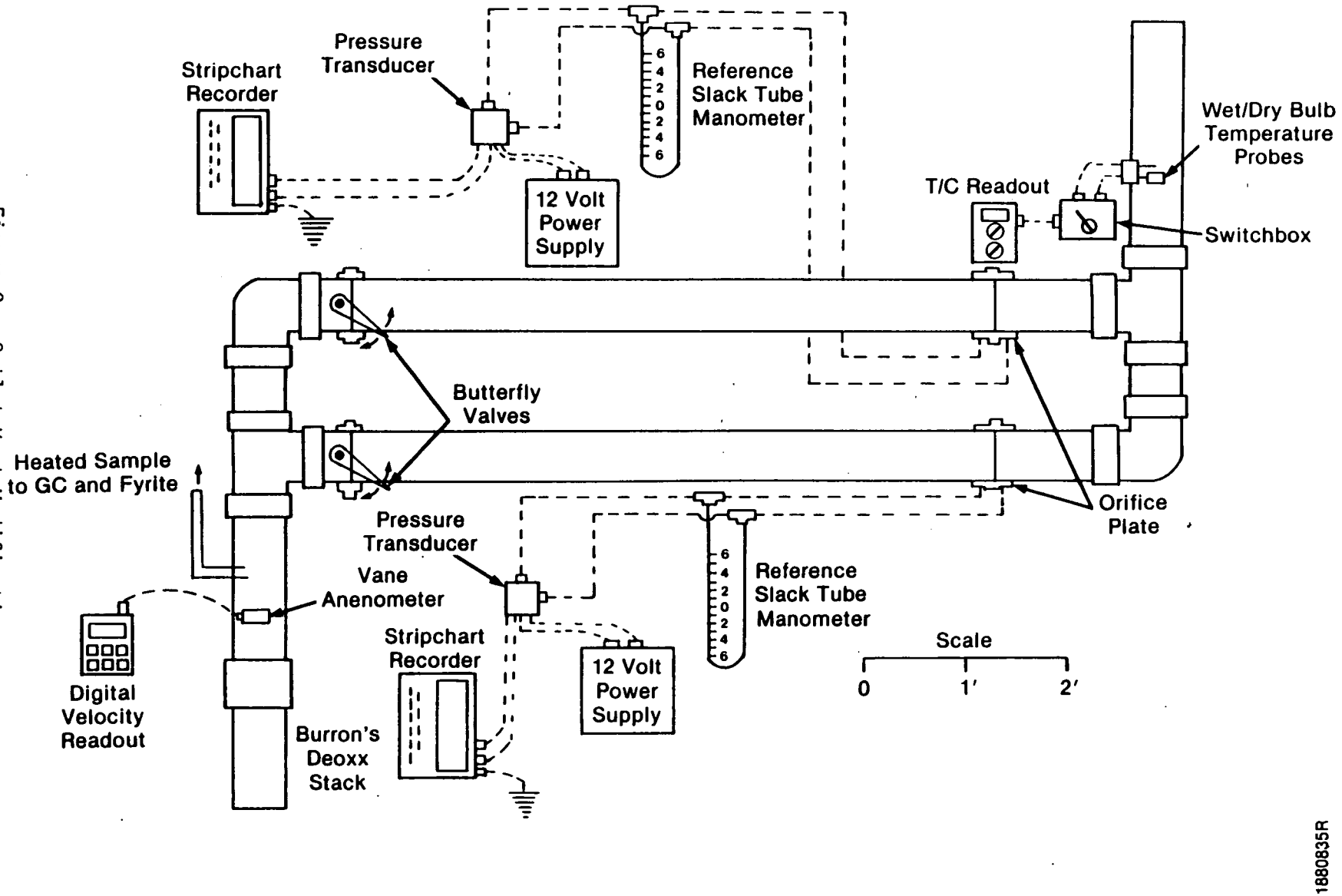

Figure 9. Outlet Vent Modifications

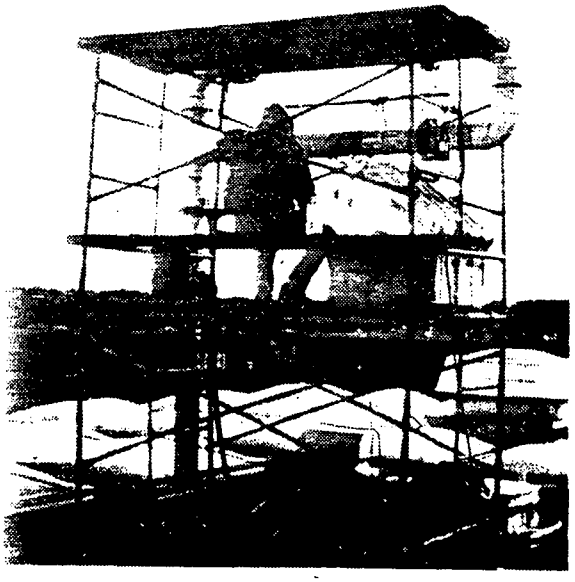

Figure 10. View of Vent Modification From Northeast Side

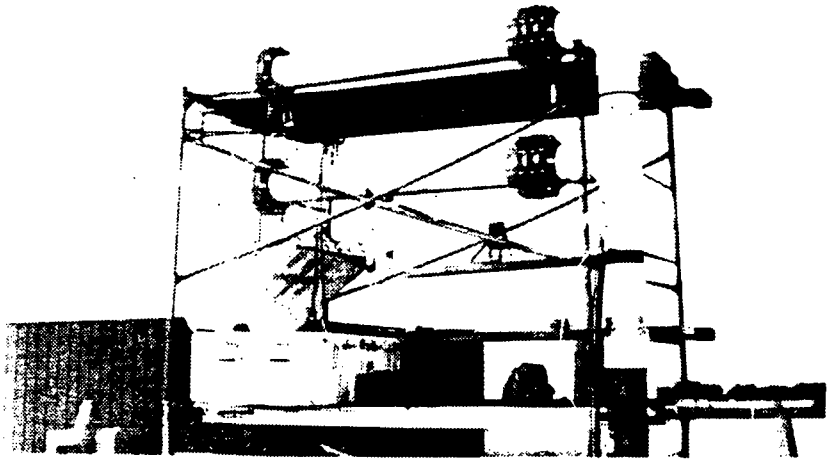

Figure 11. View of Vent Modification From Southwest Side

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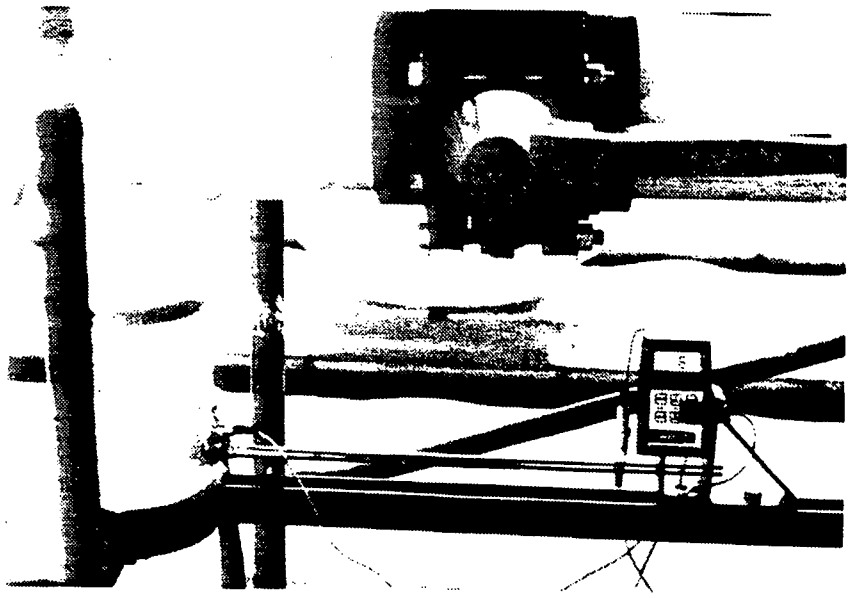

Figure 12. Close-Up of Butterfly Valve and Vane Anemometer Installation

Figure 13. Close-Up of Orifice Flange and Pressure Taps

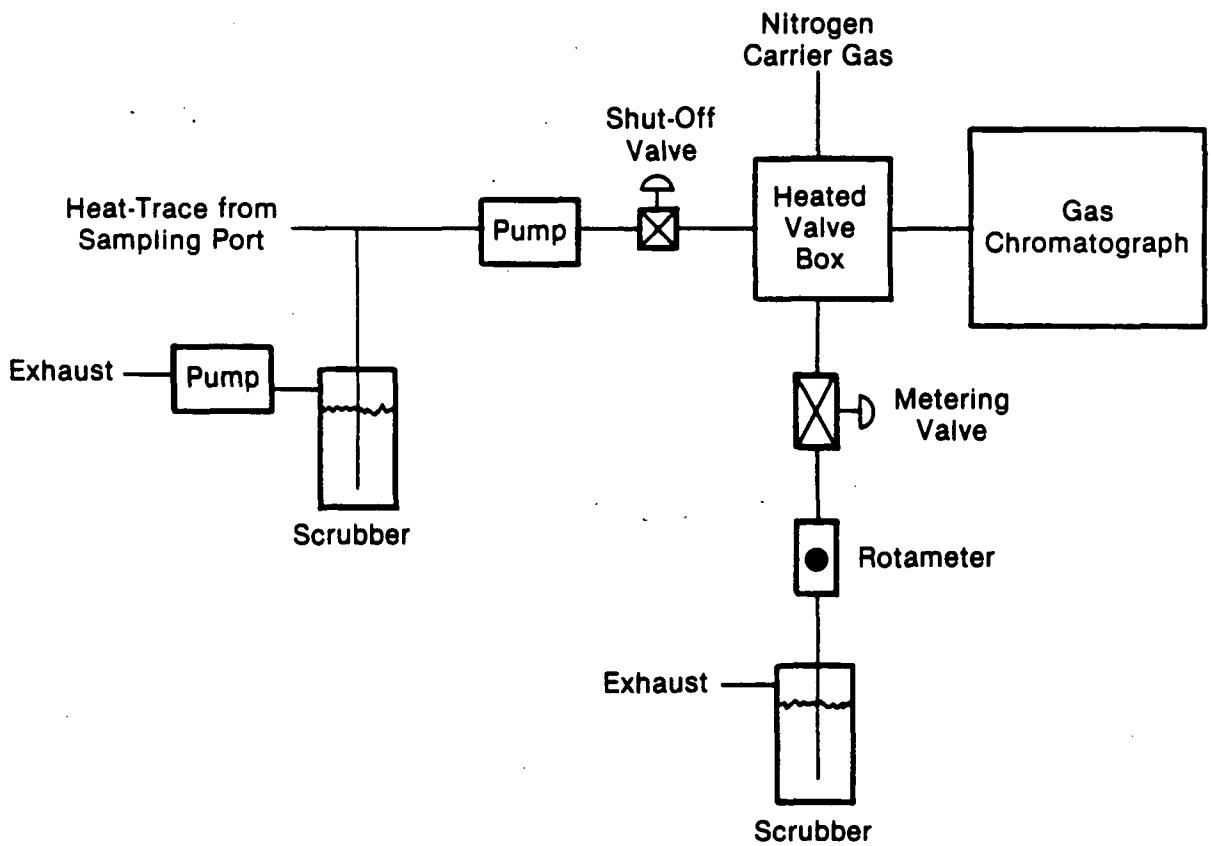

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Figure 14. Sampling/Analytical Interface

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exhausting to the atmosphere, the slipstreams and main sample streams were routed through dilute acid (1 N H_2SO_4) scrubbers to remove the EO.

Ethylene Oxide Sampling Operation--

Testing began when the DEOXX scrubber started to exhaust in preparation for the initial chamber evacuation. Each test consisted of seven evacuations, the initial chamber evacuation and pump down and six air in-bleeds and subsequent evacuations. Testing stopped at the start of the seventh air in-bleed. The start time and end time of the evacuations were identified by flow or lack of flow across the orifice plates.

The sampling lines were continually flushed with sample throughout the test day. Flow rates through the slipstreams which flushed the gas sampling loops were maintained at 100 mL/min (0.0035 cfm). Samples were isolated in the 6-port valves by closing the shut-off valves simultaneously. When the rotameters indicated no flow, the sample loops were at atmospheric pressure, and the samples were injected into the GC.

Table 5 compares the EO sampling parameters for each evacuation of each test. For most of the tests, the first sample was acquired at either one, two, three or four minutes after the start of the first evacuation. After the first sample, samples were acquired at three or four minute intervals until the end of the first evacuation. For the second through the seventh evacuations the first sample was acquired at either one, two or three minutes after the start of the evacuation. Again, samples were acquired at three to four minute intervals. The first evacuation was always longer because the initial chamber pressure was higher so a total of five or six samples were acquired during the first evacuation. For the second through seventh evacuations, a total of three or four samples were acquired during each evacuation. In test 13, the chamber was not evacuated to as low a pressure as in the other tests, so only four samples were acquired during the first evacuation and one sample during each of the subsequent six evacuations.

Volumetric Flow Rate Measurement

Volumetric flow rate measurements of scrubber exhaust were performed at the scrubber outlet location. A vane anemometer followed by two orifice plates in parallel was used to measure velocity. Two orifice plates were used to cover the range of expected flow rates and composition of the vent

TABLE 5. COMPARISON OF ETHYLENE OXIDE SAMPLING OPERATION PARAMETERS WITH TEST CONDITIONS

	Test 6-12,14,15		Test 13	
	Evacuation		Evacuation	
Parameter	1	2-7	1	2-7
Time from start of evacuation to first sample	1,2,3 or 4 minutes	1,2, or 3 minutes	3 minutes	3 or 4 minutes
Sampling Interval	3 or 4 minutes	3 or 4 minutes	4 or 5 minutes	
Total Samples Acquired	5 or 6	3 or 4	4	1
Chamber Pressure at start of evac.	23 psia	13.9 psia	33 psia	13.9 psia
at end of evac.	2 psia	2 psia	7.5 psia	7.5 psia

gas. Temperatures were measured using a bimetallic temperature probe and a pyrometer.

Vane Anemometer--

A PACER INDUSTRIES Model AD4000 vane anemometer was used to measure exhaust flows of <300 feet per minute (ft/min [90 m/min]). The vane anemometer probe head is factory calibrated using a Laser anemometer as reference in a 6-inch (15-cm) diameter wind tunnel. The reference calibration, performed in air, is contained in an internal microprocessor chip. Placement of the anemometer was upstream of the orifice plates as shown in Figure 9. A close-up of the vane anemometer placement in the stack extension is shown in Figure 12. Linear velocities were recorded manually every 2 min.

Orifice Plates--

Two standard, squared-edged orifice plates with standard pipe taps were mounted in parallel ducts as shown in Figures 9-11 to allow the determination of scrubber exhaust flow rate. The orifice diameters used were 1.763-inch (4.48-cm) and 2.591-inch (6.58-cm). The 1.763-inch (4.48-cm) diameter orifice plate was used to ensure accurate velocity head measurement during the latter part of the evacuations and when the low molecular weight of the vent stream resulted in velocities as low as 300 ft/min (90 m/min). The 2.591-inch (6.58-cm) diameter orifice was used during the initial portion of the evacuations and when the high molecular weight of the vent stream resulted in velocities approaching 1000 ft/min (300 m/min). Butterfly valves, as shown in Figure 12, were used to isolate the two orifice plates. The standard pressure taps on the orifice flanges were connected to Setra pressure transducers that were calibrated from 0-10 inches of water (inches H_2O [0-254 kg/m^2]). Output from the pressure transducers was recorded on stripchart recorders. A close-up of the orifice flanges and pressure taps is shown in Figure 13.

Stack Temperature--

Exit gas temperatures were measured at the scrubber outlet location. A bimetallic temperature sensor was placed in the duct as shown in Figure 9. Stack temperatures were digitized by a calibrated pyrometer and recorded every 2 min.

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Sampling Operation--

The two parallel orifice plates in series with the vane anemometer were used to measure velocity. As previously mentioned, vane anemometer and stack temperature readings were recorded every 2 min during the initial exhaust and subsequent air wash periods. The differential pressure measurement from the orifice plates was continuously recorded with stripchart recorders.

The initial sterilizer exhaust velocity was determined using the large (2.591-inch [6.58 cm] diameter) orifice through the depressurization and most of the pump down phase. When the flow registered less than 3 inches H_2O (76 kg/m^2) of differential pressure for the large orifice, the flow was diverted through the smaller (1.763-inches [4.48-cm]) diameter orifice. Figure 15 shows an example of the differential pressures measured using the large orifice during a typical initial exhaust.

Velocity measurements taken during the second to seventh evacuations used the same orifice plate procedures. Due to the reduced molecular weight of the exhaust gas during these evacuations, the duration of flow requiring use of the larger diameter orifice was usually shorter. However, during the second evacuation some of the heavier molecular weight gas from the first evacuation remained in the system. The exhaust of this heavier molecular weight gas lengthened the time the larger orifice plate was used to measure the pressure differential. Similarly, the first few minutes of the first evacuation contained gas from a previous evacuation.

Moisture Determination

The percent moisture of the stack gas was determined by the wet bulb/dry bulb method. The procedure measured relative humidity which was converted to percent moisture. Wet and dry bulb temperature measurements used to determine relative humidity were recorded at least once during each exhaust episode.

Molecular Weight Determination

The molecular weight of the exhaust stream, which changed with time due to EO removal, was needed to calculate the flow rate. Nitrogen, oxygen, carbon dioxide, water, EO, and CFC-12 were considered the main components of the sterilizer exhaust gas. The emissions of EO and CFC-12 were continuously

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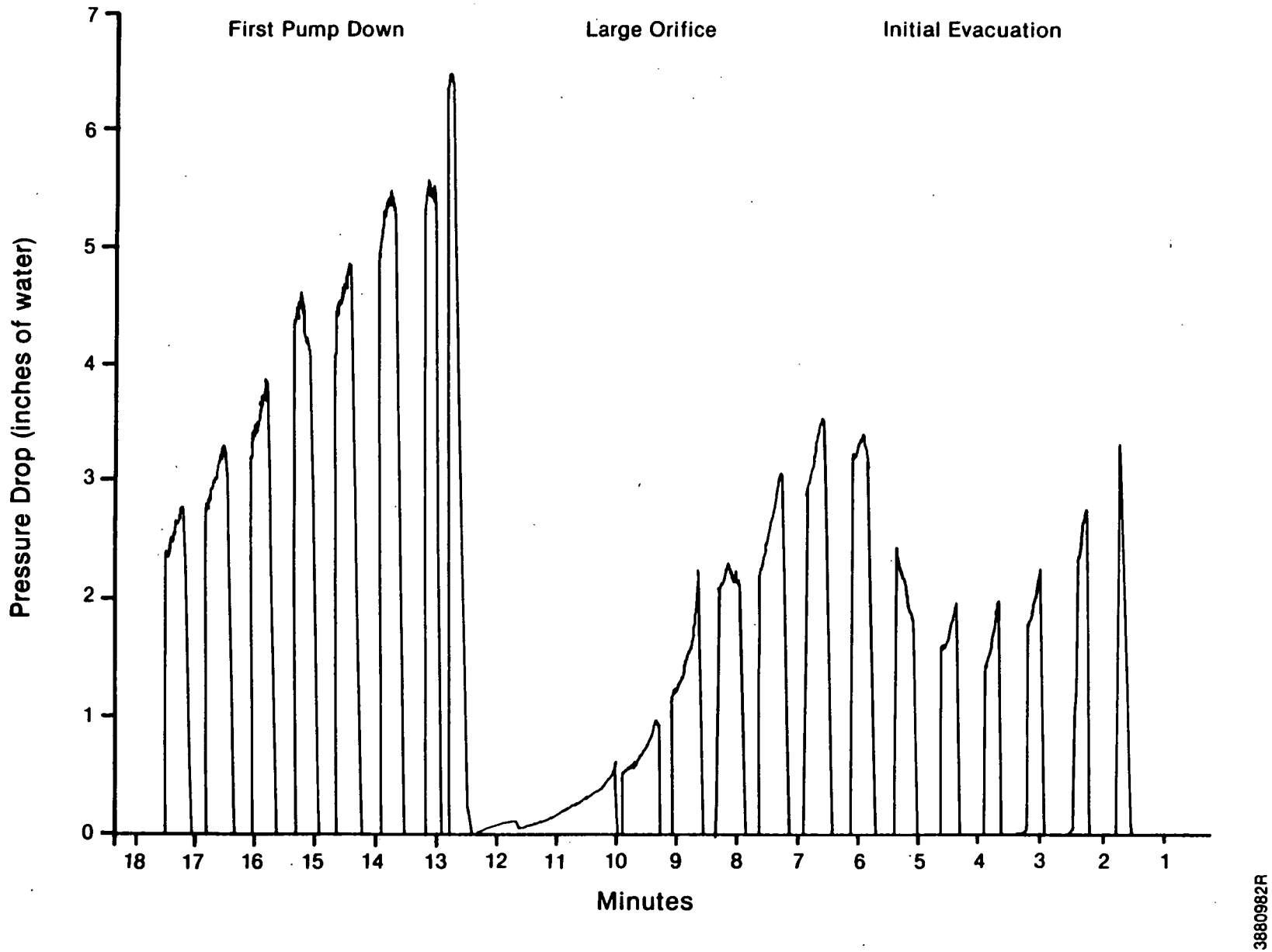

Figure 15. Measured Differential Pressures During First Evacuation

monitored by GC/FID. Emissions of oxygen and carbon dioxide were measured with Fyrite oxygen and carbon dioxide indicators. The nitrogen concentration was determined by difference.

Fyrite Oxygen And Carbon Dioxide Indicators--

BACHARACH Fyrite oxygen and carbon dioxide indicators were used to determine percent levels of oxygen and carbon dioxide in the sterilizer exhaust at the outlet sampling location. Fyrite indicators use volumetric displacement involving chemical absorption of oxygen or carbon dioxide from the sample. The reagent used to absorb carbon dioxide was potassium hydroxide, and chromous chloride was the absorbent for oxygen. Accuracy of analysis was ±0.5%.

Sampling Operation--

Percent levels of oxygen and carbon dioxide were usually measured once during each evacuation. For several of the runs oxygen was measured at 1- or 2-min intervals. These measurements were used to determine the dead volume of the scrubber system. Measurements of carbon dioxide in the exhausts were numerically negative, indicating an interference with the potassium hydroxide absorption solution. Because carbon dioxide levels were expected to be low (<1% [v]) an alternate method of determining carbon dioxide was not pursued. Sample was removed from the stack downstream of the vane anemometer. An aspirator bulb was used to pull the sample from the stack.

ANALYTICAL PROCEDURES

The analytical method used for the measurement of the EO and CFC-12 was gas chromatography with flame ionization detection (GC/FID). The CFC-12 concentration was needed for the determination of the gas stream molecular weight. The equipment and procedures used are described below.

Analytical Equipment Description

Some of the analytical equipment was shown in Figure 14. The dual FID Varian 3400 GC was equipped with a Nutech heated valve box containing two 6-port valves. An 0.25 mL loop was used on the inlet sample line and a loop of 2 mL was used on the outlet sample line. The analytical columns were 10 ft (3 m) x 1/8 inch (3 mm) O.D. stainless steel columns containing 5% Fluorcol on 60/80 Carbopack B. The FID electrometers were connected to Shimadzu CR1-A integrators.

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Operating Conditions

The GC column oven was operated isothermally at 100°C, the injector oven at 175°C, and the detector oven at 200°C. Nitrogen carrier gas flow rates were 30 mL/min on the outlet channel and 60 mL/min on the inlet channel. The FID support gas flow rates recommended by the GC manufacturer were used.

The same FID electrometer range was used for the EO and CFC-12 on the inlet channel but the range used varied from 10^{-9} to 10^{-11} depending on the inlet sample concentration. The FID electrometer range was programmed on the outlet channel. A range of 10^{-10} to 10^{-12} was used for the EO and 10^{-8} to 10^{-10} was used for the CFC-12. The electrometer range was programmed to switch at 1.1 min during the first evacuations and at 1.55 min during the second through seventh evacuations.

Analytical Sampling Procedures

The sample loops were purged with sample flowing at 100 mL/min for a minimum of 20 s. Samples were taken simultaneously at the inlet and at the outlet by closing toggle valves in-line previous to the sample loops. The pressure in the loops was allowed to equilibrate to atmospheric pressure, as indicated by lack of flow through the rotameters, before the injections were made. Data collection on the inlet channel was stopped after the elution of the CFC-12 peak. On the outlet channel, although the last peak did not elute until after 3 min, data collection was stopped after about 2.5 min to allow the integrator time to print out its report before the next injection.

The first sample was injected from 1-4 min after the start of the initial exhaust and additional samples at 3-4 min thereafter. For subsequent exhausts, sampling was started 1-3 min after the first indication of flow through the stack. Five to six samples were acquired during the first evacuation and three to four during the subsequent evacuations except during Test 13 when four samples were acquired during the initial evacuation and one sample during the subsequent evacuations.

Gas Chromatograph Calibration

Both channels of the chromatograph were calibrated for EO and CFC-12 at the beginning and end of the day. At least one standard was also analyzed between tests. Standards were purchased from Scott Specialty Gases, Scientific Gas Products, and MG Industries and ranged in EO concentration

from less than 1 ppmv to 20% (v) and in CFC-12 concentration from 1200 ppmv to 62.5% (v). In addition, lecture bottles containing 99.9% EO and CFC-12 were used to verify response at the upper levels of concentrations observed in the vent streams. Calibration curves consisted of a minimum of three standards which bracketed the sample concentrations.

CALCULATIONS

The data were reduced using LOTUS® 1-2-3 software. Rounding was performed at the completion of the calculations.

Ethylene Oxide and CFC-12 Concentration

Calibration curves were prepared by taking the logarithm of the peak area and plotting that logarithm versus the logarithm of the concentration. Although the use of logarithm-logarithm plots is a departure from normal practice, the logarithm procedure weighted each point of the calibration curve more equally than the use of a straight calibration curve. Equal weighting was important because the calibration curve covered six orders of magnitude. Under those conditions, the highest standard (100% [v]) received the greatest weight when using a straight response versus concentration curve. Essentially, the highest standard by being so much larger than the other standards determined the calibration curve. Unfortunately, the highest standard was also the standard most likely to be inaccurate due to possible curvature in the response curve at high concentrations and irregularites in response due to possible column overloading. With a logarithm-logarithm plot the high point that was most likely to be in error received less weight and the middle points that were most likely to be correct received more weight. Table 6 shows a comparison of data calculated using the logarithm calibration to data calculated using a standard curve.

The slope (M) and the y-intercept (B) were obtained from the least squares fit of the data points to the curve using Equations 7 and 8:

$$M=[n(\Sigma XY) - (\Sigma X)(\Sigma Y)/[n(\Sigma X^2) - (\Sigma X)^2] \quad \text{(Equation 7)}$$

$$B = (\Sigma Y)/n - M(\Sigma X)/n \quad \text{(Equation 8)}$$

where n is the number of standard concentrations used, X is the logarithm of the standard concentration, and Y is the logarithm of the peak area.

The calibration curves are shown in Figures 16-19. The EO inlet calibration curve is shown in Figure 16, the CFC-12 inlet calibration curve

TABLE 6. COMPARISON OF ETHYLENE OXIDE CONCENTRATIONS CALCULATED USING LOGARITHM-LOGARITHM AND STANDARD CALIBRATION CURVES FOR DATA FROM THE SCRUBBER OUTLET DURING TEST 14

Elapsed Time (min)	Concentration in ppmv	
	Logarithm Method[a]	Standard Method[b]
5	17.69	19.52
8	35.52	37.36
12	57.43	59.12
16	59.21	60.87
20	63.49	65.11
24	61.89	63.53
44	20.90	22.74
48	56.78	58.47
52	41.58	43.39
71	32.69	34.54
75	30.07	31.92
79	33.05	34.89
97	17.05	18.88
101	15.58	17.39
105	10.93	12.70
124	9.28	11.03
128	6.54	8.24
132	7.36	9.08
150	5.49	7.17
154	4.41	6.06
158	2.47	4.07
177	2.11	3.70
181	2.35	3.94
185	3.60	5.23

[a] Calibration from 1 ppmv to 12.5% (v).

[b] Calibration from 1 ppmv to 502.4 ppmv.

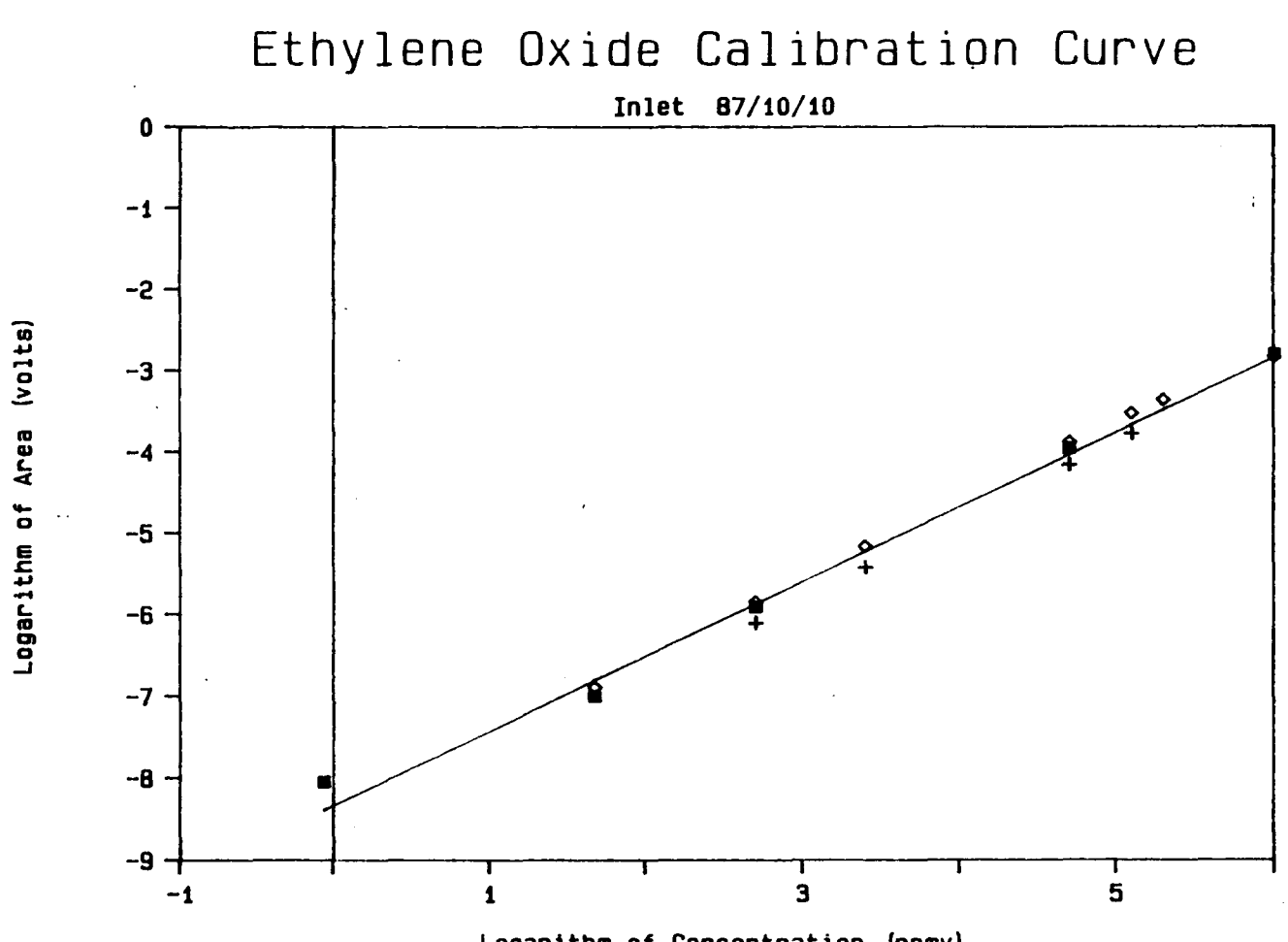

Figure 16. Ethylene Oxide Calibration Curve Used for Quantitation of Scrubber Inlet Samples

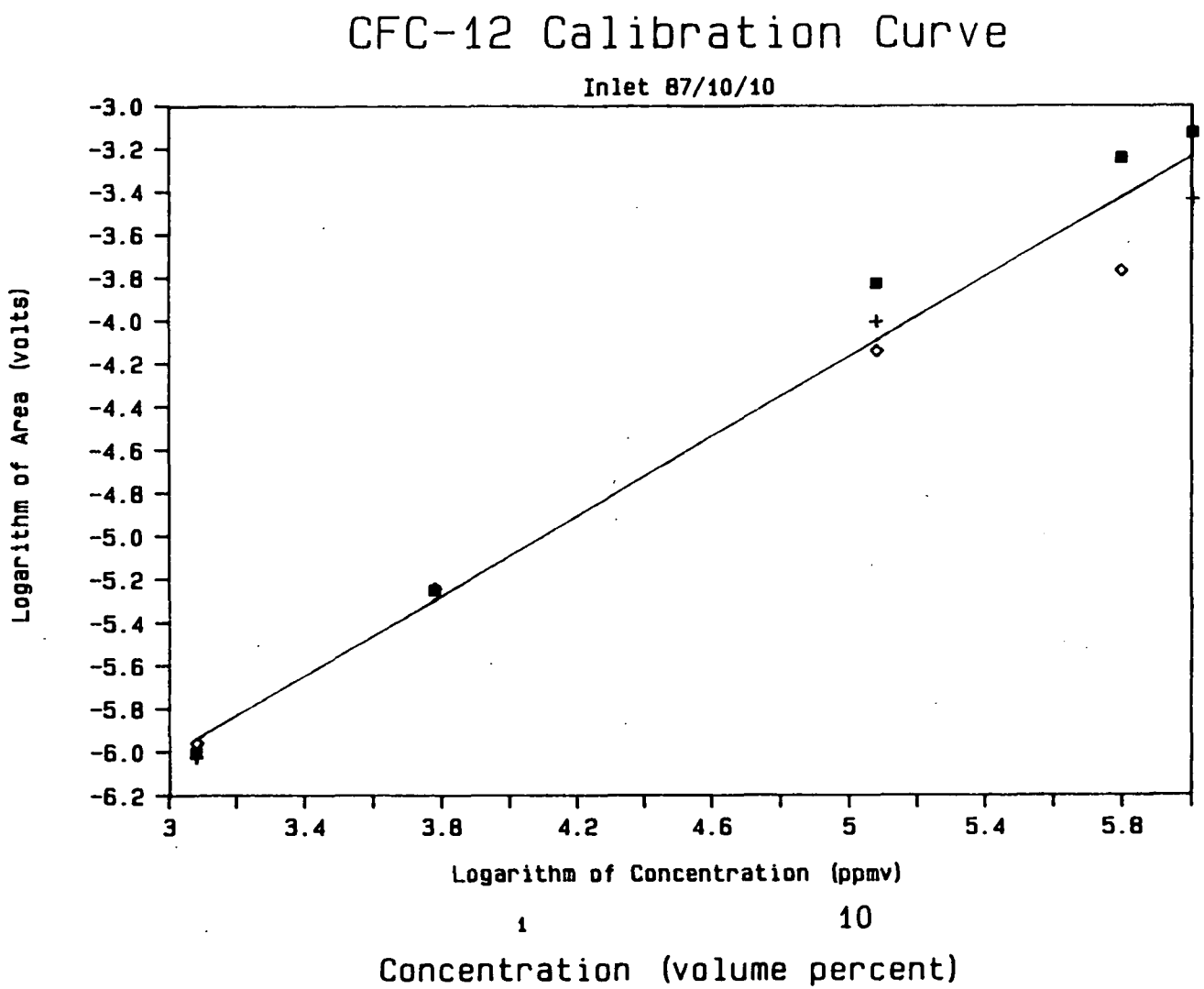

Figure 17. Chlorofluorocarbon-12 Calibration Curve Used for Quantitation of Scrubber Inlet Samples

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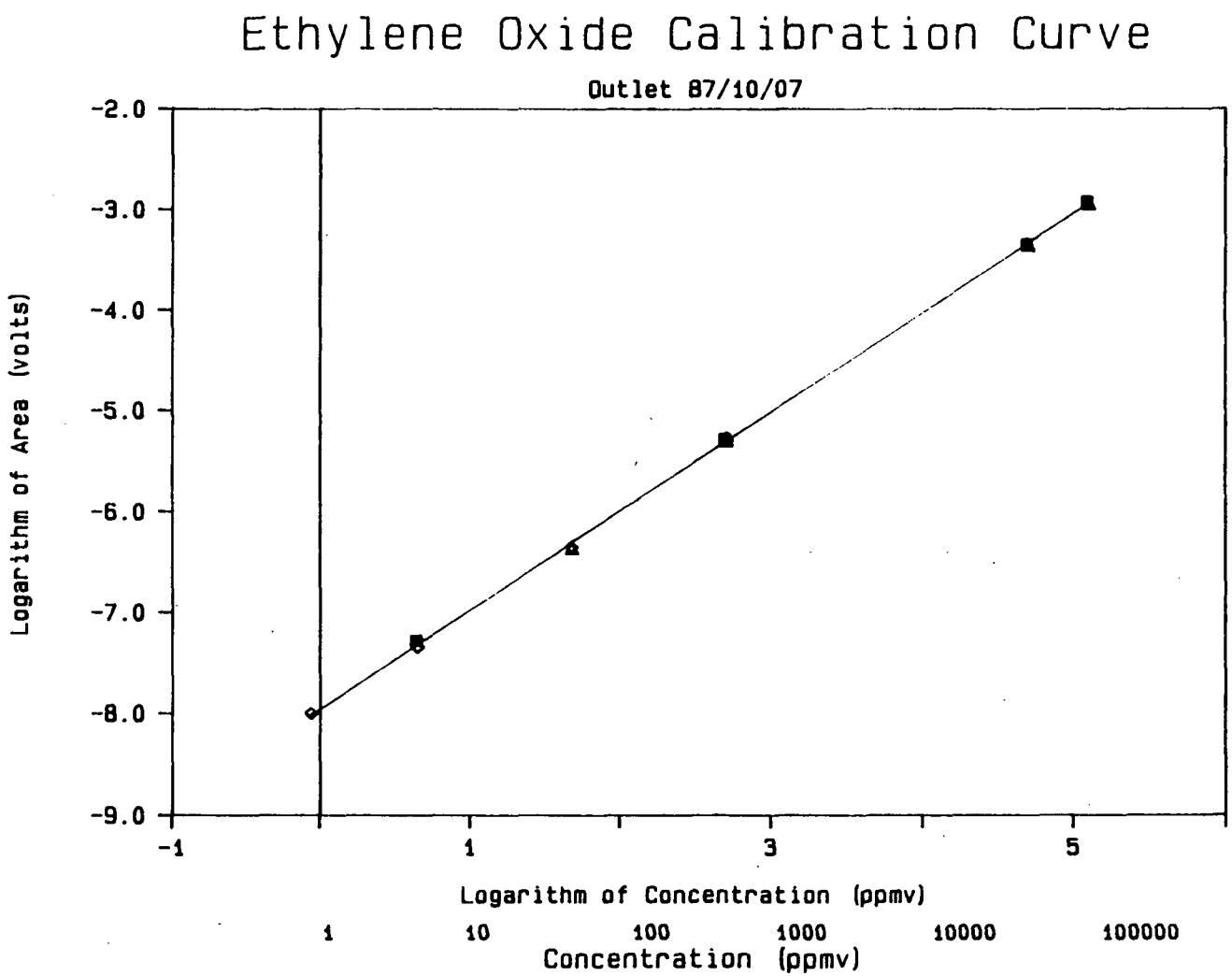

Figure 18. Ethylene Oxide Calibration Curve Used for Quantitation of Scrubber Outlet Samples

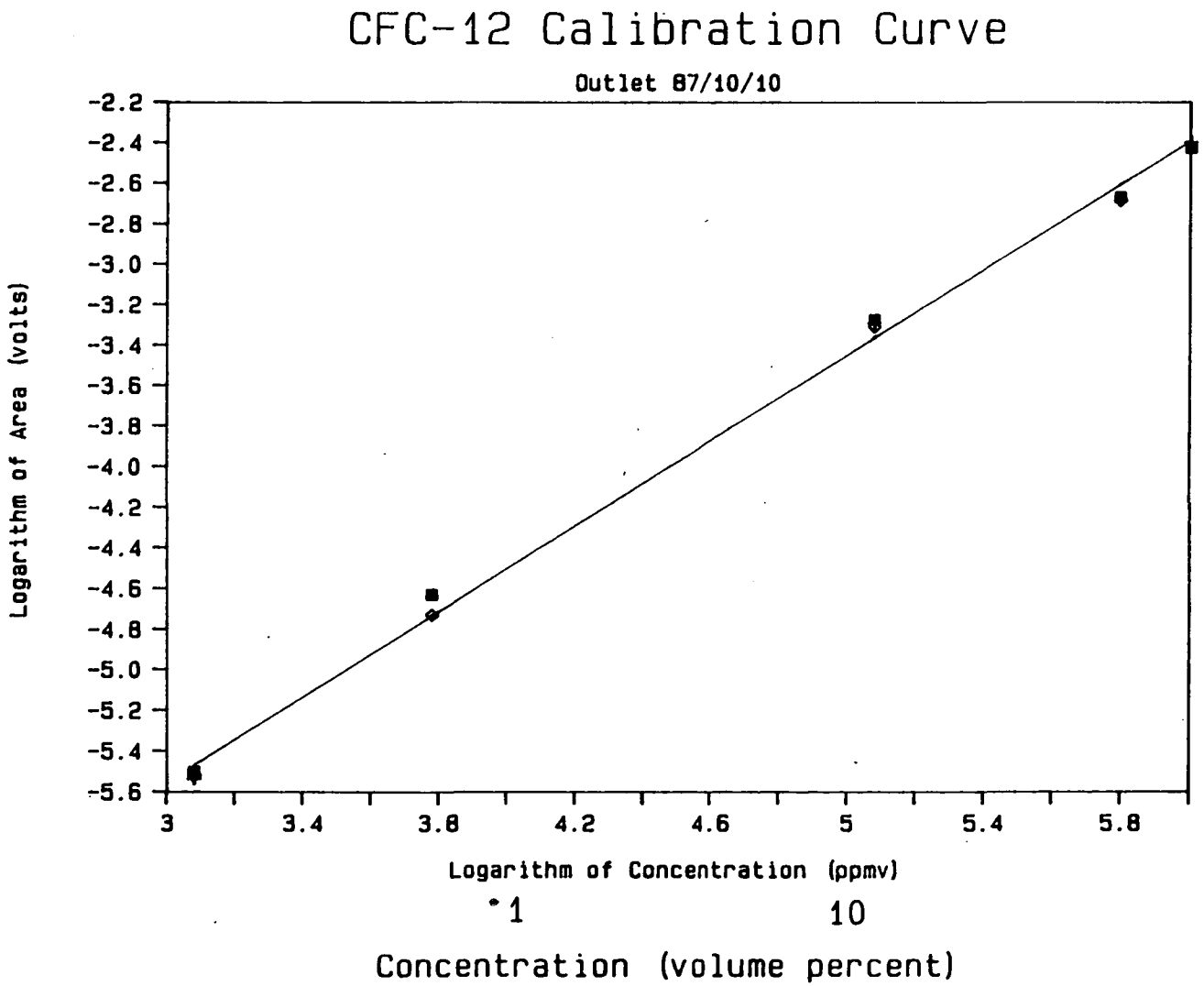

Figure 19. Chlorofluorocarbon-12 Calibration Curve Used for Quantitation of Scrubber Outlet Samples

in Figure 17, the EO outlet calibration curve in Figure 18, and the CFC-12 outlet calibration curve in Figure 19. Many of the standards were injected several times during the day as indicated by the various symbols on the graphs. The lines represent the least squares best fit using all of the data points. In general, for the inlet analyses the system was calibrated from 1 ppmv to 100% (v) for EO and from 500 ppmv to 100% (v) CFC-12 and for the outlet analyses from 1 ppmv to 12.5% (v) for EO and from 500 ppmv to 100% (v) for CFC-12.

As shown in Figures 20 and 21, at the scrubber outlet the EO and CFC-12 concentrations were interpolated at 10-sec intervals for the first evacuations. Usually, the concentrations were assumed to increase linearly, plateauing at a maximum determined by an average of the data points after the concentration versus time curve leveled off. In some cases the concentration was assumed to decrease linearly after reaching a maximum and in other cases the concentration was assumed to be constant throughout the evacuation.

For the second evacuations the concentrations were assumed to decrease linearly where enough data were present to validate that assumption. In most cases an average concentration was used. Examples of the concentration interpolations for the second evacuations are shown in Figures 22 and 23. In all cases for the third through seventh evacuations average concentrations were used.

At the scrubber inlet the EO and CFC-12 concentrations were interpolated at two-minute intervals for the first evacuations as shown in Figures 24 and 25. The same interpolation procedures were used at the scrubber inlet as at the scrubber outlet. Examples of the concentration interpolations at the scrubber inlet for the second evacuations are shown in Figures 26 and 27.

Vent Stream Molecular Weight

The molecular weight of the vent stream (MW_{vs}) is the sum of the molecular weight (MW) of each component multiplied by the mole fraction (C) of that component in the vent stream:

$$MW_{vs} = C_a MW_a + C_b MW_b + \ldots + C_z MW_z \qquad \text{(Equation 9)}$$

The components in the vent stream that were considered to contribute to the molecular weight were EO, CFC-12, oxygen, nitrogen, and water. Carbon dioxide was not included because it was present at low levels (<1 volume percent).

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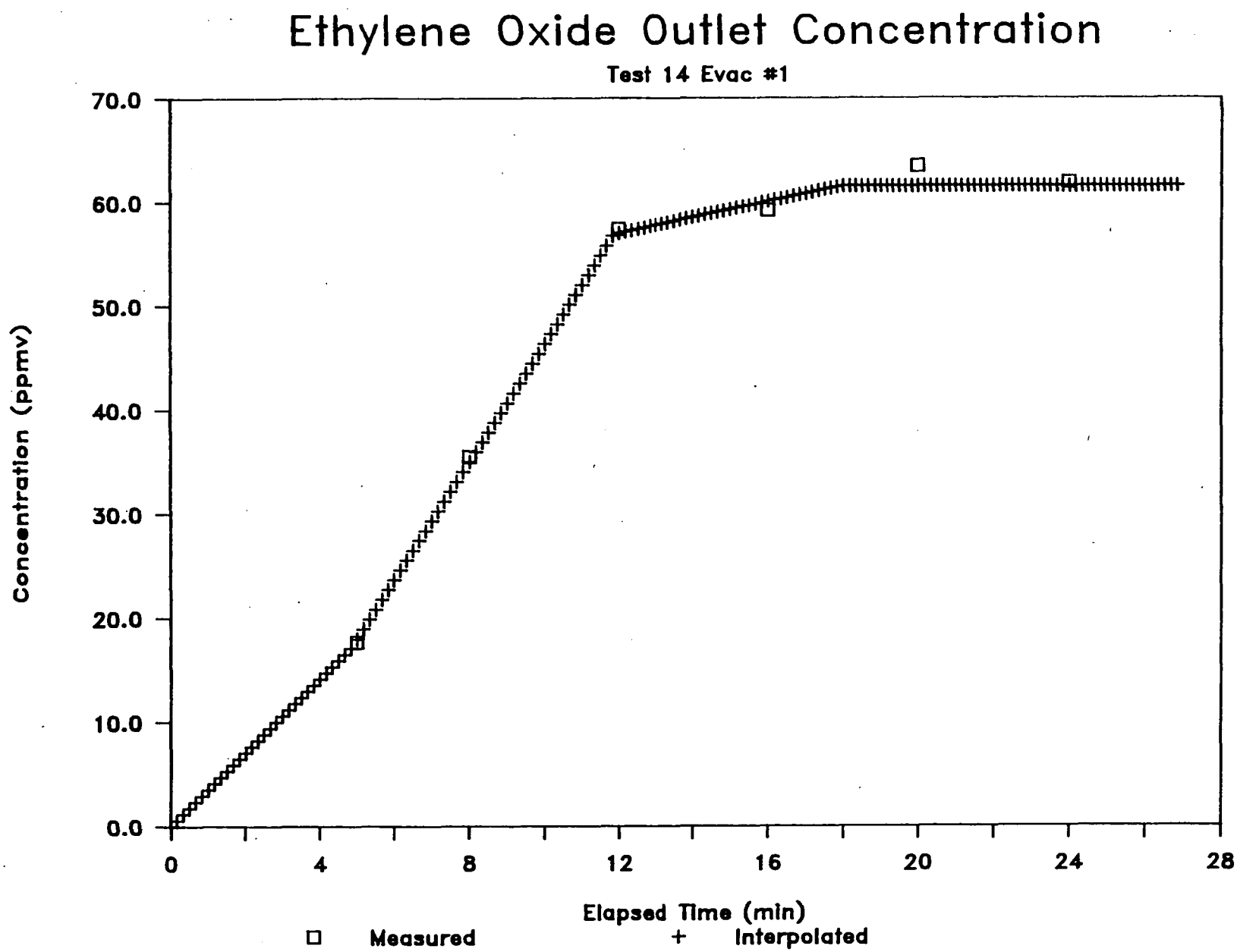

Figure 20. Interpolated EO Scrubber Outlet Concentrations for for Test 14 Evacuation 1

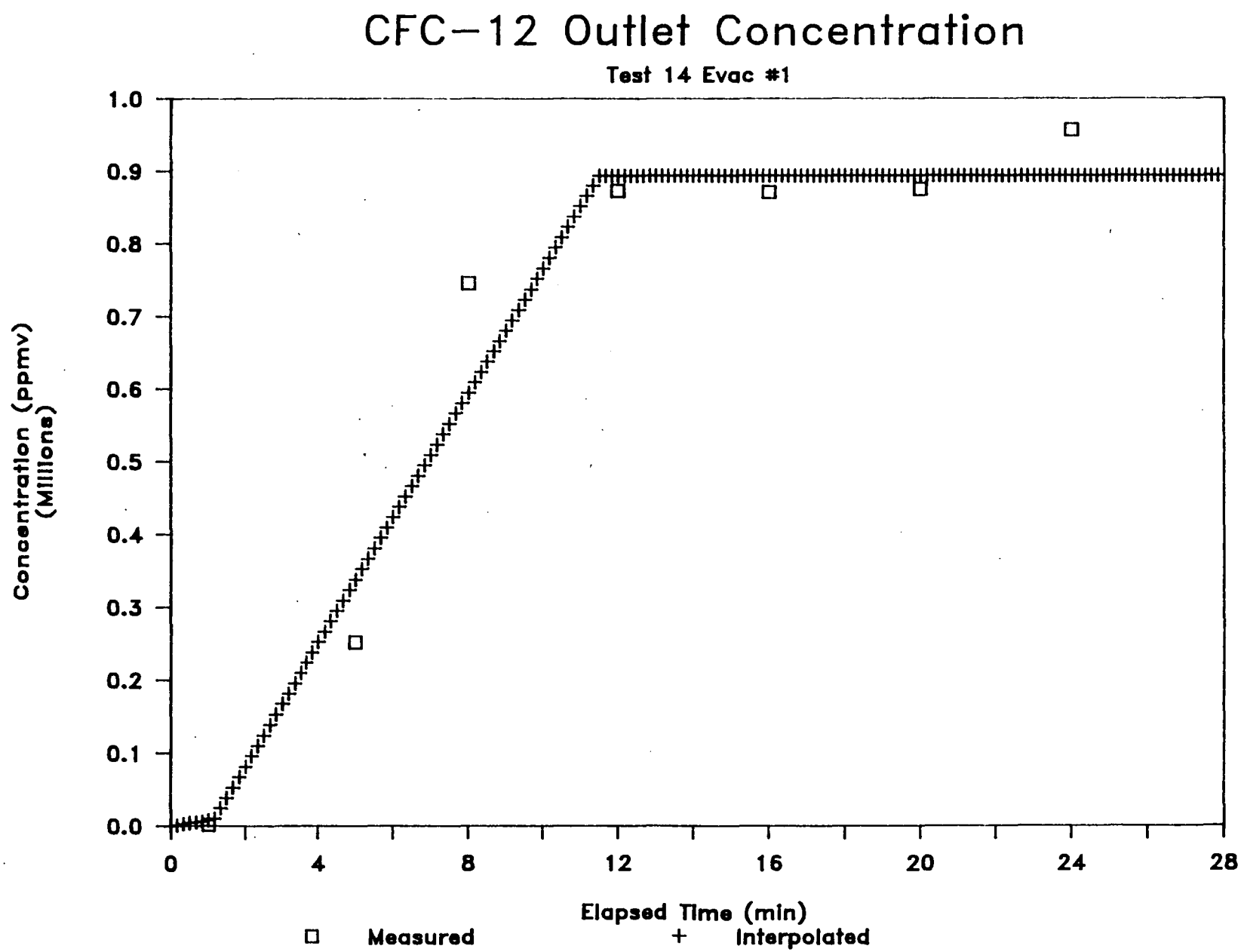

Figure 21. Interpolated CFC-12 Scrubber Outlet Concentrations for Test 14 Evacuation 2

90

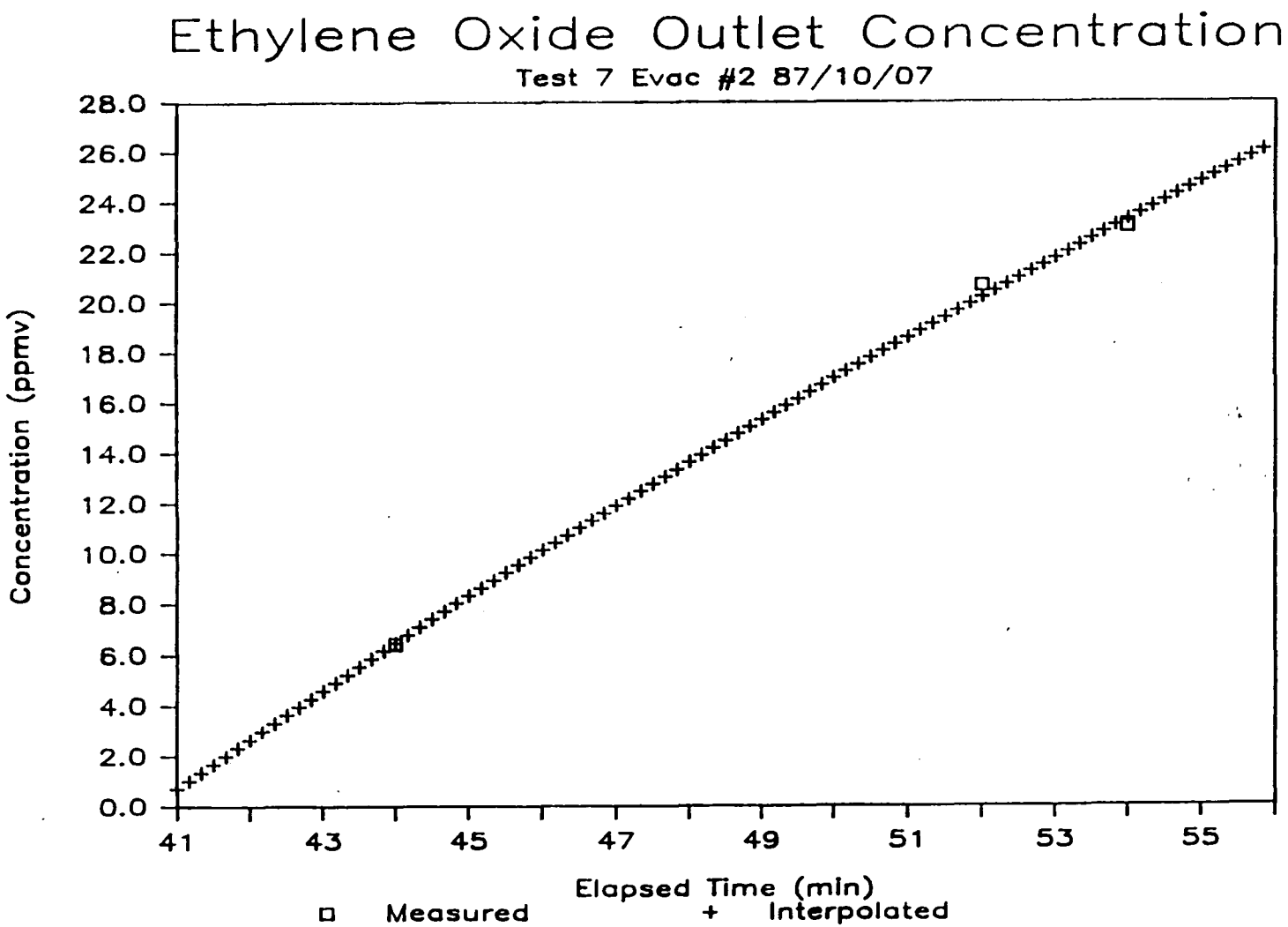

Figure 22. Interpolated EO Scrubber Outlet Concentrations for Test 7 Evacuation 2.

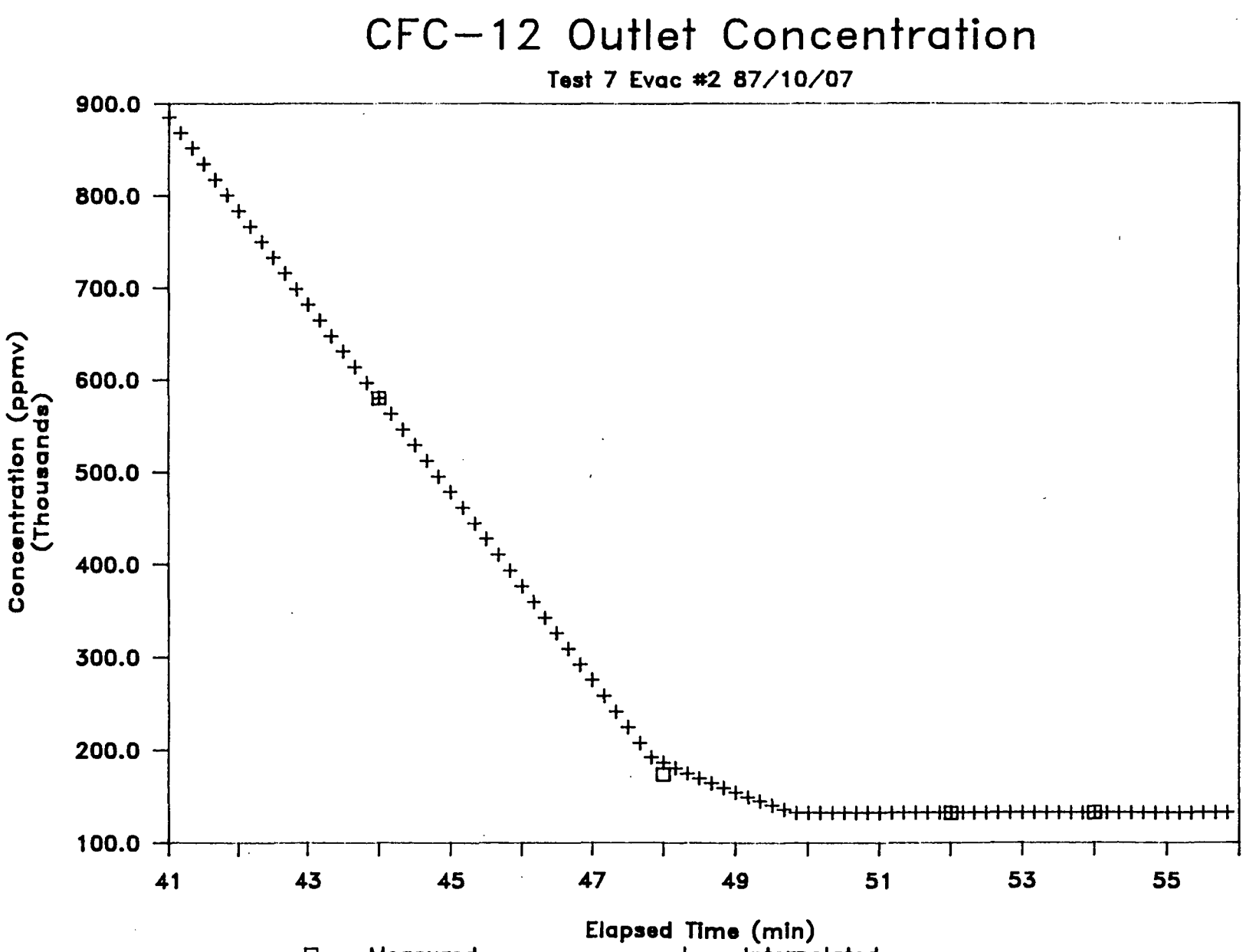

Figure 23. Interpolated CFC-12 Scrubber Outlet Concentrations for Test 7 Evacuation 2

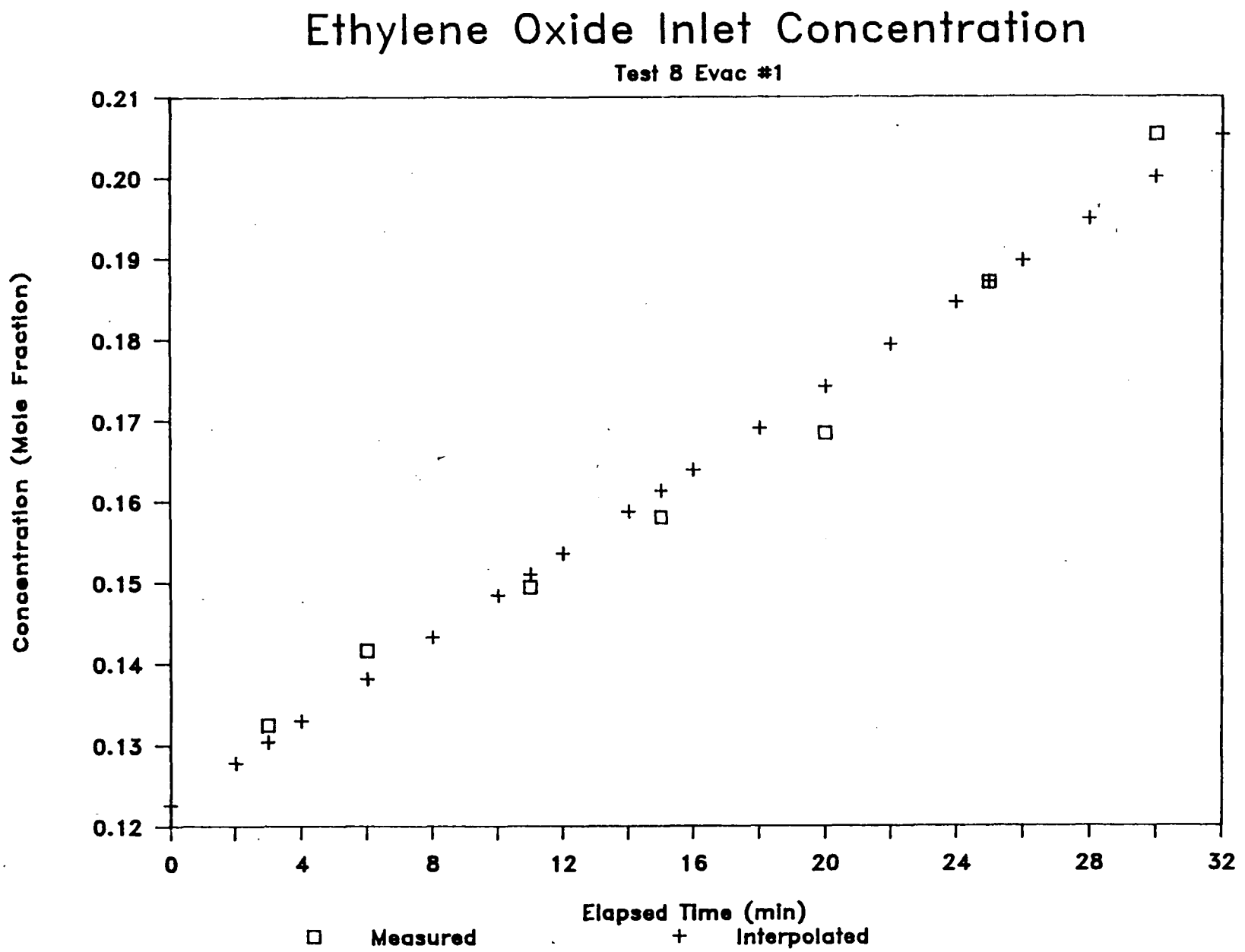

Figure 24. Interpolated EO Scrubber Inlet Concentrations for Test 8 Evacuation 1

93

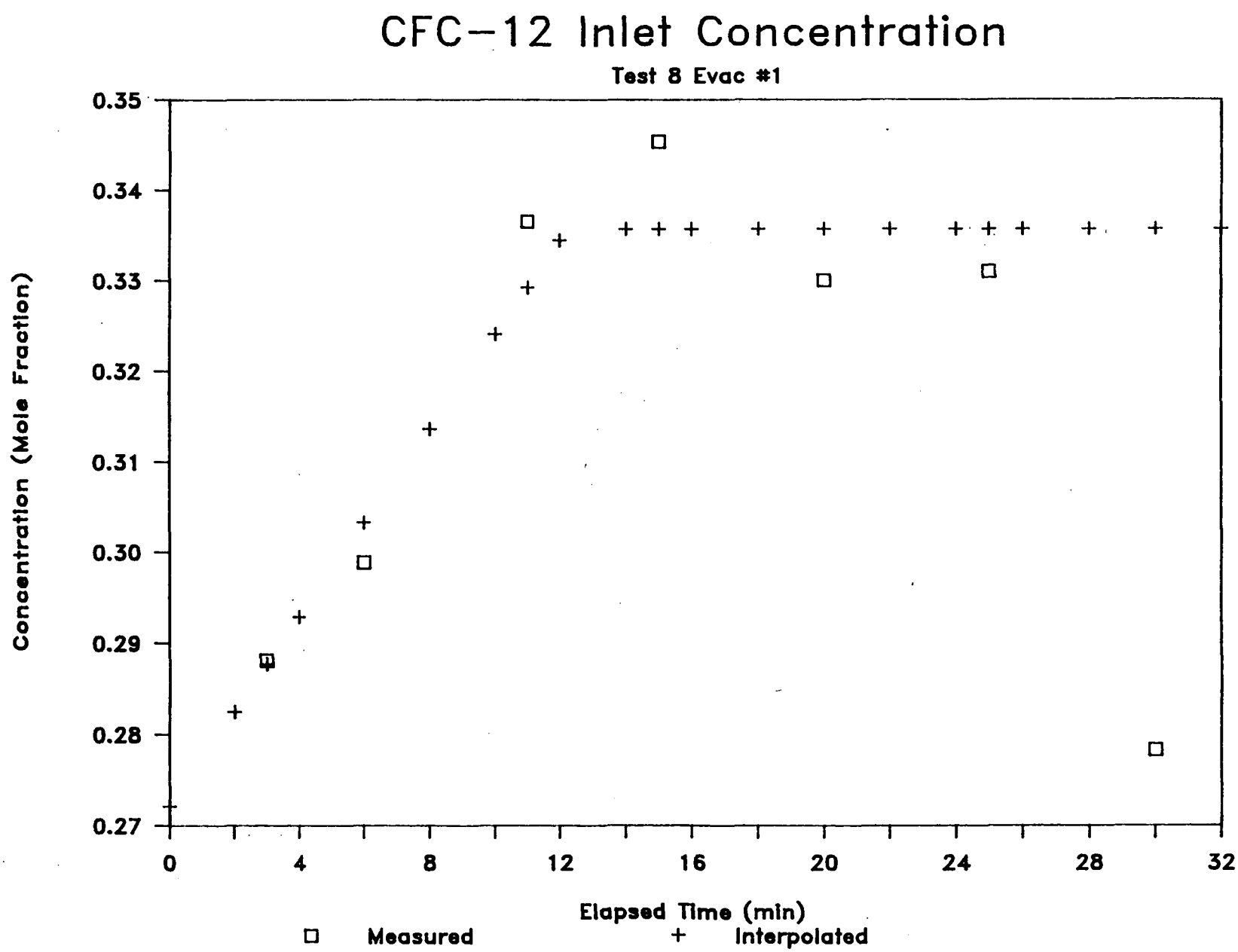

Figure 25. Interpolated CFC-12 Scrubber Inlet Concentrations for Test 8 Evacuation 1

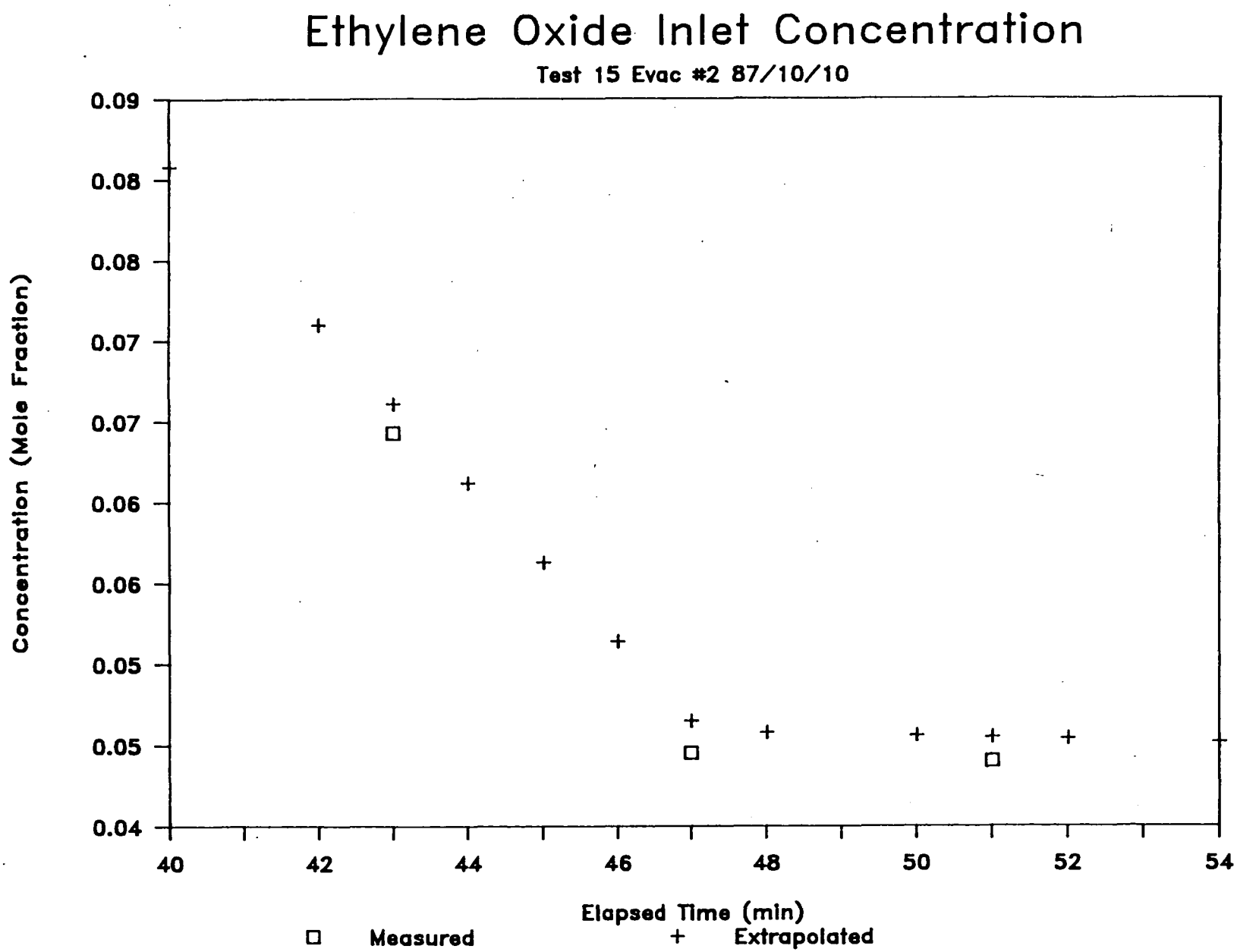

Figure 26. Interpolated EO Scrubber Inlet Concentrations for Test 15 Evacuation 1

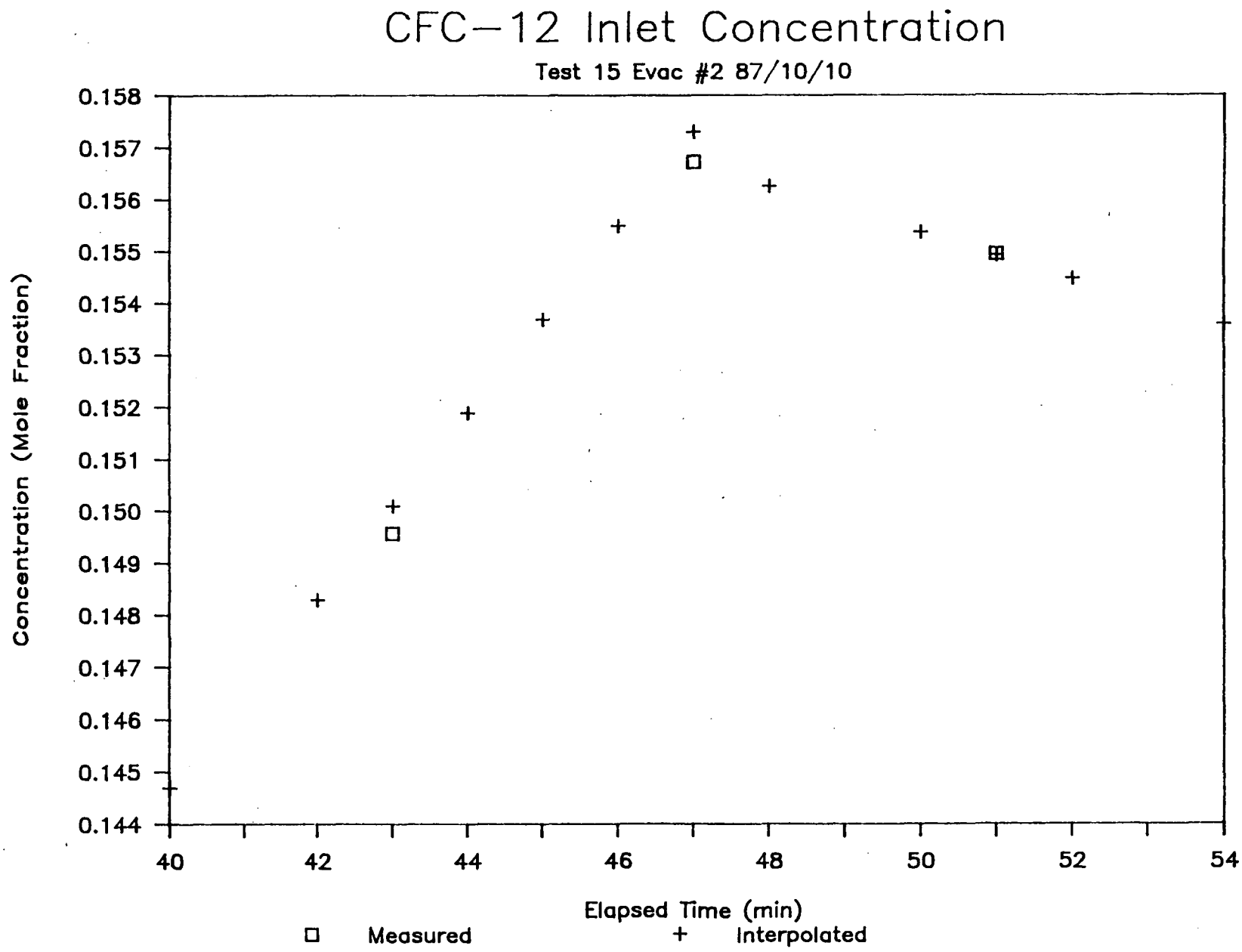

Figure 27. Interpolated CFC-12 Scrubber Inlet Concentrations for Test 15 Evacuation 2

The EO and CFC-12 concentrations were calculated as described above. The oxygen concentration was measured using Fyrite. For the first evacuations the oxygen was assumed to decrease exponentially from 20% to 0% by volume as shown in Figure 28. In several cases for the second evacuations the oxygen was assumed to increase as shown in Figure 29; however, in most cases either the average of all measurements was used or a value of 19% (v) was assumed. For the third through seventh evacuations the measured value was used or, if no measurements were taken, a value of 20% (v) was assumed.

Vent gas water content was measured using wet bulb/dry bulb measurements. Using the temperature differential and the dry bulb temperature, relative humidity was obtained from a table.[15] Another table was used to obtain the vapor pressure of water at the dry bulb temperature.[16] The mole fraction of water in the vent stream was calculated using Equation 1 presented in Section 4. The fraction of vent gas which was not attributed to EO, CFC-12, oxygen, or water was assumed to be nitrogen.

Ethylene Oxide Emission Rates

Both EO emission rates into and out of the control unit were calculated. The calculational procedures differed for the two locations because of the different procedures used to measure the flow rates.

Mass Flow Rate into the Control Unit--

The EO mass flow rate into the control unit was calculated based on the number of moles of gas exiting the chamber during each 2-min interval. Table 7 provides an example of the data used and the mass flow rates calculated during Test 6, Evacuation 1.

Assuming the chamber gas behaved as an ideal gas and using the chamber pressure (P, psia) and jacket temperature (T, K) provided on the chamber parameter printout sheet, the moles (mol) of gas leaving the chamber were given by:

$$mol = PV/RT \qquad \text{(Equation 10)}$$

where V was the chamber volume (1065 ft^3) and R was the gas constant (19.31 psia ft^3/[mol K]). Although the chamber gas probably deviated from ideal behavior, the assumption that it was ideal was a reasonable approximation at the chamber conditions used.

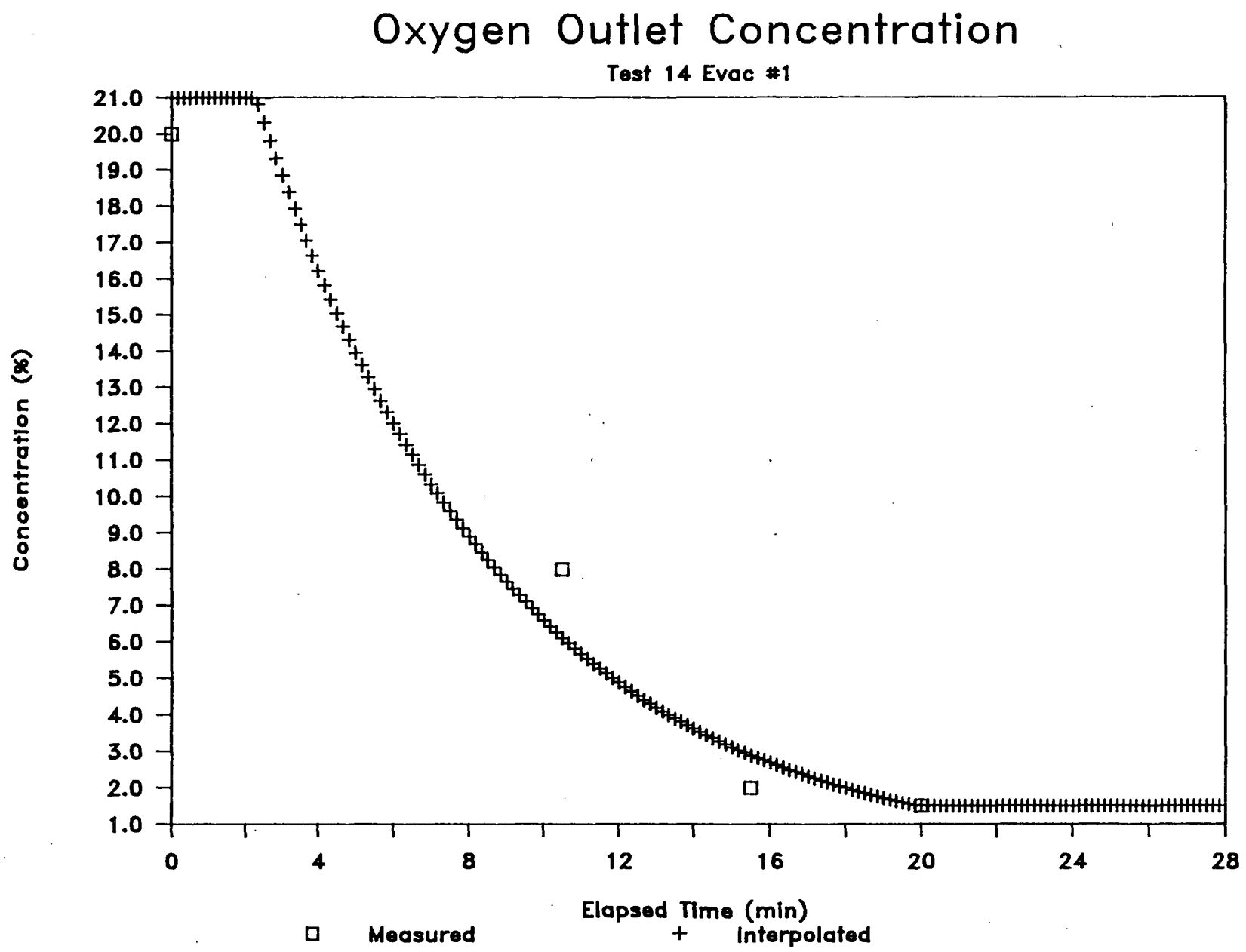

Figure 28. Interpolation of O_2 Scrubber Outlet Concentrations for Test 14 Evacuation 1

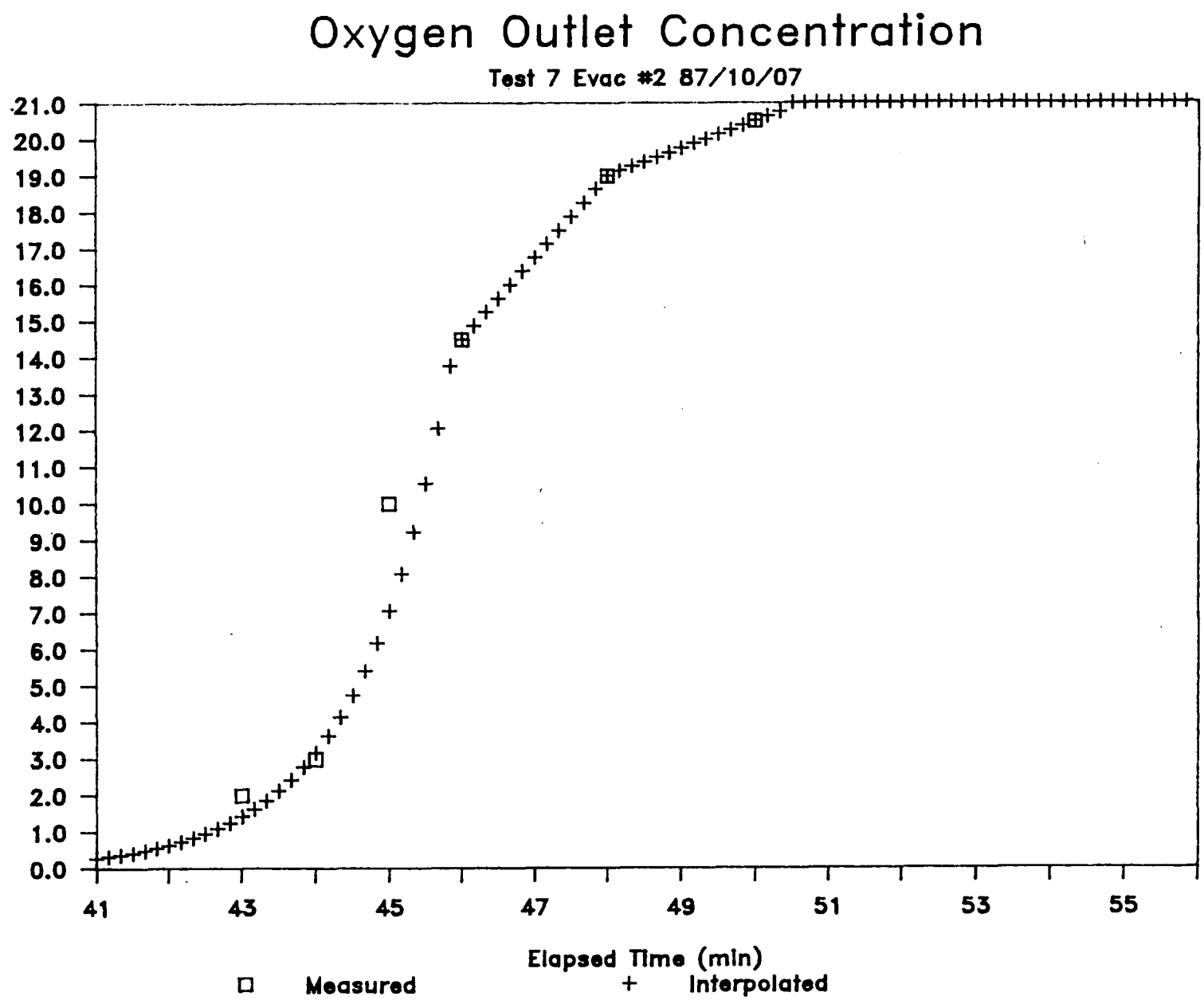

Figure 29. Interpolation of O_2 Scrubber Outlet Concentrations for Test 7 Evacuation 2

TABLE 7. ETHYLENE OXIDE MASS FLOW RATE INTO SCRUBBER DURING TEST 6, EVACUATION 1

Elapsed Time (min)	Clock Time	EO Conc. (% [v])	Molecular Weight (lb/mole)	Chamber Temp. (deg. C)	Chamber Pressure (psia)	Flow Rate (lb mol/min)	EtO Emission (lb/min)
2.00	21:41	19.79	83.03	53.1	21.4	0.18	1.57
4.00	21:43	20.43	84.04	52.2	19.2	0.18	1.63
6.00	21:45	21.07	85.56	52.7	17.2	0.17	1.59
8.00	21:47	21.71	87.16	52.7	15.6	0.14	1.29
10.00	21:49	22.35	87.22	52.6	13.5	0.18	1.74
12.00	21:51	22.99	87.29	52.0	11.3	0.18	1.87
14.00	21:53	23.63	87.36	51.9	9.5	0.15	1.58
16.00	21:55	24.26	87.45	51.9	7.5	0.17	1.81
18.00	21:57	24.90	85.66	51.8	5.6	0.16	1.76
20.00	21:59	25.54	83.87	51.5	4.2	0.12	1.33
22.00	22:01	26.18	82.08	51.3	3.3	0.08	0.88
24.00	22:03	26.82	80.30	51.1	2.6	0.06	0.70
26.00	22:05	27.46	78.51	51.6	2.2	0.03	0.41
						total lbs =	36.37

The EO mass flow rate (R_{in}, lb/min) for EO into the control unit was given by:

$$R_{in} = MW_b C_b mol/t \qquad \text{(Equation 11)}$$

where MW_b was the molecular weight of EO (44 lb mol), C_b was the mole fraction of EO in the gas, and t was the time interval (2 min). The total weight (W_{in}, lbs) of EO entering the control unit was then given by:

$$W_{in} = \Sigma R_{in} \times t \qquad \text{(Equation 12)}$$

Emission out of the Control Unit--

The EO emission out of the control unit was calculated based on the pounds of gas exiting the control unit during each 10-sec interval. The total weight (W_{out}, lbs) of EO leaving the control unit was then given by:

$$W_{out} = \Sigma m \times t \qquad \text{(Equation 13)}$$

where m was the mass flow rate in lb/min and t was the time interval (0.16 min).

To calculate the flow rate of EO from the pressure drop across standard orifices Equations 3 and 4 from Section 4 were used. A Houston Instrument Digitizer was used to convert the stripchart lines representing continuous pressure readings across the orifice plates into numerical values. A BASIC program was used to interpret the electronic signals from the digitizer and generate a LOTUS 1-2-3 print file of the data. These data were imported into LOTUS. LOTUS spreadsheets were made for the 10 test runs, the seven evacuation sequences, and the two plate sizes.

Input parameters required by the program are:

- Chart speed = 28.3 inches/hr (0.2 mm/s),
- Baseline = 0 inches H_2O (0 kg/m^2),
- Full scale = 10 inches H_2O (254 kg/m^2),
- Standards = 2,
- Start time = varies according to test times, and
- Time intervals = 10 sec (interval between data readings).

The values for the input parameters were based on information from the stripcharts. Values listed above were used for each test run and both large and small orifice plates.

The mass rate of EO flow out of the control unit was then given by Equation 5 in Section 4.

Efficiency Calculations

Efficiency was calculated in terms of a throughput efficiency and a recovery efficiency.

Throughput Efficiency--

A throughput efficiency was calculated using the emissions into and out of the control unit. The throughput efficiency (E_T) is given by Equation 14.

$$E_T = 100 \times (W_{in}-W_{out})/W_{in} \qquad \text{(Equation 14)}$$

Recovery Efficiency--

A recovery efficiency was calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control unit. The weight of EO originally charged to the chamber was obtained by multiplying the weight of 12/88 gas by 0.12. No analysis was performed on the sterilant gas to verify the EO concentration. A correction was made for the EO remaining in the chamber (W_R) which was determined by Equation 15.

$$W_R = (MW_bC_bPV)/(RT) \qquad \text{(Equation 15)}$$

The mole fraction of EO left in the chamber was obtained from samples taken after Evacuation 7 either before or after the chamber had been refilled. The recovery efficiency (E_R) is then given by:

$$E_R = 100 \times (W_c-W_R-W_{out})/(W_c-W_R) \qquad \text{(Equation 16)}$$

where W_c is the weight of EO originally charged to the chamber.

RESULTS

The sampling and analytical method for EO emissions from sterilizers ultimately must be capable of determining whether a sterilizer EO control unit is operating efficiently. To do that the method must be capable of measuring the EO emissions accurately enough to provide consistent efficiency measurements. The sampling method must deliver unbiased sample and the analytical method must accurately identify and quantitate the components of interest.

In addition the test data was used to compare several options which exist in defining the method. A comparison was made between calculating efficiency by the Throughput Method and the Recovery Method and by using a chamber with product and without. The utility of the orifice plates was evaluated by comparing emission and efficiency results obtained using the orifice plates to

results which would have been obtained if the flow rate had been estimated using the data from the chamber control monitor.

Sampling Method Evaluation

The sampling method was evaluated using a gas cylinder containing known concentrations of EO and CFC-12. The gas cylinder was first analyzed on the GC. Then the gas cylinder was treated as a sample by installing a tee between the cylinder and the sampling line. The flow rate of the gas out of the cylinder was adjusted so that there was always excess flow past the tee during sampling. Response of the cylinder sample through the sample line was compared to the response of the cylinder sample analyzed directly.

Evaluation of Inlet Sampling--

The inlet sampling bias was measured twice using a 2,508 ppmv EO and 6,022 ppmv CFC-12 standard. The total sampling and analytical bias in the EO measurement ranged from 0-7% with an average of 3.5%. The sampling bias in the EO measurement ranged from 0.2 to 11.9% with an average of 6%. In both cases the sampling was biased positively for EO indicating that the method would tend to overestimate EO emissions.

The total sampling and analytical bias in the CFC-12 measurement ranged from 4.3 to 12.5% with an average of 8.4%. The sampling bias in the CFC-12 measurement ranged from 0 to 15.2% with an average of 7.6%.

Evaluation of Outlet Sampling--

The outlet sampling bias was measured three times using a 502.4 ppmv EO and 1,200 ppmv CFC-12 standard. The total sampling and analytical bias in the EO measurement ranged from 1.9 to 12.9% with an average of 7.4%. The sampling bias in the EO measurement ranged from -7.5 to 7.1% with an average of +1.3%.

The total sampling and analytical bias in the CFC-12 measurement ranged from -9.5 to 4.8% with an average of -2.4%. The sampling bias in the CFC-12 measurement averaged 11%.

Analytical Method Evaluation

The analytical method was evaluated using a gas cylinder containing concentrations of EO and CFC-12 that were certified to ±2 percent. The gas cylinder was analyzed on the GC using the same procedure as for the standard cylinders. Using the response of the cylinder sample and the prepared

calibration curve, a measured concentration of the cylinder sample was calculated. The measured concentration was compared to the expected or known concentration of the gas cylinder.

Evaluation of Inlet Analysis--

The inlet analysis bias was measured twice using a 2508 ppmv EO and 6022 ppmv CFC-12 standard. The analytical bias in the EO measurement ranged from -0.2 to -4.4% with an average of -2.3%. In both cases the analytical bias was negative. The analytical bias in the CFC-12 measurement ranged from -2.4% to 4.3% with an average of 1%.

Evaluation of Outlet Analysis--

The outlet analysis bias was measured three times using a 502.4 ppmv EO and 1200 ppmv CFC-12 standard. The analytical bias in the EO measurement ranged from 0.3 to 10.1% with an average of 6.2 percent. In all cases the analytical bias in the EO measurement was positive.

The analytical bias in the CFC-12 measurement ranged from -5.6 to -18.5% with an average of -12 percent. In all cases the analytical bias in the CFC-12 measurement was negative, indicating that the column may be overload by the combination of the 2-mL sample size and the high CFC-12 concentration.

Method Utility in Emissions Determination

The utility of the method in determining emissions was evaluated by comparing the measured EO emissions for the six empty chamber tests on the assumption that the control device efficiency did not change with time. Emissions data are presented in Table 8.

Emissions from Uncontrolled Sterilizers--

The expected quantity of EO entering the control unit during the six empty chamber tests ranged from 41 to 44 lb and averaged 42 lb. These values were based on 12% of the total weight of the 12/88 charge. The measured quantity of EO entering the control unit during these same six tests ranged from 24 to 62 lb and averaged 47 lb. In Test 7 where the measured mass of EO entering the scrubber was low, the inlet sampling pump leaked during the first 10 minutes of the evacuation and the FID flame was extinguished during portions of the third and fourth evacuations. Test 9 and 10 were performed on a day when the EO standard calibration curve for inlet samples was lower than on other test days.

TABLE 8. CONTROL UNIT INLET AND OUTLET EO MASS FLOW RATE FOR THE EMPTY CHAMBER TESTS

Test Number	Initial EO Charged to Chamber (lb)	EO Left in Chamber ~~(10^3 lb)~~	EO Entering Control Unit Measured (lb)	EO Exiting Control Unit Measured (lb)
7	43.8	0.42×10^{-3}	24.19[a]	0.043
9	41.5	1.5	60.59[b]	0.011
10	42.4	0.22	62.12[b]	0.029
12	41.5	0.16	44.00	0.011
14	42.0	0.16	48.80	0.021
15	41.2	0.07	52.82	0.014

[a]During Test 7 there was a leak in the inlet sampling pump during the first 10 minutes of the evacuation and the FID flame was extinguished during portions of the third and fourth evacuations. Loss of these samples may explain the lower mass of EO entering the control unit during this test.

[b]The EO standard calibration curve for inlet samples on October 8, 1987 was lower than on the other test days. This would have raised the measured EO concentrations, and caused the EO mass flow into the control unit to be over estimated.

The absolute difference between measured emissions and expected emissions was >40% for three tests and was <10% for only one test. In five of the six tests the measured emissions were larger than the expected emissions.

Emissions from Controlled Sterilizers--

The measured quantity of EO emitted to the atmosphere from the control unit during the six empty chamber tests ranged from 0.011 to 0.043 lb and averaged 0.022 lb. The relative standard deviation (RSD) in these six measurements was twice the RSD for the inlet measurements indicating that more variation is associated with the scrubbing process than with the sterilization chamber.

Conclusions--

Most of the error in the EO mass flow rate and emission measurements probably resulted from errors in the interpolation of the flow rate/concentration profile. Ethylene oxide emissions were measured with greater precision at the scrubber inlet than at the scrubber outlet as was expected because of the higher concentrations at the inlet. Part of this loss of precision in EO emission measurement may be due to difficulty in identifying the EO peak in the chromatogram because of EO retention times that shifted as the EO concentration decreased.

Method Utility in Control Unit Efficiency Determination

The utility of the method in determining control unit efficiency was evaluated by comparing the measured throughput efficiencies obtained from the six empty chamber tests on the assumption that the control device efficiency did not change with time. All of the empty chamber tests were performed on the same chamber. Efficiency data for the empty chamber tests is presented in Table 9. The measured efficiency using the throughput method with the data from the six empty chamber tests ranged from 99.82 to 99.98% and averaged 99.94 percent. The median efficiency was 99.96 percent. Efficiency values were above 99.95% in five of the six tests. The one test in which the efficiency was below 99.9% was Test 7 where sampling and analytical problems were encountered as footnoted in Table 9.

TABLE 9. EFFICIENCY FROM EMPTY CHAMBER TESTS

Test Number	Throughput Efficiency	Recovery Efficiency
7[a]	99.82%	99.90%
9	99.98%	99.97%
10	99.95%	99.93%
12	99.98%	99.97%
14	99.96%	99.95%
15	99.97%	99.97%

[a]During Test 7 there was a leak in the inlet sampling pump during the first 10 minutes of the first evacuation and the FID flame was extinguished during portions of the third and fourth evacuations. The test was halted at these times until the problems were solved. This may explain the lower efficiencies measured during Test 7.

Effect of Calculational Method on Efficiency Determination

Comparisons of the groupings shown in Table 9 were done by a one-way analysis of variance (ANOVA) with sampling-calculational procedures as a fixed factor. The model was:

$$Y_{ijk} = \mu + M_i + e_{k(ij)} \qquad \text{(Equation 17)}$$

where

Y_{ijk} = the efficiency results,

μ = overall mean efficiency,

M_i = the calculational procedures, i=1 or 2, for Throughput and Recovery Procedures, respectively,

$e_{k(ij)}$ = the error term.

The M_i interaction term was tested to determine if there was a significant effect on efficiency results based on the calculational procedure used.

Basically, the error in the means of the efficiencies (the dependent variable) calculated using the Throughput and Recovery Methods are compared to the error in all the individual measurements using a F-Ratio. From the F-Ratio a probability (P) that the independent variable (the method used) has no effect can be calculated. If $P \leq 0.05$, then the effect is taken to be significant. If $P \leq 0.01$, then the effect is taken to be highly significant. A one-way ANOVA resulted in a P of 0.86 for the tests using chambers which did not contain product and 0.32 for the tests using chambers which did contain product; therefore, the procedure used to calculate the efficiency does not significantly affect the efficiency determined.

Effect of Product Presence on Efficiency Determination

The efficiency results from the tests where product was present in the chamber were compared with the efficiency results from the tests were product was not present in the chamber using a fixed factor ANOVA. The model was

$$Y_{ijk} = \mu + M_i + F_j + MF_{ij} + e_{k(ij)} \qquad \text{(Equation 18)}$$

where

Y_{ijk} = the efficiency results,

μ = the overall mean efficiency,

M_i = the procedure, i = 1 or 2, for Throughput or Recovery Procedure, respectively,

F_j = the chamber condition, j = 1 or 2, for chamber without and with product, respectively,

MF_{ij} = the MF_{ij} interaction term, and

$e_{k(ij)}$ = the error term.

A fixed factor ANOVA was used because the interaction terms, M_i and F_j, represented parameters that were fixed, i.e. the chamber either did or did not contain product. The M_i interaction term represented the effect of calculational procedure on the efficiency measurement. The F_j interaction term represented the effect of the presence of product on the efficiency measurement. The MF_{ij} interaction term represented the combined effect of the calculational procedure and the chamber condition on the efficiency measurement. The error term represented the random error of the method. The variances in calculating the efficiencies by the various methods were compared using an F-Ratio. From the F-Ratio, a probability that the independent variable does not effect the efficiency was calculated. If $P \leq 0.05$, then the effect is taken to be significant. The results of the ANOVA calculations are reported in Table 10.

None of the dependent variables tested had a $P \leq 0.05$. Therefore, there was no significant effect on the efficiency measurement due to the presence of product in the chamber. Furthermore, there was no interaction between the calculational method used and the presence or absence of product in the chamber. Thus, the efficiency results were within random error of the overall mean efficiency.

Orifice Plate Measurements Compared to Use of Monitor Data

Several outlet EO emissions were calculated using the chamber pressure and temperature data used to calculate inlet flow rates. Results are reported in Table 11. No correction was made for the change in the gas composition which occurred while the gas was in the scrubber. The largest change in gas composition occurs during the first evacuation when the gas composition changes from 30/70 % (v) EO/CFC-12 entering the scrubber to <1/>99 % (v) EO/CFC-12 exiting the scrubber. This meant that during the first evacuation approximately 30% of the moles of gas entering the control unit did not exit the control unit. Thus, the actual flow rate of the gas coming out of the control unit was probably less than the flow rate calculated by this method. This method should over-estimate EO emissions, resulting in an under-estimation of the control unit efficiency.

TABLE 10. FIXED FACTOR ANALYSIS OF VARIANCE RESULTS

Source	Sum of Squares	Degrees of Freedom	Mean Square	F-Ratio	P
M_i	0.00048	1	0.00048	0.3034	0.59
F_j	0.00133	1	0.00133	0.8427	0.37
MF_{ij}	0.00012	1	0.00012	0.0758	0.79
$e_{k(ij)}$	0.02532	16	0.00158		

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TABLE 11. EMISSIONS AND EFFICIENCIES CALCULATED USING ESTIMATED FLOWS

Test Number	Weight EO Emitted (lb)	Throughput Efficiency	Recovery Efficiency
6	0.006	99.99%	99.99%
7	0.036	99.85%	99.92%
8	0.012	99.95%	99.98%
9	0.010	99.98%	99.98%
10	0.006	99.99%	99.99%
15	0.014	99.97%	99.97%

Statistical comparisons of data in Table 11 with data in Tables 8 and 9 using a one-way ANOVA with flow-calculational procedures as a fixed factor showed that the EO emissions from the scrubber calculated using orifice plate data were not significantly different from the EO emissions estimated using chamber temperatures and pressures. The probability that there was no difference in the calculated EO emissions was 0.35; in the calculated throughput efficiencies, 0.59; and in the calculated recovery efficiencies, 0.25. A probability of 0.05 indicated a significant difference. The calculated efficiencies were not significantly different due to the high efficiency of the EO control unit. Therefore, in tests performed on units that are closed systems, flow estimation may be a possible alternative to orifice plate installation.

Vane Anemometer Data Compared to Orifice Plate Data

Several outlet EO emissions were calculated using the vane anemometer data. Results are reported in Table 12. The vane anemometer velocity readings were multiplied by the square root of the ratio of the molecular weight of air to the molecular weight of the vent gas stream. The corrected velocity readings were converted to volumetric flow rates by multiplying by the cross sectional area of the stack. The volumetric flow rates were corrected to standard conditions and converted to molar flow rates. Multiplying the molar flow rates by the vent gas molecular weight gave the mass flow rates. A correction was made for the time no flow was observed by multiplying the mass flow rate by 0.375. (Actual flow out of the stack occurs during only 37.5% of the total time required to evacuate the chamber.)

Comparison of data in Table 12 with data in Tables 8 and 9 show that the calculated EO emissions are much greater and the efficiencies lower using the vane anemometer data. This is because the vane anemometer data tends to overestimate the flow rate. Figure 15 shows the cyclical nature of the flow emitted from the scrubber. The vane anemometer was read at two minute intervals, providing a velocity reading based on the flow during the proceding 16-second interval. Thus, the vane anemometer provides grab samples of the flow rate versus the orifice plates which provide a continuous pressure differential readout. The quality of the vane anemometer data may be improved by taking more frequent velocity readings but could never surpass the quality of the orifice plate data due to the mechanics of the anemometer measurements.

TABLE 12. EMISSIONS AND EFFICIENCIES CALCULATED USING VANE ANEMOMETER DATA

Test Number	Weight EO Emitted (lb)	Throughput Efficiency	Recovery Efficiency
9	0.232	99.62%	99.44%
10	0.175	99.72%	99.59%
12	0.235	99.47%	99.43%

DISCUSSION

During the test several interesting problems arose and observations were made regarding the operation of the EO control device, the sterilization exhaust process, and the analytical system. These problems and observations will be discussed in this section as well as some possible modifications to the method.

Ethylene Oxide Control Device Operation

The system is designed so that the sterilization chambers can not exhaust until the control device is ready. At the end of the exposure cycle, the scrubber receives a signal from the sterilizer control panel that the chamber is ready to exhaust. The scrubber system starts up and requires a two-minute period before chamber evacuation can begin. During this two-minute period the gas from the previous chamber exhaust is emitted from the stack. At the end of the two-minute period, evacuation of the current chamber gas begins. An additional five to seven minutes is required before the chamber gas reaches equilibrium measured by the oxygen content taken during the 10 minutes of the first and second chamber exhausts.

Thus, during the first two minutes of the evacuation the concentrations of EO and CFC-12 should be the same as they were at the end of the previous exhaust and should be fairly constant. During the next five to seven minutes the EO and CFC-12 concentrations should change rapidly as the old chamber gas is swept out of the stack and the remaining chamber gas is diluted by the new chamber gas entering the scrubber. After 10 minutes the measured concentrations should level off to lower values than in the previous evacuation.

With this process cycle, a minimum of three samples would be required to characterize each evacuation, one during the first two minutes, one between two and seven minutes, and one after 10 minutes. The tested sampling/analytical method allows only three samples to be taken during each evacuation. With careful planning the exhaust could be sampled at one minute, five minutes, and 11 minutes. It is recommended that a minimum of six samples be taken. Two samples could be taken during each of the three predicted phases of the evacuation. This criterion would require either an analytical system capable of acquiring samples at 1-min intervals, a dual analytical

system for each sampling port, or the collection of samples in a suitable container for later analysis.

Chamber Evacuation Process

The chamber is evacuated in pulses generated by a solenoid valve opening and closing to prevent the chamber from evacuating too rapidly. At the facility tested, the solenoid was open for 15 sec and closed for 25 sec. Operating with relay control, the gas flow out of the chamber and control unit is not continuous; however, the sampling system is a continuous process. The sampling system is composed of pumps which constantly are pulling sample out of the stack. Since, the chamber is not constantly exhausting, it could be possible for the sampling system to pull ambient air back through the stack, diluting the sample.

To maintain sample integrity, the sampling system must not pull more sample out of the stack than what is contained in the stack during the time period when the solenoid valve is closed. This can be accomplished by controlling the rate at which the sampling pumps pump and by increasing the size of the stack extension. The stack extension used for this test contained approximately 2.6 ft^3 and the main sample pump pulled a maximum of 10-15 L/min. So during the 25 sec period when the solenoid valve was closed, the pump pulled a maximum of 10 L of sample which is <10% of the stack extension volume. Thus, under the test conditions dilution of the sample when the solenoid valve was closed should not have occurred.

Analytical Method

The analytical method is deficient in several areas. Some are due to the characteristics of the vent gas and others to the characteristics of the analytical column.

Problems Due to Vent Gas Characteristics--

Three characteristics of the vent gas which pose problems for the on-line analysis of EO and CFC-12 are the relative concentrations of the EO and CFC-12, the high CFC-12 concentrations present in the first evacuation, and the presence of other interfering materials in the vent gas. The quantitation of CFC-12 is required for determining the molecular weight of the vent gas. The molecular weight is only needed if an orifice plate or a vane anemometer is used to measure the flow rate.

At the scrubber outlet, the EO is present at low ppmv levels and the CFC-12 is present at levels ranging anywhere from 500 ppmv to 99 volume percent. This wide difference in concentration makes the analysis of the two components on the same analytical column very difficult, but it can be done by programming the detector range. A sensitive range can be used for the EO and a less sensitive range for the CFC-12. To program the detector range successfully, near baseline separation of the two compounds must be obtained. Although this is possible with the analytical column chosen, baseline separation extends the time required for analysis and reduces the number of samples which can be collected and analyzed during an evacuation. Also, programming the detector range is further complicated when using the Fluorcol column due to the dependence of retention time on sample concentrations.

The high concentration of CFC-12 (90-99% [v]) in the first evacuation complicates the quantitation of the CFC-12 for two reasons, the calibration curve tends to be nonlinear over the entire concentration range and 99.9% (v) CFC-12 is necessary for the high point on the calibration curve. Accuracy of the CFC-12 quantitation may be improved by dilution of the sample. Sample dilution will introduce errors caused by sample handling and may be difficult, but not impossible, to do with on-line analysis. Alternately, the CFC-12 injected on the column could be reduced by using small sample loops (0.1 mL), but this would increase the difficulty of detecting the EO if both compounds were analyzed on the same analytical column.

The presence of other components in the vent gas creates two problems. First, components eluting near the EO peak may create confusion in correctly identifying and quantitating the EO peak. Second, components which elute after the EO and CFC-12 extend the analysis time and decrease the number of on-line samples that can be collected and analyzed during an evacuation. Although these compounds are present at low concentrations, they create analytical difficulties because of the low EO concentrations (ppmv) which must be measured.

Problems Due to the Analytical Column--

With the current analytical column the retention times of EO and CFC-12 shift with concentration. Increases in EO concentration decreases EO retention time. Interaction of EO with the column coating and packing seems to be minimal and totally dependent upon EO concentration at the temperature

tested (100°C). A column temperature higher than the optimum phase temperature was necessary to maximimize the number of samples obtained during each evacuation; however, the increased sample throughput at the higher temperature compromised the efficiency of the column. The magnitude of the EO retention time shifts may be reduced by operating at lower column temperatures but the required analysis time would increase and the number of samples analyzed during an evacuation would decrease.

The CFC-12 retention time shift with increasing concentrations occurs at concentrations above 12 percent. Thus, the CFC-12 retention time shift is only a problem during the first two evacuations. The use of small loops (0.1 mL) or the dilution of the samples should eliminate this problem.

The time required for complete analysis of a vent sample limits the number of samples that can be analyzed. Over 3 min are needed to elute the major components of the vent gas. This limits the number of samples which can be analyzed during an evacuation to three. A minimum of six samples per evacuations is recommended.

Recommended Method Modifications

First, the field test data indicate that a minimum of six samples should be acquired from the scrubber outlet during each evacuation, two samples during the first 2 min, two samples between 2 and 9 min, and 2 samples after 10 min. This could best be accomplished off-line by taking grab samples in syringes or small gas sampling bags or cans and analyzing them later. However, this technique requires sample containers of the appropriate material of construction and proper storage procedures.

Second, the acquistion of off-line grab samples, allows the analysis to be performed under optimal conditions. That is, the column can be operated at lower temperatures, reducing the magnitude of the retention time shifts.

Third, the CFC-12 and EO should each be analyzed on a separate analytical system to optimize linearity. The CFC-12 should be analyzed on a system with a small gas sample loop (0.1 mL) and the EO on a system with a large loop (2 mL).

Conclusions

The sampling/analytical method adequately determined EO mass flow rate into and emissions out of the control unit; however, shifting EO retention

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times caused difficulty in measuring EO concentrations in the scrubber outlet emissions. Scrubber EO emissions based on orifice plate data gave similar efficiencies as efficiencies calculated from scrubber EO emissions estimated from chamber temperatures and pressures. The test data indicate that sampling at the control unit inlet and measuring control unit outlet flow rates with orifice plates, may not be necessary to obtain reasonable estimates of control unit efficiencies. Analytical bias of the method at the control unit outlet may be decreased by quantitating EO and CFC-12 on separate columns. Error in interpolation of the flow/concentration profile may be decreased by taking a minimum of six samples during each evacuation. Off-line sampling may improve both the quantitative ability of the analytical method and reduce the error in EO mass flow rate by optimizing analytical conditions and maximizing the number of samples that can be acquired. Also, the sampling/analytical method measured efficiencies precisely, and the efficiencies calculated were independent of the calculational procedure used, and the presence of product in the chamber.

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2014 NATA TSD

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Common Acronyms and Abbreviations

µg/m^3	microgram(s)/cubic meter
AERMOD	atmospheric dispersion model developed by the American Meteorological Society and the U.S. Environmental Protection Agency's Regulatory Model Improvement Committee
ASPEN	Assessment System for Population Exposure Nationwide
ATSDR	Agency for Toxic Substances and Disease Registry
CAA	Clean Air Act
CHAD	Consolidated Human Activity Database
CAP	criteria air pollutant
CMAQ	Community Multiscale Air Quality model
CONUS	Contiguous United States (modeling domain for CMAQ)
EC	exposure concentration
EPA	Environmental Protection Agency
EGU	electricity generating unit
HAP	hazardous air pollutant
HAPEM	Hazardous Air Pollutant Exposure Model
HEM	Human Exposure Model
HI	hazard index
HQ	hazard quotient
IRIS	Integrated Risk Information System
ISC	Industrial Source Complex
MOVES	Motor Vehicle Emissions Simulator
NATA	National-scale Air Toxics Assessment
NEI	National Emissions Inventory
NMIM	National Mobile Inventory Model
OAQPS	Office of Air Quality Planning and Standards
PAH	polycyclic aromatic hydrocarbon
PM	particulate matter
$PM_{2.5}$	particulate matter less than 2.5 microns in diameter
PM_{10}	particulate matter less than 10 microns in diameter
POM	polycyclic organic matter
RfC	reference concentration
RTR	Risk and Technology Review
SCC	Source Classification Code
S/L/T	state, local or tribal agency
URE	unit risk estimate
WRF	Weather Research Forecasting model

1. Introduction

1.1. Overview

The National Air Toxics Assessment (NATA) is the U.S. Environmental Protection Agency's (EPA; referred to throughout this document as "we") ongoing thorough evaluation of air toxics across the United States. EPA developed NATA as a state-of-the-science tool to inform both national and localized efforts to collect air toxics information, characterize emissions and help prioritize pollutants and areas of interest for further study to gain a better understanding of risks. The goal of NATA is to identify those air toxics which are of greatest potential concern in terms of contribution to population risk. Ambient and exposure concentrations and estimates of risk and hazard for air toxics in each state are typically generated at the census tract level. The 2014 NATA is the sixth version of this national assessment.

This NATA Technical Support Document (TSD) describes the data and approaches EPA used to conduct the 2014 NATA, including descriptions of how we:

- compiled emissions data and prepared them for use as model inputs (Section 2);
- estimated ambient concentrations of air toxics (Section 3);
- estimated exposures to air toxics for populations (Section 4);
- selected toxicity values (Section 5);
- characterized human-health risks and hazards (Section 6); and
- addressed variability and uncertainty (Section 7).

References to additional documents are included (Section 8) to facilitate access to more detailed technical information on the emissions inventories, dispersion modeling, photochemical modeling, exposure modeling and toxicity values.

The TSD also includes the following appendixes:

- Appendix A – a glossary of the key terms and their definitions
- Appendix B – a list of air toxics included in NATA
- Appendix C – a list of source classification codes (SCCs) for diesel particulate matter (diesel PM)
- Appendix D – procedures used to estimate NATA background concentrations
- Appendix E – additional model evaluation summaries
- Appendix F – documentation on HAPEM7 and its use in NATA

We also provide a "Supplemental Data" folder with this document that contains the Microsoft® Access™ and Microsoft® Excel™ files referenced throughout this TSD.

This TSD satisfies basic documentation protocol expected of EPA products and provides a resource for the technically oriented user community by summarizing the data sources, methods, models and assumptions used in the 2014 NATA. This document does not provide quantitative results for NATA and thus presents no exposure or risk estimates. You can find results and other specific information for NATA, including for the 2014 NATA and previous assessments, on the NATA website (https://www.epa.gov/national-air-toxics-assessment).

1.2. Purpose and Overview of NATA Steps

Each NATA involves the same basic steps needed to produce the final assessment. These NATA steps are depicted in Figure 1-1.

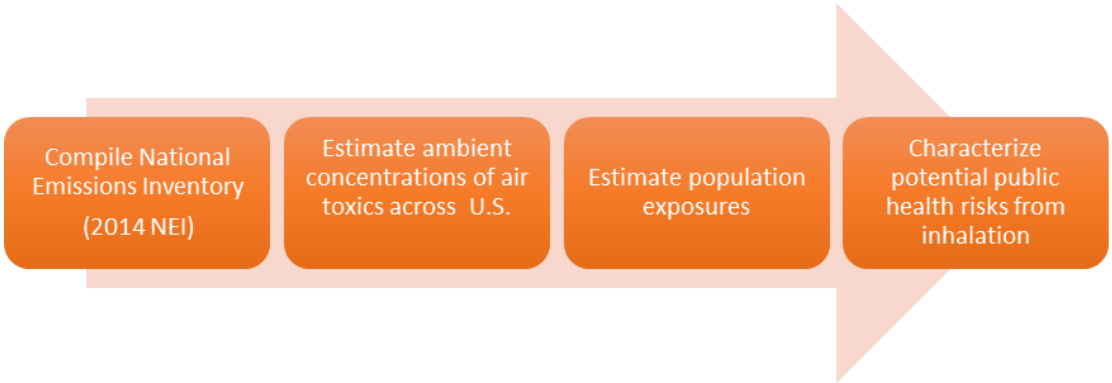

Figure 1-1. 2014 NATA – basic steps

The first and most time-consuming step in NATA is assembling the National Emissions Inventory (NEI), a detailed, nationwide inventory of air toxics emissions. This NATA's emissions data are from the 2014 NEI version 2. The NEI includes emissions from point, nonpoint and mobile sources, as well as emissions from biogenic sources and fires. These source data are the foundation of NATA's air quality modeling. Section 2 of this document details the steps EPA used to construct this extensive database.

After preparing the NEI emissions and other needed data (e.g., meteorological data), we use these data as inputs to two air quality models used to estimate ambient air concentrations of air toxics: the American Meteorological Society/Environmental Protection Agency Regulatory Model (AERMOD) atmospheric dispersion model and the Community Multiscale Air Quality (CMAQ) photochemical model. AERMOD is used for all NATA air toxics modeled, and CMAQ is used for a list of 52 air toxics that are incorporated into CMAQ multipollutant version 5.2. CMAQ provides the overall mass, chemistry and formation for hazardous air pollutants (HAPs) formed secondarily in the atmosphere (e.g., formaldehyde, acetaldehyde and acrolein), whereas AERMOD provides spatial granularity and more detailed source attribution. CMAQ also provides the biogenic and fire concentrations, as these sources are not run in AERMOD. Only AERMOD is run in areas outside the lower 48, or contiguous, U.S. states (referred to as CONUS) that are included in NATA: Alaska, Hawaii, Puerto Rico and the Virgin Islands. Special steps are taken to estimate secondary HAPs, fires and biogenics in these areas. Section 3 of this document details the steps EPA used to model for NATA.

For the HAPs modeled in both CMAQ and AERMOD, we combine the model-calculated annual average concentrations using a hybrid approach. We next use these concentrations, along with the other

concentrations calculated by AERMOD, to prepare census tract-level concentrations of all modeled air toxics. Then, using the HAPEM7 exposure model, we account for human activity patterns and develop exposure concentrations, or ECs, for each census tract. Finally, we estimate census tract-level risks by applying health benchmark data to the ECs. Sections 4 through 6 of this TSD detail these steps.

In every NATA assessment, EPA's state, local and tribal (S/L/T) air agency partners play an integral role. First, S/L/T specialists review early versions of NEI's source data for their area, working with local industry and other emissions sources to develop and forward corrections to their area's emissions data. They also review preliminary risk results during early stages of the NATA modeling process, which often reveals other inaccuracies in the data. This review and feedback process helps ensure that NATA's input data are as accurate as possible in the final version.

For the 2014 NATA, we first modeled using version 1 of the 2014 NEI (v1), performing the initial modeling runs in late 2016. Our S/L/T partners reviewed these v1 source data as well as two rounds of first-pass modeling and risk results. We incorporated their corrections into what became the 2014 NEI version 2 and fully remodeled using these data in the summer of 2018. This produced the final NATA results. We then previewed these final results with S/L/T agencies and released the 2014 NATA in August 2018.

Figure 1-2 provides a more detailed flowchart showing the emissions sources used in the air quality models and how the hybrid approach fits into the overall approach.

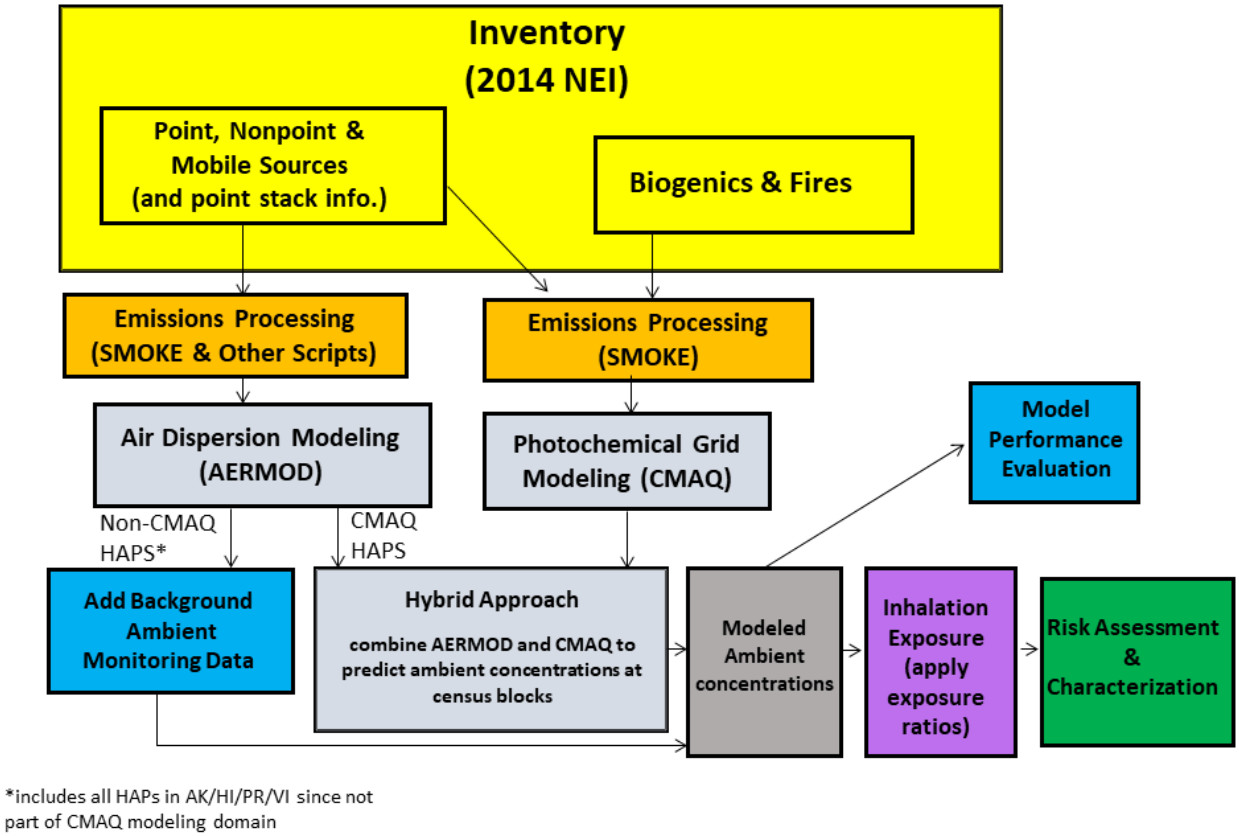

Figure 1-2. Detailed steps and approach used for 2014 NATA

1.3. What NATA Is

NATA is a first-pass, screening tool intended to evaluate the human-health risks posed by air toxics across the United States. NATA provides screening-level estimates of the risk of cancer and other potentially serious health effects from inhaling air toxics.

NATA uses emissions data compiled for a single year as inputs to air quality models. The models use these source data along with meteorological data for the same year to estimate ambient air concentrations of certain air toxics. EPA then combines these modeled concentrations with census data and other information to calculate exposure concentrations of the air toxics. We also estimate cancer risks and potential noncancer health effects associated with chronic inhalation exposure to the toxics.

EPA generates NATA results for each U.S. state at county and census tract levels. We also generate results for Puerto Rico, the Virgin Islands and the District of Columbia. These results help state, local and tribal agencies prioritize air toxics, emission sources and locations of interest for further study. They also help air agencies plan and implement national, regional and local efforts to reduce toxic air pollution.

NATA provides a "snapshot" of outdoor air quality as it relates to air toxics. It also suggests the risks to human health if air toxic emission levels were to remain the same as those estimated for the assessment year. The estimates only reflect risks associated with chronic (assumed to be lifetime) inhalation exposures to air toxics at the population level. Assumptions and methods we use to complete the assessment limit the types of questions that NATA can answer reliably. You should consider these limitations, described throughout this document and summarized in Section 7, when interpreting the NATA results or when using them to address questions posed outside of NATA.

NATA results can provide general answers to questions about emissions, ambient air concentrations and exposures and risks across broad geographic areas (such as counties, states and the nation) for the year modeled in the assessment.

NATA can answer questions such as the following:

- Which air toxics pose the greatest potential risk of cancer or adverse noncancer effects across the entire United States?
- Which air toxics pose the greatest potential risk of cancer or adverse noncancer effects in certain areas of the United States?
- Which air toxics pose less, but still significant, potential risk of cancer or adverse noncancer effects across the entire United States?
- When risks from long-term inhalation exposures to all outdoor air toxics are considered together, how many people could experience a lifetime cancer risk greater than levels of concern (e.g., 1-in-1 million or 100-in-1 million)?
- When considering potential adverse noncancer effects from long-term exposures to all outdoor air toxics together for a given target organ or system, how many people could experience exposures that exceed the reference levels intended to protect against those effects (i.e., a hazard quotient greater than 1)?

1.4. The History of NATA

As discussed on the NATA website (https://www.epa.gov/national-air-toxics-assessment), EPA's first national-scale air toxics study was the Cumulative Exposure Project (Caldwell et al. 1998). EPA developed this project based on estimates of air toxics emissions present before the Clean Air Act (CAA) was amended in 1990. The Cumulative Exposure Project estimated outdoor air toxics concentrations in each contiguous-U.S. census tract.

For the first NATA, EPA enhanced the Cumulative Exposure Project framework to include estimates of population exposure and health risk. The first NATA used a more refined inventory of air toxics emissions developed for 1996, known at that time as the National Toxics Inventory. EPA submitted this assessment for a technical peer review in January 2001 to a panel of EPA's Science Advisory Board (EPA 2001b). The panel provided detailed comments later that year on the validity of the overall approach, the elements of the assessment (including the data, models and methods used) and the manner in which these components were integrated into a national-scale assessment (EPA 2001a).

EPA incorporated many of the Science Advisory Board's suggestions into NATA and published the results of that assessment in 2002. Since then, four assessments have been completed – representative of air toxic emissions in 1999, 2002, 2005 and 2011, respectively – based on significant triennial updates of the national emission inventories. In general, the scope of NATA has progressively expanded with subsequent versions, and some methods have been refined and improved. Table 1-1 summarizes the six NATAs EPA has conducted to date.

Table 1-1. Summary of the six completed NATAs

Inventory Year	Year Completed/ Published	Air Toxics Modeled [a,b]	Key Attributes
1996	2002	33 – Includes 32 HAPs, focusing on those of concern in urban areas, plus diesel PM	ASPEN used to model ambient concentrations HAPEM4 used to model inhalation exposures
1999	2006	177 – Includes 176 HAPs, including all those with chronic-health toxicity values at the time, plus diesel PM	ASPEN used to model ambient concentrations HAPEM5 used to model inhalation exposures Doubled the number of emission sources covered compared to 1996 NATA
2002	2009	181 – Includes 180 HAPs, including four4 with additional health information, plus diesel PM	ASPEN and HEM (with ISCST3) used to model ambient concentrations HAPEM5 used to model inhalation exposures

Inventory Year	Year Completed/ Published	Air Toxics Modeled [a,b]	Key Attributes
2005	2010	179 – Includes178 HAPs for which emissions data and chronic-health toxicity values were available, plus diesel PM	Emissions inventory updated to include recent information on industrial sources, residual-risk assessments, lead emissions from airports and other sources ASPEN and HEM-3 (with AERMOD, a more refined dispersion model) used to model ambient concentrations; HEM used for more source types than in 2002 Exposure factors derived from 2002 NATA used to estimate inhalation exposures CMAQ model (EPA 2015f) used to estimate secondary formation of acetaldehyde, acrolein and formaldehyde and decay of 1,3-butadiene to acrolein
2011	2015	180 – Includes 179 HAPs for which emissions data and chronic-health toxicity values were available, plus diesel PM	CMAQ and HEM-3 more fully integrated as a hybrid modeling system for about 40 HAPS and diesel PM to improve mass conservation. HEM-3 used with background for remaining HAPs not covered by the hybrid approach (also for areas outside the contiguous U.S. CMAQ modeling domain) HAPEM7 modeled inhalation exposures for a subset of air toxics and used to provide exposure factors for the remaining air toxics
2014	2018	181 – Includes 180 HAPs for which emissions data and chronic-health toxicity values were available, plus diesel PM	AERMOD used as main dispersion model. CMAQ and AERMOD fully integrated as a hybrid modeling system for 51 HAPS and diesel PM. AERMOD used with background for remaining HAPs not covered by the hybrid approach (also for areas outside the contiguous U.S. CMAQ modeling domain) HAPEM7 modeled inhalation exposures for a subset of air toxics and used to provide exposure factors for the remaining air toxics

[a] Note that "air toxics" and "HAPs" are sometimes used interchangeably. In this document, however, "air toxics" refers to HAPs plus diesel PM. HAPs are those air toxics which we are required to control under Section 112 of the 1990 CAA Amendments (EPA 2015h). Diesel PM is not a HAP but is likely carcinogenic to humans, although we have not yet developed a unit risk estimate for it. Given these concerns, the adverse noncancer effects of diesel PM are estimated in NATA (using an Integrated Risk Information System reference concentration) but its cancer risks are not estimated.

[b] The number of air toxics included in a NATA emission inventory can be slightly larger than the number of air toxics actually modeled. Some air toxics are not modeled because of uncertainty in the emissions numbers or in the ability to model air concentrations or health risk accurately. For example, asbestos is included in the inventory but not modeled and not included in the counts presented in this table.

Notes: HAPs = hazardous air pollutants; diesel PM = diesel particulate matter; ASPEN = Assessment System for Population Exposure Nationwide; HAPEM4, HAPEM5, HAPEM7 = Hazardous Air Pollutant Exposure Model, version 4, 5 and 7; HEM = Human Exposure Model; CMAQ = Community Multiscale Air Quality model. ISC and AERMOD are Gaussian dispersion models.

1.5. How EPA and State, Local and Tribal Air Agencies Use NATA Results

We designed NATA to help guide efforts to reduce toxic air pollution and to provide information that can be used to further the already significant emissions reductions achieved in the United States since 1990. EPA and S/L/T air agencies use NATA to identify those air toxics and source sectors (e.g., point or mobile sources) having the highest exposures and health risks. The assessment results also help us

identify geographic patterns and ranges of risks across the country and across individual states and county areas within states.

Specifically, we use NATA results to:

- identify pollutants and industrial source categories of greatest concern;
- improve understanding of health risks posed by air toxics;
- help set priorities for the collection of additional information;
- set priorities for improving emission inventories;
- expand and prioritize EPA's network of air-toxics monitors;
- support communities in designing their own local assessments;
- enhance targeted risk-reduction activities; and
- provide a multiple-pollutant modeling framework linking air toxics to the Criteria Pollutant Program (EPA 2015c).

Similarly, S/L/T air agencies use NATA to:

- prioritize pollutants and emission source types;
- identify places of interest for further study;
- get a starting point for local assessments;
- focus community efforts; and
- inform monitoring programs.

1.6. How NATA Results Should *Not* Be Used

As described above, NATA is a screening-level assessment, designed to answer specific types of questions. The underlying assumptions of NATA and its methods limit the range of questions that can be answered reliably.

NATA results should *not* be used:

- as a definitive means to pinpoint specific risk values within a census tract;
- to characterize or compare risks at local levels (such as between neighborhoods);
- to characterize or compare risks between states;
- to examine trends between or otherwise compare NATAs;

- as the sole basis for developing risk reduction plans or regulations;
- as the sole basis for determining appropriate controls on specific sources or air toxics; or
- as the sole basis to quantify benefits of reduced air toxic emissions.

The limitations of the assessment methods prevent NATA from serving as a stand-alone tool. Furthermore, although EPA reports results at the census tract level in NATA, average risk estimates are far more uncertain at this level of spatial resolution than at the county or state level. To analyze air toxics in smaller areas, such as census blocks or in a suspected "hotspot," other tools such as site-specific monitoring and local-scale assessments coupled with refined and localized data should be used.

These caveats are integral to the proper interpretation of NATA results. You should use NATA results only to address those questions for which the assessment methods are suited.

Moreover, as noted above, NATA results from different assessment years generally should not be compared to each other. From one assessment to the next, EPA has improved its methodology and incorporated additional data. These improvements make comparing assessments inappropriate. Differences in emissions, ambient or exposure concentrations, or risks between two assessments may be due to improvement in the assessment methodology or to actual changes in emissions, populations or other "real-life" characteristics – or to some combination of all these.

EPA does not use NATA as the sole source of information leading to regulations or guiding the enforcement of existing rules. Some of the methods used to conduct NATA are like those used in air-related risk assessments conducted under the CAA mandate (such as residual risk assessments of HAP emissions from point sources, or assessments of exposures to criteria air pollutants (CAPs) for evaluations of National Ambient Air Quality Standards), NATA fundamentally differs from such assessments in that it is not a regulatory program.

1.7. The Risk Assessment Framework NATA Uses

In NATA we use methods consistent with the general risk assessment framework used throughout EPA. This section overviews EPA's risk assessment framework and summarizes the NATA process. Later sections detail the analytical components of this process.

EPA has published a series of guidelines (EPA 2015d) that establishes and explains the methods recommended for assessing human-health risks from environmental pollution. This series makes recommendations for carcinogen risk assessment, exposure assessment, chemical mixtures risk assessment and other major EPA-wide risk assessments. EPA has also developed the three-volume Air Toxics Risk Assessment (ATRA) Reference Library (EPA 2004a,b; EPA 2006a) as a reference for those conducting air toxics risk assessments. This library details the fundamental principles of risk-based assessment for air toxics, how to apply those principles in various settings, and strategies for reducing risk at the local level. EPA's guidelines and methods are consistent with the National Research Council's recommendations on conducting risk assessments (NRC 1983, 1994).

As described in more detail in these guidelines and documents, EPA's risk assessment process has three phases (Figure 1-3), the second of which has two parts.

- The first phase (problem formulation) comprises the initial planning and scoping activities and definition of the problem, which results in the development of a conceptual model.
- The second phase (analysis) includes two components:
  - Exposure assessment; and
  - Toxicity assessment.
- The third phase is risk characterization, a synthesis of the outputs of the exposure and toxicity assessments to characterize health risks for the scenario described in the initial phase.

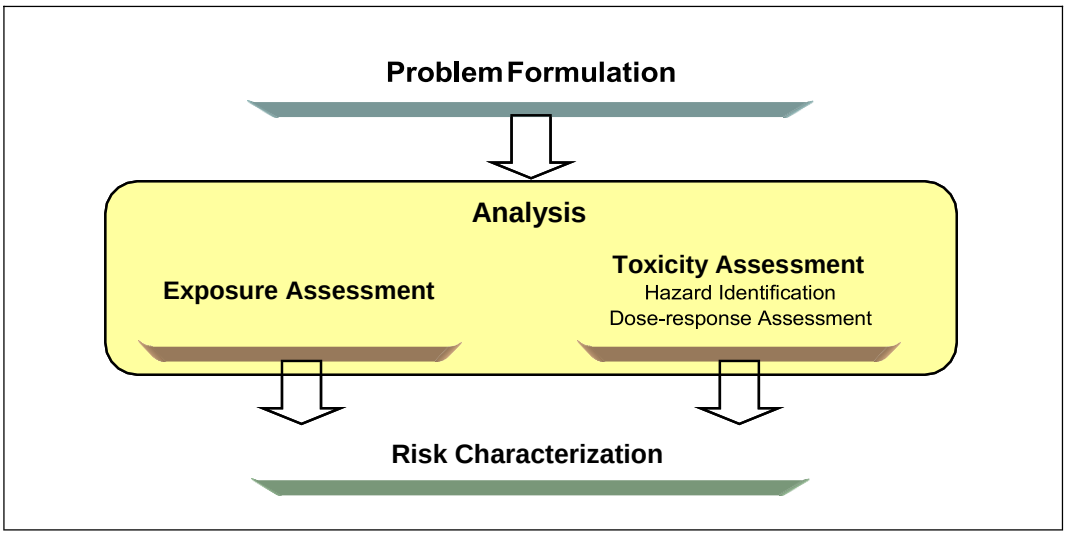

Figure 1-3. The general air toxics risk assessment process

Source: Adapted from EPA (2004a).

An air toxics risk assessment starts with problem formulation. This first step begins with the systematic planning and scoping needed before any analyses are begun. This planning process helps ensure that the objectives of the assessment are met, resources are used efficiently and the overall effort is successful.

One important product of the problem formulation step is a conceptual model that describes how releases of air toxics might pose risks to people. The conceptual model serves as a guide or "road map" to the assessment. It defines the physical boundaries, potential sources, emitted air toxics, potentially exposed populations, chemical fate and transport processes, expected routes of exposure and potential health effects. The planning and scoping activities and problem formulation we conduct before carrying out the analyses, are critical – they set the course for the assessment and inform EPA's decisions regarding specific methods, models and data sources to use. The following section (1.8) describes the conceptual model developed for NATA – the product of the first phase.

Meanwhile, the rest of this document is concerned primarily with describing the analysis phase of the general air toxics risk assessment process (and specifically with describing the analyses conducted for NATA). The analysis phase is the stage at which we use the risk assessment processes to evaluate the problem at hand. Section 1.9 outlines the analytical steps, with detailed descriptions of each step presented in later sections of this document.

1.8. The Scope of NATA

The national-scale assessment described in this document is consistent with EPA's definition of a cumulative risk assessment, as stated in EPA's Framework for Cumulative Risk Assessment (EPA 2003, p. 6), as "an analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors." The Framework emphasizes that a conceptual model is an important output of the problem formulation phase of a cumulative risk assessment. The conceptual model defines the actual or predicted relationships among exposed individuals, populations or ecosystems and the chemicals or stressors to which they might be exposed. Specifically, the conceptual model lays out the sources, stressors, environmental media, routes of exposure, receptors and endpoints (i.e., measures of effects) relevant to the problem or situation that is being evaluated. This model takes the form of a written description and a visual representation of the relationships among these components.

The conceptual model can sometimes include components that are not addressed specifically or quantitatively by an assessment, but that are nevertheless important to consider.

Section 2.4 of the report for the 1996 NATA presented to EPA's Science Advisory Board for review (EPA 2001b) included a conceptual model. Some of the specifics included in that conceptual model have since evolved as newer assessments have been completed (for example, the number of air toxics evaluated has increased substantially since the 1996 NATA). The fundamental components included in NATA and the relationships among them, however, have been generally consistent for all six NATAs completed to date. Moreover, the conceptual model described in this document is very similar to the one presented in the documentation for the 1996 NATA.

NATA is national in scope, covering the United States, Puerto Rico and the U.S. Virgin Islands. It focuses on long-term inhalation exposures to air toxics. In general, NATA is intended to provide EPA with the best possible national-scale population-level estimates of exposure to and risks associated with air toxics, considering data availability, technical capabilities and other potentially limiting factors. The conceptual model for the 2014 NATA is presented in Figure 1-4. Each component included in the model is described briefly in the sections that follow.

1.8.1. Sources of Air Toxic Emissions That NATA Addresses

Sources of primary air toxic emissions included in NATA (i.e., the NATA categories) are point, nonpoint, mobile, biogenics and fires in the contiguous United States. Point, nonpoint and mobile sources are included from Alaska, Hawaii, Puerto Rico and the U.S. Virgin Island (with impacts from biogenics and fires estimated). Examples of point sources are large waste incinerators and factories. Nonpoint sources include residential wood combustion (RWC), commercial cooking, and consumer and commercial solvents. Mobile sources include vehicles found on roads and highways, such as cars and trucks, and nonroad equipment, including lawn mowers and construction equipment. Nonroad sources also include marine vessels, trains and aircraft.

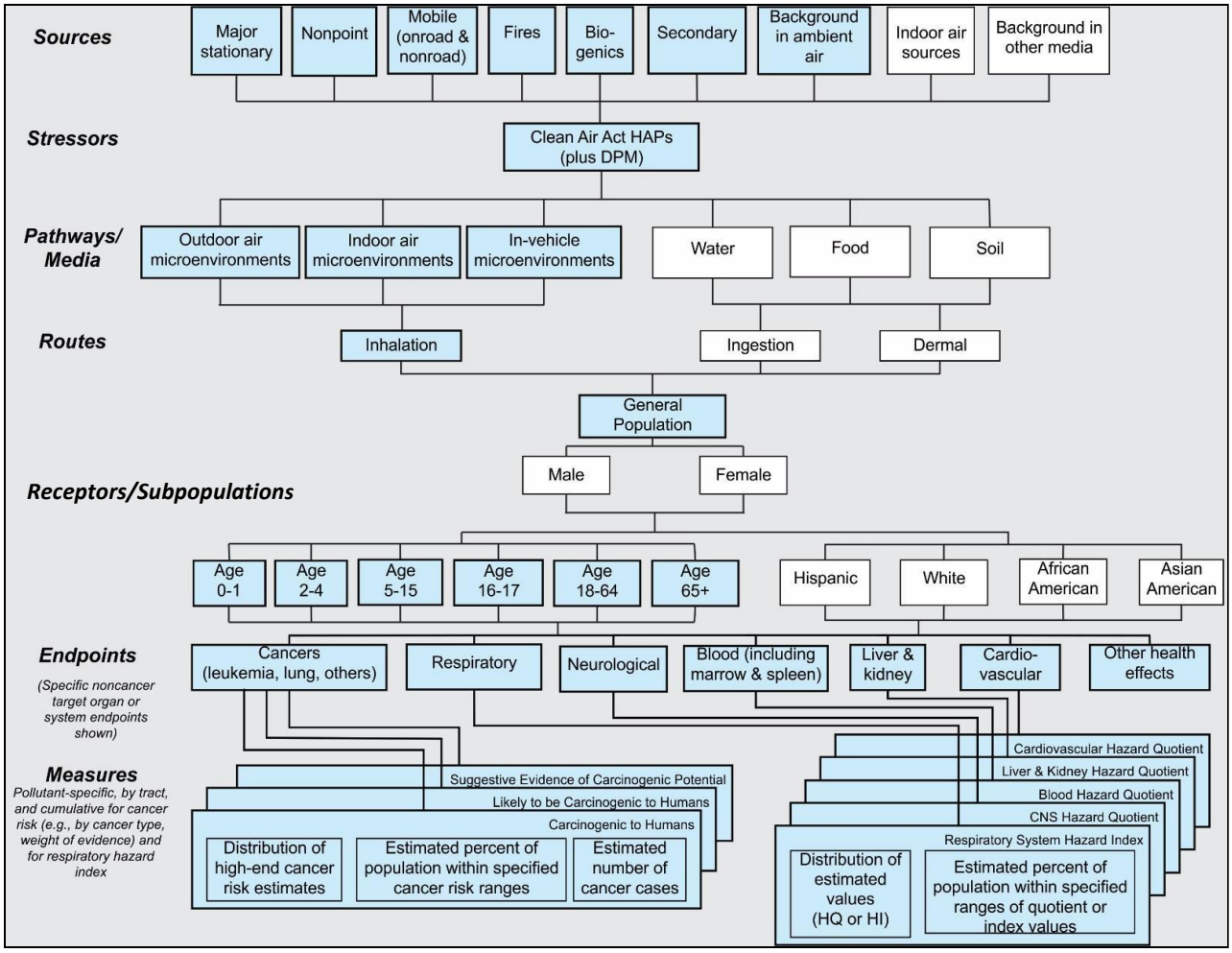

Figure 1-4. Conceptual model for NATA

Blue boxes indicate elements included in the 2014 NATA; clear boxes indicate elements that could be included in future assessments. In the "Sources" included here, "Major stationary" includes both major and area sources as defined for regulatory purposes in the CAA. "Nonpoint" refers to smaller (and sometimes less discrete) sources that are typically estimated on a top-down basis (e.g., by county). Additional explanation of source types included in NATA is presented in Section 2. DPM refers to diesel particulate matter. HQ and HI refer to hazard quotient and hazard index, respectively.

NATA only considers outdoor sources of air toxics. It does not address indoor sources of toxics, for example, those emitted from household chemicals. In addition, NATA background estimates do not consider background air toxics from other media, such as water.

NATA presents results by both these broad source categories and by more detailed NATA source groups. Details on this and other aspects of emission sources are presented in Section 2; details on air quality modeling and characterization are presented in Section 3.

1.8.2. Stressors that NATA Evaluates

The stressors evaluated through NATA can include any of the 187 HAPs defined in the 1990 CAA (190 HAPs were included originally but 3 have since been removed from the list). The set of air toxics included in NATA is determined by the emission and toxicity data available at the time of the

assessment. Diesel PM, an indicator of diesel exhaust, is included in the set of stressors for NATA. The spreadsheet file "NATA_Pollutants.xlsx" within the Supplemental Data folder accompanying this TSD lists the pollutants that the 2014 NATA assesses and provides more detailed information on the NEI and NATA pollutants. In Appendix B of this document, Table B-I lists the CAA pollutants that are not included in the 2014 NATA and the reason for their omission.

1.8.3. Exposure Pathways, Routes and Time Frames for NATA

Exposure to air toxics from all sources is determined by multiple interactions among complex factors, including the locations and nature of the emissions, the emission-release conditions, local meteorology, locations of receptor populations, and the specific behaviors and physiology of individuals in those populations. The combination of air toxics that people inhale, and the chemical interactions among those air toxics, influence the risks associated with these exposures. This high level of complexity makes aggregating risk across both substances and sources useful for depicting the magnitude of risks associated with inhalation of air toxics.

The air quality modeling step of NATA includes evaluating the transport of emitted particles and gases through the air to receptors. NATA modeling accounts for transformation of substances in the atmosphere (also referred to as secondary formation) and losses of substances from the air by deposition, where data are available and the modeling approach supports it. For air toxics with sufficient ambient monitoring data, or with emissions data primarily due to point sources, we estimate background concentrations. With fate and transport of emissions considered, and the presence of some background concentrations, NATA estimates outdoor ambient concentrations across the nation.

NATA focuses on exposures due to inhalation of ambient air. Human receptors are modeled to account for an individual's movement among microenvironments, such as residences, offices, schools, exterior work sites and automobiles, where concentration levels can be quite different from general outdoor concentrations. The exposure assessment estimates air concentrations for each substance within each modeled microenvironment. The exposure assessment also accounts for human activities that can affect the magnitude of exposure (e.g., exercising, sleeping). This component of NATA accounts for the difference between ambient outdoor concentrations and the exposure concentrations (ECs; i.e., long-term-average concentrations to which people are exposed after accounting for human activities).

To date, NATA has not estimated air toxic concentrations in water, soil or food associated with deposition from air, or the bioaccumulation of air toxics in tissues. Similarly, NATA has not estimated human exposures to chemicals via ingestion or dermal contact. EPA considers these pathways important, but refined tools and data required to model multipathway concentrations and human exposures on the national scale are not yet readily available for use for many air toxics.

NATA estimates average annual outdoor concentrations, which are used to develop long-term inhalation exposures for each of the air toxics. For cancer and chronic (long-term) health effects, the exposure is assumed to be continuous over a lifetime (i.e., 70 years for the purposes of this analysis). Subchronic and acute (lasting less than 24 hours) exposures are not estimated in NATA because the emissions database contains only annual-total emissions. If the emission inventories are later expanded to cover short-term (e.g., hourly, daily) emission rates, we would consider incorporating shorter exposure times into NATA.

1.8.4. Receptors that NATA Characterizes

NATA characterizes average risks to people belonging to distinct human subpopulations. The overall population is divided into cohorts based on residential location, life stage (age) and daily activity pattern. A cohort is generally defined as a group of people within a population assumed to have identical exposures during a specified exposure period. Residential locations are specified according to U.S. Census tracts, which are geographic subdivisions of counties that vary in size but typically contain about 4,000 residents each. Life stages are stratified into six age groups: 0–1, 2–4, 5–15, 16–17, 18–64, and 65 and older. Daily-activity patterns specify time spent in various microenvironments (e.g., indoors at home, in vehicles, outdoors) at various times of day. For each combination of residential census tract and age, 30 sets of age-appropriate daily activity patterns are selected to represent the range of exposure conditions for residents of the tract. A population-weighted typical exposure estimate is calculated for each cohort, and this value is used to estimate representative risks, as well as the range of risks, for a "typical" individual residing in that tract. Risk results for individual cohorts are not included in NATA results.

To date, NATA evaluations have not included non-human receptors (e.g., wildlife and native plants). The complexity of the varied ecosystems across the vast area NATA covers precludes considering potential adverse ecological impacts at this time. Local- and urban-scale assessments can be developed to include non-human receptors, contingent on the availability of necessary resources, data and methodologies. We currently, however, have no plans to include non-human receptors in NATA.

1.8.5. Endpoints and Measures: Results of NATA

NATA reports estimated cancer risks and noncancer hazards attributed to modeled sources. Key measures of cancer risk developed for the 2014 NATA include:

- upper-bound estimated lifetime individual cancer risk; and
- estimated numbers of people within specified risk ranges (e.g., number of individuals with estimated long-term cancer risk of 1-in-1 million or greater or less than 100-in-1 million).

For noncancer effects, the key measures presented in the 2014 NATA are hazard indexes summed across all air toxics modeled for the respiratory system. Other target organs and systems are also shown.

NATA characterizes cancer risk and potential noncancer effects based on estimates of inhalation exposure concentrations determined at the census tract level. This approach is used only to determine geographic patterns of risks within counties, and not to pinpoint specific risk values for each census tract. We are reasonably confident that the patterns (i.e., relatively higher levels of risk within a county) represent actual differences in overall average population risks within the county. We are less confident that the assessment pinpoints the exact locations where higher risks exist, or that the assessment captures the highest risks in a county. EPA provides the risk information at the census tract level rather than just the county level, however, because the county results are less informative (in that they show a single risk number to represent each county). Information on variability of risk within each county would be lost if tract-level estimates were not provided. This approach is consistent with the purpose of NATA, which is to provide a means to inform both national and more localized efforts to collect air toxics information and to characterize emissions (e.g., to help prioritize air toxics and areas of interest for more refined data collection such as emissions testing or monitoring). Nevertheless, the assumptions

made in allocating mobile and nonpoint source emissions within counties can result in significant uncertainty in estimating risk levels, even though general spatial patterns are reasonably accurate.

1.9. Model Design

Consistent with the general approach for air toxics risk assessment described in Section 1.7 and illustrated in Figure 1-3, the analysis phase of NATA includes two main components: estimating exposure and estimating toxicity. The outputs of these analyses are used in the third phase, risk characterization, which produces health-risk estimates that can be used to inform research or risk management. These two phases (analysis and risk characterization) represent the "core" of EPA's assessment activities associated with NATA. This set of activities is referred to here as the "NATA risk assessment process."

The NATA risk assessment process can be characterized by four main steps:

1. compiling the nationwide inventory of emissions from outdoor sources;
2. estimating nationwide ambient outdoor concentrations of the emitted air toxics;
3. estimating population exposures to these air toxics via inhalation; and
4. characterizing potential health risks associated with these inhalation exposures.

The fourth step (risk characterization) also requires that quantitative dose-response or other toxicity values be identified for each air toxic included in the assessment. These values are taken from those developed by other EPA and non-EPA programs. Although this step does not require a "new" quantitative dose-response assessment to be conducted as part of NATA, it does require that we make important scientific and policy decisions regarding the appropriate values to use in NATA. Because these decisions are critical to the risk results, the identification of appropriate dose-response values is also described in this TSD in Section 5. The NATA risk assessment process is illustrated in Figure 1-5. The development of the emission inventory, air quality modeling, inhalation exposure modeling and risk characterization must be conducted sequentially – completing each step requires outputs from the previous step, and toxicity values are required to carry out the risk-characterization calculations. Cancer risks and the potential for noncancer health effects are estimated using available information on health effects of air toxics, risk-assessment and risk-characterization guidelines, and estimated population exposures.

Each of these five components is described briefly here and explained in detail in the remainder of this document:

- Section 2 explains the source types and air toxics included in the NATA emissions inventory. It also describes the processes we carried out to prepare the emissions for the air quality models.
- Section 3 discusses the models and procedures used to estimate ambient concentrations of air toxics, with links and references to technical manuals and other detailed documentation for the models used for NATA.

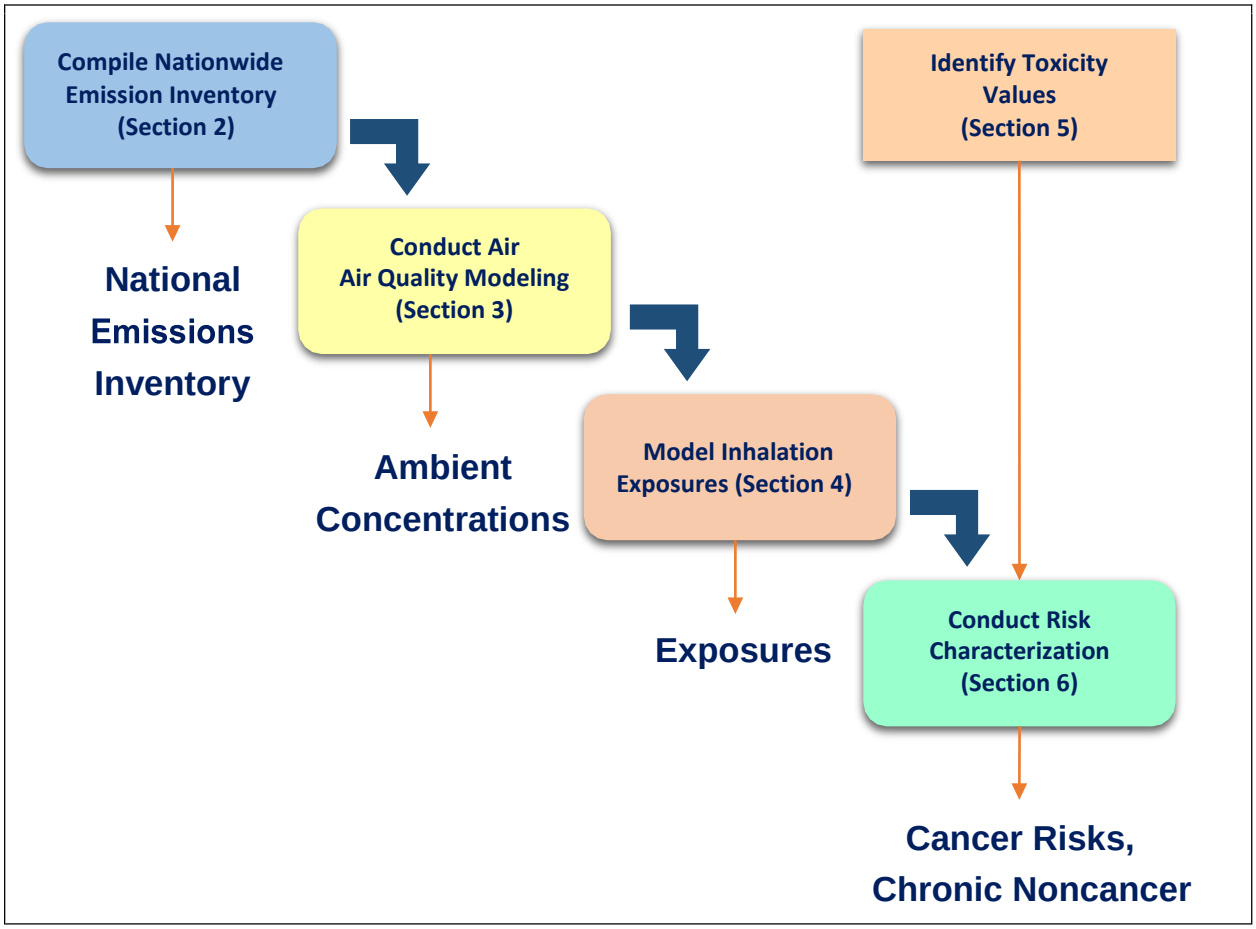

Figure 1-5. The NATA risk assessment process and corresponding sections of this TSD

- Section 4 explains the processes used to estimate population-level exposure to outdoor ambient levels of air toxics, accounting for information on activities and other characteristics that can affect inhalation exposures.
- Section 5 discusses the dose-response values used for NATA, the sources from which these values are obtained and assumptions made specific to NATA.
- Section 6 provides the calculations used to estimate cancer risk and potential noncancer hazard.
- Section 7 describes the uncertainties and limitations associated with the NATA process that must be considered when interpreting NATA results.

As noted at the beginning of this section, this document is intended to serve as a resource accompanying the most recent national-scale assessment – the 2014 NATA. Accordingly, although the following sections contain information on the NATA process that are generally applicable to all previous NATAs, references to specific technical processes and supporting details typically emphasize what we did for the 2014 NATA.

1.9.1. The Strengths and Limitations of the Model Design

EPA developed NATA to inform both national and localized efforts to characterize air toxics emissions and health risks (e.g., prioritize air toxics or areas of interest for monitoring and community assessments). Because of this targeted objective, tools other than NATA may be more appropriate for assessing health risks outside the specific purpose of NATA (e.g., for evaluating risks from either a broader or more specific perspective).

To further define and clarify what NATA should not be used for, this section contains descriptions of some of the important data and results that are not included in NATA:

- NATA does not include information that applies to specific locations. The assessment focuses on variations in air concentration, exposure and risk among geographic areas such as census tracts, counties and states. All questions asked, therefore, must focus on the variations among these geographic areas (census tracts, counties, etc.). Moreover, as previously mentioned, results are far more uncertain at the census tract level than for larger geographic areas such as states or regions. (Section 7 contains discussions on the higher uncertainty at small geographic scales such as census tracts.)

- NATA does not include data appropriate for addressing epidemiological questions such as the relationship between cancer risks or noncancer health effects and proximity of residences to point sources, roadways and other sources of air toxics emissions.

- The results do not include impacts from sources in Canada or Mexico other than as general background sources. Thus, the results for states bordering these countries do not comprehensively reflect sources of transported emissions that could be significant.

- NATA does not include results for individuals. Within a census tract, all individuals are assigned the same ambient air concentration, chosen to represent a typical ambient air concentration. Similarly, the exposure assessment uses activity patterns that do not fully reflect the actual variations among individuals.

- The results do not include exposures and risk from all compounds. For example, of the 181 air toxics included in the 2014 NATA, only 138 air toxics have been assigned dose-response values. In EPA's judgment, the remaining air toxics do not have adequate data to quantitatively assess their impacts on health. Therefore, they do not contribute to the aggregate cancer risk or target-organ-specific hazard indexes estimated in NATA. Of note, the assessment does not quantify cancer risk from diesel PM, although EPA has concluded that the general population is exposed to levels close to or overlapping with levels that have been linked to increased cancer risk in epidemiology studies. NATA, however, does quantify noncancer effects of diesel PM.

- Other than lead, which is both a CAP and a HAP, the results do not include the air pollutants, known as CAPs (particulate matter, ground-level ozone, carbon monoxide, sulfur oxides, nitrogen oxides), for which the CAA requires EPA to set National Ambient Air Quality Standards (other than CAP impacts on secondary formation of formaldehyde, acetaldehyde and acrolein).

- The results do not reflect all pathways of potential exposure. The assessment includes risks only from direct inhalation of the emitted air toxics compounds. It does not consider air toxics

compounds that may deposit onto soil, water and food and subsequently enter the body through ingestion or skin contact.

- The assessment results reflect exposure at outdoor, indoor and in-vehicle locations, but only to compounds released into the outdoor air. The assessment does not include exposure to air toxics emitted indoors, such as those from stoves, those that out-gas from building materials or those from evaporative benzene emissions from cars in attached garages. The assessment also does not consider toxics released directly to water and soil.
- The assessment does not fully reflect variation in background ambient air concentrations. Background ambient air concentrations are average values over broad geographic regions.
- The assessment may not capture all sources that have episodic emissions (e.g., facilities with short-term deviations in emissions resulting from startups, shutdowns, malfunctions and upsets). Where available, episodic emission information is used (e.g., for electricity generating units). In the absence of additional data, we assume emission rates are uniform throughout the year.
- Short-term (acute) exposures and risks are not included in NATA.
- Atmospheric transformation and losses from the air by deposition are not accounted for in NATA air toxics that are not modeled in CMAQ.
- The evaluations to date have not assessed ecological effects, given the complexity of the varied ecosystems across the vast area covered by NATA.

2. Emissions

The systematic compilation of a detailed, nationwide inventory of air toxics emissions is the first major step in the NATA risk assessment process. This section contains descriptions of the emissions used for the 2014 NATA. Section 2.1 describes the emissions data sources and preparation of the emissions used in NATA. Section 2.2 discusses the processing of emissions for input into the CMAQ model, and Section 2.3 discusses the processing for input into the AERMOD model.

2.1. Sources of Emissions

NATA is intended to address outdoor emissions of all hazardous air pollutants (HAPs) and diesel particulate matter (PM), together called "air toxics" in this document. To model air toxics, emissions of both air toxics and criteria air pollutants (CAPs, including CAP precursors such as ammonia and volatile organic compounds) are used to address the chemical interactions that occur across all pollutants.

> Sometimes "air toxics" and "HAPs" are used interchangeably. In this document, however, "air toxics" refers to the HAPs that EPA is required to control under Section 112 of the 1990 Clean Air Act (EPA 2015h) plus diesel PM. The 1990 Clean Air Act Amendments required EPA to control 189 HAPs (EPA 2018) and provided for revisions to be made to that list. Currently, the list includes 187 HAPs. Diesel PM is not a HAP; however, it has been included in this and previous NATAs. Some evidence indicates that localized high lifetime cancer risks are associated with exposure to diesel PM. However, EPA currently does not have sufficient evidence to develop a unit risk estimate for it. Therefore, the potential adverse noncancer effects associated with diesel PM are estimated in NATA (using an Integrated Risk Information System reference concentration), but its cancer risks are not.

The 2014 NATA combines modeling from CMAQ and AERMOD for the contiguous United States. CMAQ multipollutant modeling addresses all sources in the 2014 National Emissions Inventory (NEI) for CAPs and about 50 HAPs. Emissions from outside the United States are represented by CMAQ boundary conditions as discussed in Section 3.3.2. For the remaining "non-CMAQ" HAPs and non-CMAQ parts of the modeling domain (i.e., Alaska, Hawaii, Puerto Rico and the U.S. Virgin Islands), only AERMOD is used. For these pollutants and geographic regions, spatially uniform background concentrations based on remote concentrations are added to the AERMOD-modeled data to represent influences from transport and emissions outside the modeling domain (Section 3.6.1). Like previous NATAs, AERMOD modeling addresses all pollutants covered by NATA – and all anthropogenic sources except prescribed and agricultural burning.

The main source of the emissions data for the CAPs and HAPs modeled for NATA is the 2014 NEI version 2. The NEI is a comprehensive and detailed estimate of air emissions of CAPs and HAPs from all air emissions sources in the United States, including the territories of Puerto Rico and the U.S. Virgin Islands, and offshore sources and commercial marine vessels (CMVs) in federal waters. A complete NEI, consisting of point stationary sources, nonpoint sources, mobile sources and fires, is prepared every 3 years by EPA. It is based primarily upon emission estimates and emission model inputs provided by S/L/T air agencies for sources in their jurisdictions, supplemented by data developed by EPA. These data are submitted electronically to the Emissions Inventory System (EIS). CAPs are required under EPA's Air Emissions Reporting Requirements (AERR). HAPs are submitted voluntarily. Lead is both a HAP and a CAP, so it must be submitted under the AERR. For the 2014 NEI, states are required to report facilities with lead emissions greater than or equal to 0.5 tons per year (TPY). In addition to CAPs and HAPs, the 2014 NEI includes speciated particulate matter (PM) and diesel PM. In previous NATAs, diesel PM was

generated in an emissions modeling step after the NEI was produced. But in the 2014 NEI, diesel PM is available along with NEI CAPs and HAPs. As in previous NATAs, the NEI diesel PM is computed as the PM10 emissions for on-road and nonroad engines burning diesel or residual oil fuels. Although stationary engines also can burn diesel fuel, only mobile source sectors are used for estimating diesel PM emissions.

To build as complete an NEI as possible, EPA augments the S/L/T-submitted data using various sources of information, including the Toxics Release Inventory (TRI), and applies HAP-to-CAP emission-factor ratios to CAP emissions reported by S/L/T.

Table 2-1 contains a summary of the sources of emissions data in the NEI. More detailed information on all data sources can be found in the 2014 NEI documentation.

Table 2-1. Summary of emissions sources in the 2014 NEI v2

Source	Description
Stationary point	Most stationary point-source HAP data were submitted voluntarily by S/L/T. For some point sources, EPA gap-filled HAPs. Sources of data included: TRI data for 2014, augmentation of HAPs using emission-factor ratios (of HAP to CAP) applied to S/L/T-reported CAP emissions and rule-based emission factors (e.g., emissions factors using the 2010 test program conducted in support of Mercury and Air Toxics rule), and methane emissions reported by landfill operators in compliance with Subpart HH of the Greenhouse Gas Reporting Program (GHGRP) as a "surrogate" activity indicator. In some cases, 2011 data were pulled forward for some facilities.
Point airports	EPA estimates used the Federal Aviation Administration (FAA) Emission Dispersion Modeling System using landing and takeoff (LTO) information from FAA databases and updated where S/L/T-provided LTO. For smaller airports (general aviation) without detailed aircraft-specific activity data, straight emission factors were used. Lead emissions were estimated based on per-LTO emissions factors, assumptions about lead content in the fuel and lead-retention rates in the piston engines and oil. For some airports, estimates were provided by S/L/T. NEI has over 19,000 airports (including heliports and seaplanes); all are inventoried as point sources. In addition to LTOs, EPA's emissions estimates for airports included emissions of ground support equipment.
Point rail yards	The 2014v2 NEI includes non-zero emissions estimates for nearly 1000 rail yards. EPA emission estimates are associated with the operation of switcher engines at each Class I rail yard. EPA estimates were developed by the Eastern Regional Technical Advisory Committee's (ERTAC) rail group using a "top-down" approach that apportions 2014 national fuel use data to rail yards and used national fleet-wide information to create weighted average emission factors. For some rail yards, emission estimates were provided by S/L/T. HAP emissions were estimated by applying fractions to the VOC or PM estimates. There are also railyard emissions in the nonpoint inventory (see locomotives).
Stationary nonpoint	Includes many different source stationary source categories that are generally too ubiquitous to be inventoried as point sources and are therefore estimated at the county level. Examples of these sources include residential heating, consumer and commercial product usage, commercial cooking, oil and gas production, and industrial, commercial and institutional fuel combustion (where not in the point inventory). Emission estimates for these are developed by EPA and/or submitted by S/L/T. Where S/L/T submitted CAPs but not HAPs, missing HAP emissions were augmented.

Source	Description
Biogenics	Based on Biogenic Emission Inventory System (BEIS3.61) using 2014 meteorology from the Weather Research Forecasting Model (WRF). Gridded emissions were used in NATA and summed to annual county-level estimates for the NEI. Includes VOC, NO_X and three HAPs: formaldehyde, acetaldehyde and methanol.
Locomotives	Emissions at county-level resolution for Class I line haul, Class II/III line haul, passenger, commuter and rail yards. ERTAC's rail group developed EPA estimates for Class I line haul and Class II/III line haul. S/L/T also submitted data for locomotives. All passenger, commuter and county-level rail yards estimates were from S/L/T. EPA rail yard emissions were included as point-source rail yards as described above. HAPs were estimated by applying toxic fractions to the VOC or PM estimates.
CMVs	Emissions from category 1 and category 2 (C1/C2) and category 3 (C3) marine vessels at ports or underway. C1/C2 includes fishing boats, ferries and tugboats and is assumed to use diesel fuel; C3 includes oceangoing vessels and large ships and are assumed to use residual fuel. Emission estimates were developed using 1) activity data (kilowatt hours or kW), 2) engine operating load factors and 3) emission factors and HAP speciation profiles. This "bottom up" approach was used for the first time for the 2014 NEI. For some areas, estimates were provided by S/L/T. For 2014v2, the Lake Michigan Air Directors Consortium (LADCO) submitted emissions estimate for several states. HAPs were added based on the toxic fractions used in the EPA estimates.
On-road	Except for California, on-road emissions were generated using the SMOKE-MOVES emissions modeling framework, which leverages emission factors generated by the latest released version of the Motor Vehicle Emissions Simulator (MOVES) (MOVES2014a, code version: 20151201, database version: movesdb20151028); county and SCC-specific activity data and hourly meteorological data. These models used state- or EPA-provided input details specific to each county. California's emissions were developed via their EMFAC on-road model, but VOC HAPs were speciated from California-reported VOCs consistent with the MOVES2014a speciation. EPA added DIESEL-PM10 and DIESEL-PM25 for all diesel fuel SCCs, and they were set equal to the PM_{10} and $PM_{2.5}$ emissions from these diesel SCCs.
Nonroad, excluding airports, locomotives and CMVs	Except for California, EPA estimated these emissions using the MOVES2014a model, which incorporates the NONROAD2008 model for criteria pollutants. Several S/L provided inputs to the model. MOVES2014a also replaces toxic emission estimates for nonroad previously generated using the National Mobile Inventory Model (NMIM), which was used for 2011 and earlier NEIs. MOVES2014a incorporates updated nonroad emission factors for HAPs. MOVES2014a was used for all states other than California, which uses their own model. EPA added DIESEL-PM10 and DIESEL-PM25 for all diesel fuel SCCs, and they were set equal to the PM_{10} and $PM_{2.5}$ emissions from these diesel SCCs.
Fires	For purposes of NATA, fires include agricultural burning, prescribed burning and wildfires. EPA estimated agricultural burning (included in stationary nonpoint) using remote-sensing data, crop-usage maps and emission factors as daily point estimates. Many states submitted their own data as county estimates; these were used ahead of EPA estimates. EPA estimates were modeled as daily point estimates, and the state-submitted data were converted to point estimates for modeling. EPA developed day- and location-specific prescribed burning and wildfire emissions via the SMARTFIRE2 system (which includes the BlueSky modeling framework) with inputs from state agencies where available. Georgia and Washington state submitted emission estimates (day and location specific).

2.1.1. Pollutants and Pollutant Groups

NATA air quality modeling requires emissions of criteria air pollutants (CAPs) and their precursors in addition to HAP and diesel PM. We also need to aggregate the emissions of certain NEI pollutants to match the NATA pollutants. This section discusses the pollutants and pollutant groups in the NEI used in NATA and the aggregation needed to generate the NATA pollutants.

In CMAQ, we model CAPs and precursors and about 50 air toxics, including diesel particulate matter. Table 2-2 shows the specific air toxics used in CMAQ. For AERMOD, we model nearly all HAPs covered by the NEI; those that are not modeled are due to lack of emissions or risk considerations. Table B-I in Appendix B provides more detail about each HAP excluded. For NATA, we aggregated NEI pollutants that can be reported as either a group or as specific individual pollutants belonging to the group into pollutant groups for the NATA modeling and results. This aggregation was done in the emissions modeling process, prior to the air quality modeling. Table 2-2 lists the groups. For example, individual glycol ethers are grouped into the single NATA HAP "glycol ethers." The spreadsheet file "NATA_Pollutants.xlsx" within the Supplemental Data folder accompanying this TSD shows the individual HAPs and groups used in AERMOD and CMAQ. The following subsections give more details about some specific NATA pollutant groups.

Table 2-2. Pollutant groups

Group
Chromium Vi (Hexavalent)
Cresol cresylic acid (mixed isomers)
Cyanide compounds
Glycol ethers
Nickel compounds
PAHPOM
Polychlorinated biphenyls (aroclors)
Xylenes (mixed isomers)

2.1.1.1. Assignment of PAHs into PAH modeling groups

Polycylic aromatic hydrocarbons and polycylic organic matter (PAHPOM) are lumped together as a single group in NATA. However, the individual compounds in these groups have widely varying risks. As a result, we modeled the PAHPOM in separate groups based on their unit risk estimate (URE). For NATA, we summed the concentrations and risks across all PAHPOM risk groups. For the tabular emission summaries on the NATA website (https://www.epa.gov/national-air-toxics-assessment), the individual PAHPOM compounds (i.e., in Table 2-3) are provided.

The PAH groups are based on the groups established for the 2014 NATA and are listed below along with the individual PAHs assigned to each. Note that two pollutants representing polycylic organic matter in the NEI are unspeciated: pollutant code 250 (PAH/POM–Unspecified) and pollutant code 130498292 (PAH, total). These are assigned to PAH_880E5.

Table 2-3. PAH/POM pollutant groups

PAH Group	NEI Pollutant Code	NEI Pollutant Description	URE 1/(µg/m^3)
PAH_000E0	120127	Anthracene	0
PAH_000E0	85018	Phenanthrene	0
PAH_000E0	129000	Pyrene	0
PAH_101E2	56495	3-Methylcholanthrene	0.01
PAH_114E1	57976	7,12-Dimethylbenz[a]Anthracene	0.114
PAH_176E2	189640	Dibenzo[a,h]Pyrene	9.6E-03
PAH_176E2	189559	Dibenzo[a,i]Pyrene	9.6E-03
PAH_176E2	191300	Dibenzo[a,l]Pyrene	9.6E-03
PAH_176E3	50328	Benzo[a]Pyrene	9.6E-04
PAH_176E3	192654	Dibenzo[a,e]Pyrene	9.6E-04
PAH_176E3	53703	Dibenzo[a,h]Anthracene	9.6E-04
PAH_176E3	194592	7H-Dibenzo[c,g]carbazole	9.6E-04
PAH_176E3	3697243	5-Methylchrysene	9.6E-04
PAH_176E3	41637905	Methylchrysene	9.6E-04
PAH_176E4	56553	Benz[a]Anthracene	9.6E-05
PAH_176E4	205992	Benzo[b]Fluoranthene	9.6E-05
PAH_176E4	205823	Benzo[j]fluoranthene	9.6E-05
PAH_176E4	226368	Dibenz[a,h]acridine	9.6E-05
PAH_176E4	224420	Dibenzo[a,j]Acridine	9.6E-05
PAH_176E4	193395	Indeno[1,2,3-c,d]Pyrene	9.6E-05
PAH_176E4	5522430	1-Nitropyrene	9.6E-05
PAH_176E5	207089	Benzo[k]Fluoranthene	9.6E-06
PAH_176E5	86748	Carbazole	9.6E-06
PAH_176E5	218019	Chrysene	9.6E-06
PAH_192E3	8007452	Coal Tar	9.9E-04
PAH_880E5	83329	Acenaphthene	4.8E-05
PAH_880E5	208968	Acenaphthylene	4.8E-05
PAH_880E5	203338	Benzo(a)Fluoranthene	4.8E-05
PAH_880E5	195197	Benzo(c)phenanthrene	4.8E-05
PAH_880E5	192972	Benzo[e]Pyrene	4.8E-05
PAH_880E5	203123	Benzo(g,h,i)Fluoranthene	4.8E-05
PAH_880E5	191242	Benzo[g,h,i,]Perylene	4.8E-05
PAH_880E5	56832736	Benzofluoranthenes	4.8E-05
PAH_880E5	91587	2-Chloronaphthalene	4.8E-05
PAH_880E5	284	Extractable Organic Matter (EOM)	4.8E-05
PAH_880E5	206440	Fluoranthene	4.8E-05
PAH_880E5	86737	Fluorene	4.8E-05
PAH_880E5	779022	9-Methyl Anthracene	4.8E-05
PAH_880E5	26914181	Methylanthracene	4.8E-05

PAH Group	NEI Pollutant Code	NEI Pollutant Description	URE 1/(µg/m^3)
PAH_880E5	2422799	12-Methylbenz(a)Anthracene	4.8E-05
PAH_880E5	65357699	Methylbenzopyrene	4.8E-05
PAH_880E5	90120	1-Methylnaphthalene	4.8E-05
PAH_880E5	91576	2-Methylnaphthalene	4.8E-05
PAH_880E5	832699	1-Methylphenanthrene	4.8E-05
PAH_880E5	2531842	2-Methylphenanthrene	4.8E-05
PAH_880E5	2381217	1-Methylpyrene	4.8E-05
PAH_880E5	130498292	PAH, total	4.8E-05
PAH_880E5	198550	Perylene	4.8E-05
PAH_880E5	250	PAH/POM – Unspecified	4.8E-05

2.1.1.2. Metal groups

NATA includes metal compound groups consistent with metal emissions in the NEI. Metal emissions in the 2014 NEI represent only the mass of the metal with a few exceptions for specific compounds of **hexavalent chromium** (chromium VI) and **nickel** of known composition. Prior to modeling, we applied factors that convert the emissions of specific metal compounds to the portion of the compound that is metal. Table 2-4 shows the HAPs that have metal speciation factors other than 1.

> **Example: Adjusting Emissions for Chromium VI Compounds**
>
> Chromic acid (VI) (H_2CrO_4) has a molecular weight of about 118.01. Chromium, with an atomic mass of 52, is the toxic element of interest in this metal compound. Emissions reported in NEI are therefore multiplied by 0.4406 (i.e., 52 / 118.01), and the resulting emission rate is used in NATA modeling.

The three nickel compounds and three chromium VI compounds in the 2014 NEI are shown in the table below with the corresponding adjustment factors to compute the emissions that account for just the metal portion of the compound. Note that after applying the adjustments, the chromium VI compounds are grouped into chromium VI and the nickel compounds are grouped into nickel. These are generally small in mass compared to the metal-only pollutants (nickel and chromium VI) and are only present for stationary sources.

Table 2-4. Metal speciation factors for NEI metal compounds

Description	NATA Pollutant Group	pollutant_cd (CAS)	Metal Speciation Factor
Nickel oxide	NICKEL COMPOUNDS	1313991	0.7858
Chromium trioxide	CHROMIUM VI (HEXAVALENT)	1333820	0.52
Chromic acid (VI)	CHROMIUM VI (HEXAVALENT)	7738945	0.4406

We made two changes to the 2014 metal CN factors from 2011:

- We removed the 0.5 factor from calcium cyanamide because the unit risk is for that particular HAP and not cyanide compounds.
- We corrected the nickel oxide factor from 0.7412 to 0.7858, which is the ratio of the molecular weight of nickel (58.6934) to the molecular weight of nickel oxide (74.6928).

2.1.1.3. Diesel PM

Diesel PM is neither a CAP nor HAP as defined by Section 112 of the CAA, however it was identified as a mobile source air toxic in EPA's 2007 rule, "Control of Hazardous Air Pollutants From Mobile Sources final rule" (EPA 2007a). Prior to the 2014 NEI, it was generated separately for NATA modeling from the NEI and was not included as a separate NEI pollutant. However, starting with the 2014 NEI, diesel PM emissions are included in the NEI, as discussed above. The NEI-generated diesel PM emissions from the mobile-source, engine-exhaust PM_{10} emissions were used for engines burning diesel or residual-oil fuels. These sources include on-road, nonroad, point-airport-ground support equipment, point-locomotives, nonpoint locomotives, and all PM from diesel or residual-oil-fueled nonpoint CMVs. Diesel PM emissions were set equal to PM_{10} emissions for these engines. Although stationary engines also can burn diesel fuel, only mobile-related diesel engine SCCs were used.

2.1.1.4. Pollutant information file

The spreadsheet file "NATA_Pollutants.xlsx" within the Supplemental Data folder accompanying this TSD includes a crosswalk that contains NEI pollutant codes/descriptions, NATA group information, CMAQ names, metal adjustment factors, URE, RfC and target organ information.

2.1.2. Emissions Categorization: NEI and NATA

As explained on the NEI website, the 2014 NEI includes five data categories: point, nonpoint (formerly called "stationary area"), nonroad mobile, on-road mobile, and events consisting of wild and prescribed fires. NEI summaries are generally provided by sectors and tiers, which describe the type of emission source (e.g., industrial processes – oil and gas production). Some sectors and tiers cut across data categories since stationary sources are inventoried as both point and nonpoint. For example, the NEI sector "Fuel Combustion – Commercial/Institutional – Oil" results from large institutions inventoried as point sources (e.g., large universities with onsite steam plants) as well as commercial/institutional entities that are small and ubiquitous in nature, so their emissions are inventoried as county sums.

NATA summaries are provided by NATA broad summary categories and by more detailed source groups. The broad NATA summary categories are point, nonpoint, on-road, nonroad, fires, biogenics and secondary. Some of these categories are named the same as the NEI data categories, but they are not identical. For example, the NEI nonpoint category includes CMVs and locomotives, while the NATA category does not. Similarly, the NATA nonroad category includes airports, CMVs and locomotives, while the NEI category does not. Table 2-5 contains comparisons between the NEI data categories and the NATA categories. "Secondary" is not included in Table 2-5 since it not a primary emissions category covered in the NEI, but rather a result of atmospheric chemistry from the modeled emissions of CAPS and HAPs.

Table 2-5. Map of NEI data categories to NATA categories

NEI Data Category	NATA Category (Reflecting NATA Summary Results)
Point	***Point[1]***
Emissions estimates for sources that are individually inventoried and usually located at a fixed, stationary location (although portable sources such as some asphalt- or rock-crushing operations are also included). Point sources include large industrial facilities and electric power plants but also increasingly include many smaller industrial and commercial facilities, such as dry cleaners and gas stations, that had traditionally been included as nonpoint sources. The choice of whether these smaller sources are estimated individually and included as point sources or inventoried as a nonpoint source aggregated to county or tribal areas is determined by the separate S/L/T air agency.	Same as NEI point except: Excludes portable sources, which are not modeled in either CMAQ or AERMOD because no geographic information other than the state code is included. Excludes airports and railyards, which are nonroad mobile.
Nonpoint	***Nonpoint***
Sources that individually are too small in magnitude or too numerous to inventory as individual point sources and that can often be estimated more accurately as a single aggregate source for a county or tribal area. Examples are residential heating and consumer solvent use. Agricultural, CMVs and locomotive emissions are included. Biogenic emissions that come from vegetation are also included.	Same as NEI nonpoint except excludes locomotive, CMV, biogenic emissions and agricultural fires.
On-road	***On-road***
Emissions estimates for mobile sources, such as cars, trucks and buses. EPA's MOVES2014a model currently generates these estimates (except in California, which uses different models).	Same as NEI on-road.
Nonroad	***Nonroad***
Emissions estimates for nonroad equipment such as lawn and garden equipment, agricultural, construction, industrial and commercial equipment and recreational equipment. EPA's MOVES2014a model generates these estimates (except in California, which uses different models).	Same as NEI nonroad, but the NATA nonroad also includes CMVs, locomotives, aircraft engine emissions occurring during LTOs, and the ground support equipment and auxiliary power units associated with the aircraft.

NEI Data Category	NATA Category (Reflecting NATA Summary Results)
Event	***Fires***
Prescribed and wildfire emissions computed as day- and location-specific events	Wildfires, prescribed burning and agricultural burning. These are modeled in CMAQ but not AERMOD. Wildfires and prescribed burning are generated via the SMARTFIRE2 model at specific geographic coordinates for each day, and are assigned to 12-km grid cells for input into CMAQ. Agricultural burning estimates are in the NEI as county-level emissions, but EPA-derived data are developed as day- and location-specific emissions, and S/L/T-submitted data are county level but prepared for CMAQ as point sources with day-specific emissions as explained in the 2014 modeling platform documentation.
	Biogenic Emissions
	Emissions of formaldehyde, acetaldehyde and methanol from vegetation (trees, plants and soils) computed from the Biogenic Emission Inventory System within CMAQ. These are gridded to 12-km cells and modeled in CMAQ, but are not modeled in AERMOD.

[1]In results presented online for assessments for the 2002 and earlier NATA inventories, point sources were divided into major sources and area sources; these were sometimes referred to as stationary sources. Major sources are defined in the CAA as stationary sources that have the potential to emit either at least 10 TPY of a HAP or at least 25 TPY of any combination of HAPs. Area sources are stationary sources for which the locations are known but that emit at levels below the major source emissions thresholds. This terminology is not used in the 2014 NATA, and stationary-source emissions are referred to only as point-source or nonpoint-source emissions. Point sources in the NATA results refer to those sources, including smaller sources, for which a specific location for their emissions is identified by latitude and longitude descriptions, and nonpoint sources are those stationary sources that are not point sources.

2.1.3. Differences Between the 2014 NEI and Emissions Used for NATA

Two modeling platforms were developed for the two air quality models run for NATA, CMAQ and AERMOD. The starting-point emission files for both were based primarily on “flat file” formats (FF10) of the 2014 NEI produced by the EIS for the Sparse Matrix Operator Kernel Emissions (SMOKE) modeling system. On-road emissions were generated by SMOKE-MOVES (Motor Vehicle Emissions Simulator; EPA 2015g), which produced the FF10 used as the starting point for the AERMOD emissions processing.

Although 2014 NEI v2 is the main basis of the emissions fed into the air quality models for NATA, there were minor differences between the 2014 NEI v2 and emissions data used for the NATA modeling.

These differences are:

- FIPS code corrections were made to the 2014 NEI v2 Alaska CMV emissions for counties 02201, 02232 and 02280 to put them into nonretired counties. See Section 2.3.8 for more details.
- Small changes in the data occurred between the time the flat file was exported from EIS and the NEI was posted on the public website. For the modeling platforms, the data were exported on November 1, 2017. A few emissions changes were made to the 2014 NEI prior to its release on EPA’s

website in February 2018. Most emissions changes were incorporated into the FF10; those that were not were insignificant or were for pollutants not used in the platform:

- Change for primary $PM_{2.5}$ and PM_{10} from 0.754 tons to 0.846 tons affecting facility 16691911 (SOL 95-18 Wastewater Management Facility) in Wyoming
- Changes to the following pollutants not used in the platform: condensable and filterable portion of particulate matter and the speciated components (EC, OC, SO4, NO3 and PMFINE) affecting facility 16691911 (SOL 95-18 Wastewater Management Facility) in Wyoming and facility 4195111 (Covanta Alexandria/Arlington Inc) in Virginia.

In addition, facility inventory changes (e.g., geographic coordinates, FIPS and release parameters) were made in the EIS after the modeling file was generated. These changes are reflected in the summaries of 2014 NEI v2 on EPA's website. Facility ID and FIPs changes will cause differences in facility or county summaries between the modeling file and 2014 NEI v2. Table 2-6 summarizes the differences in point inventory between the 2014 NEI v2 and NATA's modeling files.

Table 2-6. Point inventory differences between the modeling file and 2014 NEI v2

FACILITY_ID CHANGES	
Alabama	Facility 17057711 (Integrity Cabinets) has two HAPs split between this ID and 17133511 in the FF10, but all emissions are under 17057711 in the NEI. Same total emissions.
Minnesota	Geringhoff Manufacturing has ID 17066711 in the FF10, and 17903811 in the NEI.
Ohio	TRINITY HIGHWAY PRODUCTS LLC has two HAPs under ID 8102011 in the FF10; entire facility is ID 16535611 in the NEI; ID 8102011 is an alternate ID for this facility in EIS. WHEMCO - OHIO FOUNDRY INC has HAPs under alternate ID 8103111 in EMF; entire facility is ID 16806011 in the NEI; ID 8103111 is an alternate ID for this facility in the NEI. Facility 14756011 (Gerken Materials Inc) has FIPS 39069 in the FF10, 39043 in the NEI.
FIPS CHANGES	
Louisiana	Facility 8024611 (Noranda Alumina LLC) has FIPS 22095 in the FF10, 22093 in the NEI.
Minnesota	Facility 6384211 (Viking Gas Transmission - Cushing) has FIPS 27097 in the FF10, 27153 in the NEI. Facility 9496511 (University of MN - Landscape Arboretum) has FIPS 27053 in the FF10, 27019 in the NEI. Facility 6455811 (Hardrives Inc - Plant 701) has FIPS 27053 in the FF10, 27145 in the NEI. Facility 6951111 (Brown-Wilbert Vault Co - Lakeville) has FIPS 27039 in the FF10, 27139 in the NEI. Facility 7038911 (Northern Improvement Co - Nonmetallic) has FIPS 27027 in the FF10, 27021 in the NEI. Facility 13596111 (Cannon Falls Energy Center) has FIPS 27037 in the FF10, 27049 in the NEI. Facility 17095711 (Two Harbors Birch Bark Processing & Pellet Plant) has FIPS 27137 in the FF10, 27075 in the NEI.
Ohio	Facility 14756011 (Gerken Materials Inc) has FIPS 39069 in the FF10, 39043 in the NEI.
Utah	Facility 6432511 (Northwest Pipeline GP- Moab Compressor Station) has FIPS 49037 in the FF10, 49019 in the NEI. Facility 8178511 (Chevron Products Co - Salt Lake Refinery) has FIPS 49035 in EMF, 49011 in the NEI.
Virginia	Facility 6683711 (CHURCH & DWIGHT CO INC) has FIPS 51570 in EMF, 51041 in the NEI.
RELEASE POINT COORDINATE AND PARAMETER CHANGES	
	S/L/T made facility inventory changes after the SMOKE FF10 was produced due to the submittal of the year 2016 emissions inventory. These differences were not quantified.

Differences that result from differences in emissions processing (which reflect the specific role and function of the resulting inventory within the context of the NATA risk assessment process) are more accurately described as post-processing procedures rather than substantive changes.

Release parameter changes were made to the SMOKE flat file to fill in missing data or change out-of-range stack parameters. Data reporters of point sources must provide height, diameter, temperature and either velocity or flowrate, but they do not have to provide fugitive parameters.

Prior to emissions processing, we default missing or out-of-range stack or fugitive parameters and compute the velocity from the flowrate (if velocity is not provided). We chose to do the defaulting prior to the emissions processing and include the defaulted parameters directly into the FF10 prior to input into SMOKE. This is done for two reasons: 1) to provide better transparency in the FF10 files with respect to the data used in the model, and 2) to ensure that emission inputs are consistent across CMAQ and AERMOD models, since both use the FF10 as the starting point. The out-of-range parameters were chosen to be consistent with the range checks used in the Emissions Inventory System (EIS). The fugitive defaults were consistent with what has been used in previous NATAs.

Table 2-7 shows the changes made and why. The "Records changed" column indicates how many records were changed and provide the keywords used in the FF10 that indicate that a release parameter was changed and the situation. Even though SMOKE does not use the fugitive release point parameters, they are included in the table to make it complete.

Table 2-7. Release parameter defaults/changes to the FF10 inventory files for point sources

Field	Existing Value	New Value	Conditions/Notes	Number of Records Defaulted or Changed and Comment[1]
For point *sources* with stack releases (ERPtype NOT equal to "1")				
stkhgt	missing	use pstk[2] or global defaults[2]	None	None
stkdiam	missing	use pstk[2] or global defaults[3]	None	None
stkvel	missing	calculate from stkflow and stkdiam if not missing; otherwise reference by SCC from pstk[2] or global defaults[3]	vel = 4*stkflow/(pi*stkdiam^2) If the flow and diam are missing such that you cannot compute, use new value based pstk or global defaults	1,473,185 No pstk values used *ERPVelCompute*
stktemp	missing	use pstk[2] or global defaults[3]	None	None
stkhgt	Outside SMOKE range	use minimum value or maximum value in feet	Less than 1 ft (0.3048 m) or greater than 1300 ft (396 m)	None

Field	Existing	New Value	Conditions/Notes	Number of Records
stkdiam	Outside SMOKE range	use minimum value or maximum value in ft	Less than 0.001 ft (0.0003048 m) or greater than 300 ft (91.4 m)	None
stkvel	Outside SMOKE range	use minimum value or maximum value in ft/s	Less than 0.001 ft/s (0.0003048 m/s) or greater than 1000 ft/s (304.8 m/s)	Below min[4]: 18,817 Above max[4]: 11,742 *ERPVelRange*
stktemp	Outside SMOKE range	use minimum value or maximum value in F	Less than -30 F (-34.4 C or 248.15 K) or greater than 4000 F (2204.4 C or 2477.6 K)	None
For fugitive release points (not used in CMAQ)				
fug_width_ydim	missing	32.808 ft	None	3,856,867; *ERPFugMissing*
fug_length_xdim	missing	32.808 ft	None	3,888,847; *ERPFugMissing*
fug_angle	missing	0	None	3,932,478; *ERPFugMissing*
fug_height	missing	10 ft	fug_width_ydim and /or fug_length_xdim are missing	3,556,330; *ERPFugMissing*
fug_height	missing	0	WHEN fug_width_ydim and fug_length_xdim are not missing and > 0	12,742; *ERPFugHeight0*
For coke ovens: any release point that emits coke oven emissions (pollutant code 140)–all pollutants at that				
stkhgt	<126 ft	126 ft	erptype NOT = “1”	2159; *ERPCokeoven126*
fug_height	<126 ft	126 ft	erptype = “1”	2829; *ERPCokeoven126*
fug_length_xdim	<50 ft	50 ft	erptype = “1”	2767; *ERPCokeovenFug50*
fug_width_ydim	<50 ft	50 ft	erptype = “1”	2767; *ERPCokeovenFug50*

Comments were put into the modeling file to indicate why a record was changed:

ERPVelCompute – velocity computed from the flowrate provided in the inventory

ERPHtRange – height in the inventory was out of range

ERPDiamRange – diameter in the inventory was out of range

ERPVelRange – velocity in the inventory or velocity calculated from the flowrate in the inventory was out of range

ERPTempRange – temperature in the inventory was out of range

ERPFugHeight0 – fugitive height in the inventory was set to 0 because the width and length were not missing

ERPFugMissing – fugitive height, length and width were missing or fugitive length and/or width were missing.

ERPCokeoven126 – fugitive or stack height of release point emitting coke oven emissions was less than 126 ft

ERPCokeovenFug50 – fugitive length or width was less than 50 ft.

Pstk provides default stack parameters and is provided with other SMOKE ancillary files (ge_dat directory) on the website. The pstk file is formatted: region_cd, scc, stkhgt (m), stkdiam (m), stktemp (K) and stkvel (m/s)

Global defaults (converted to English): stkvel = 13.1234 ft; stktemp=72.05 F, stkdiam=0.6562 ft, stkhgt=9.8425 ft

Out-of-range values exist because the flow range checks in EIS allow some velocities to be above or below the range, and we run the velocity check after computing the missing flowrates.

Other emissions processing changes include:

- For on-road emissions, there were differences in the HAP VOCs in California. These were due to changes in the post-processing approach to adjust California-submitted pollutants consistent with the MOVES2014a speciation. The NATA inventory also includes a more refined set of SCCs that includes road type to support spatial allocation of county-level emissions to finer scales.

- Sources with FIPS state-county codes ending in 777 (in-flight lead and asphalt plants that have no geographic coordinates) were removed from the inventory.

- Nonpoint tribal data (FIPS beginning in 88) were not used in the modeling because spatial surrogates were not available and possible double counting would introduce uncertainty.

- To minimize over-concentration of fire emissions into individual grid cells, we spatially allocated fires (from the event category, modeled only in CMAQ) that were larger than 20,000 acres on a single day. Those fires were allocated into overlapping CMAQ grid cells based on fire polygons, where available, or circles otherwise.

- Other miscellaneous changes included air toxic name conversions, placing individual air toxics into groups, and similar transcription and phraseology conversions (e.g., to crosswalk the identity of an emitted air toxic to a substance with a quantitative dose-response value).

2.1.4. Overview of Differences in Emissions for CMAQ and AERMOD

By design, there were differences in the sources of emissions used by CMAQ and AERMOD. Differences in the emissions inputs to the two models were due to design differences in how the models were run. The emissions input into AERMOD excluded NATA categories more appropriately addressed by CMAQ, namely biogenics and three types of fires: wildfires, prescribed burning and agricultural-field burning. Biogenic emissions were generated within CMAQ using the Biogenic Emission Inventory System (BEIS) model with hourly meteorological inputs to generate hourly gridded (12 km x 12 km) emissions of several photochemical-model species, including three HAPs: formaldehyde, acetaldehyde and methanol. This category of emissions is routinely part of CMAQ runs and is more appropriately modeled in CMAQ due to its broad spatial and refined temporal resolution and meteorological dependence. Wildfires and prescribed and agricultural burning were also included in the CMAQ run but not in AERMOD because CMAQ provides for in-line plume rise of fires to higher vertical layers based on the acres burned. These algorithms are also used for agricultural burning, which is grouped with the other fires to allow us to retain source attribution from the fire and biogenic CMAQ zero-out runs (although not between the different fire types) discussed in Section 3.3.1.

In addition to differences in the sources of emissions used for the two models, there were also differences in the way we processed or modeled the emissions. Emissions modeling transforms the emissions inventory into the format needed by the air quality model and provides the source characterization. The emission inventory primarily contains annual emissions represented as either point sources with locations specified by latitude and longitude or county-level sources specified by FIPS code (county code). In the inventory, large facilities are inventoried as point sources; while more ubiquitous sources, such as wood stoves, solvent use, and cars and trucks, are inventoried at the county level.

Emissions modeling is performed in three main steps: spatial allocation, temporal allocation and speciation. Spatial allocation provides the models with the horizontal characterization of the emissions source. For example, emissions modeling provides AERMOD with locations for point sources and locations and spatial extent of sources emitted over large or small areas, and it provides CMAQ with gridded emissions. Vertical allocation of emissions is performed within the air quality models using stack parameter information and other model inputs.

Temporal allocation produces hourly variation in emissions based on the monthly, day-of-week and/or diurnal variation associated with the specific type of source.

Speciation takes the inventory pollutant and converts it to the pollutant used by the air quality model (or in subsequent processes). For example, the compound nickel oxide is converted to nickel because the risk information is only for the nickel portion of the compound. For AERMOD, sources also must be characterized using parameters that may not be in the inventory, such as release heights (which are not inventoried for mobile and nonpoint sources) and initial vertical dispersion (which is not in the inventory for any source).

Emissions processing for CMAQ and AERMOD is described in Sections 2.2 and 2.3, respectively. However, Section 2.2 contains only a summary since a separate technical support document is available that describes the CMAQ emissions modeling in detail.

Table 2-8 summarizes the spatial allocation differences between the models. As seen in Table 2-8, CMAQ uses 12-km horizontal resolution along with vertical resolution for point sources and fires, whereas AERMOD spatial resolution depends on the source category. Both models use hourly emissions, however CMAQ uses pollutant-specific hourly emissions whereas AERMOD uses the same hourly variation for all sources in a "run group," as described in Section 2.3.

Table 2-8. Differences in spatial characterization of sources between CMAQ and AERMOD

Category	NEI Resolution	Spatial Approach for AERMOD	Spatial Approach for CMAQ
Point (excluding airports)	Point	Point – vertical stack and fugitive based on NEI information on emission-release point	12-km grid cells
Airports	Point	Point – runways & 10 m^2 areas consistent with NEI geographic coordinates	12-km grid cells
Locomotives	Point (railyards) and County/Shape	Nonpoint – 12-km grid cells in the CONUS domain, tract (non-CONUS) Point – point fugitives	12-km grid cells
CMVs, ports and underway	County/Shape	Shapes from the NEI; separate shapes used for CMV at ports versus underway	12-km grid cells
On-road, nonroad equipment and other nonpoint	County	12-km or 4-km grid cells, depending on the category, in the CONUS domain; 9-km grid cells for AK; 3-km grid cells for HI, PR and VI	12-km grid cells
Agricultural burning and biogenic emissions	County	Not modeled	12-km grid cells
Fires (prescribed and wild)	Point	Not modeled	12-km grid cells

2.2. Preparation of Emissions Inputs for CMAQ

EPA routinely prepares emissions for photochemical grid models such as CMAQ by developing an emissions modeling platform, and the SMOKE modeling system is used as the primary emissions modeling tool. An emissions modeling platform includes the emission inventories, the ancillary data files (e.g., for speciation, temporal allocation and spatial allocation) and the approaches used to transform inventories for use in air quality modeling.

The platform used for this study has been developed based on the 2014 NEI version 2 and is the multipollutant 2014v7.1 platform (modeling case name: "2014fd_nata_cb6_14j"). We will denote this as the CMAQ NATA platform. This platform generated the emission inputs for the version of CMAQ used for NATA (version 5.2) using all CMAQ HAPs from the NEI emissions as opposed to generating them from speciation of VOC.

This version of CMAQ includes more air toxics than previous multipollutant versions – 51 HAPs and diesel PM. Specifically, chloroprene, ethyl benzene, acrylic acid, styrene, acetonitrile, methyl chloride, carbonyl sulfide and hexane were added in CMAQ for this 2014 NATA application.

A TSD describing this platform is found on the emissions modeling platforms website. See in particular: https://www.epa.gov/air-emissions-modeling/2014-version-71-platform. Emissions inputs and ancillary data for speciation and for temporal and spatial allocation are available at the emissions modeling platform ftp site.

A summary of the platform's key features is below.

2.2.1. Modeling Domain

For CMAQ, emissions are prepared for the CMAQ 12-km contiguous United States (or "CONUS") modeling domain (12US2) shown in Figure 2-1.

This grid uses a Lambert-Conformal projection, with Alpha = 33º, Beta = 45º and Gamma = -97º, with a center of X = -97º and Y = 40º. Table 2-9 describes the grid.

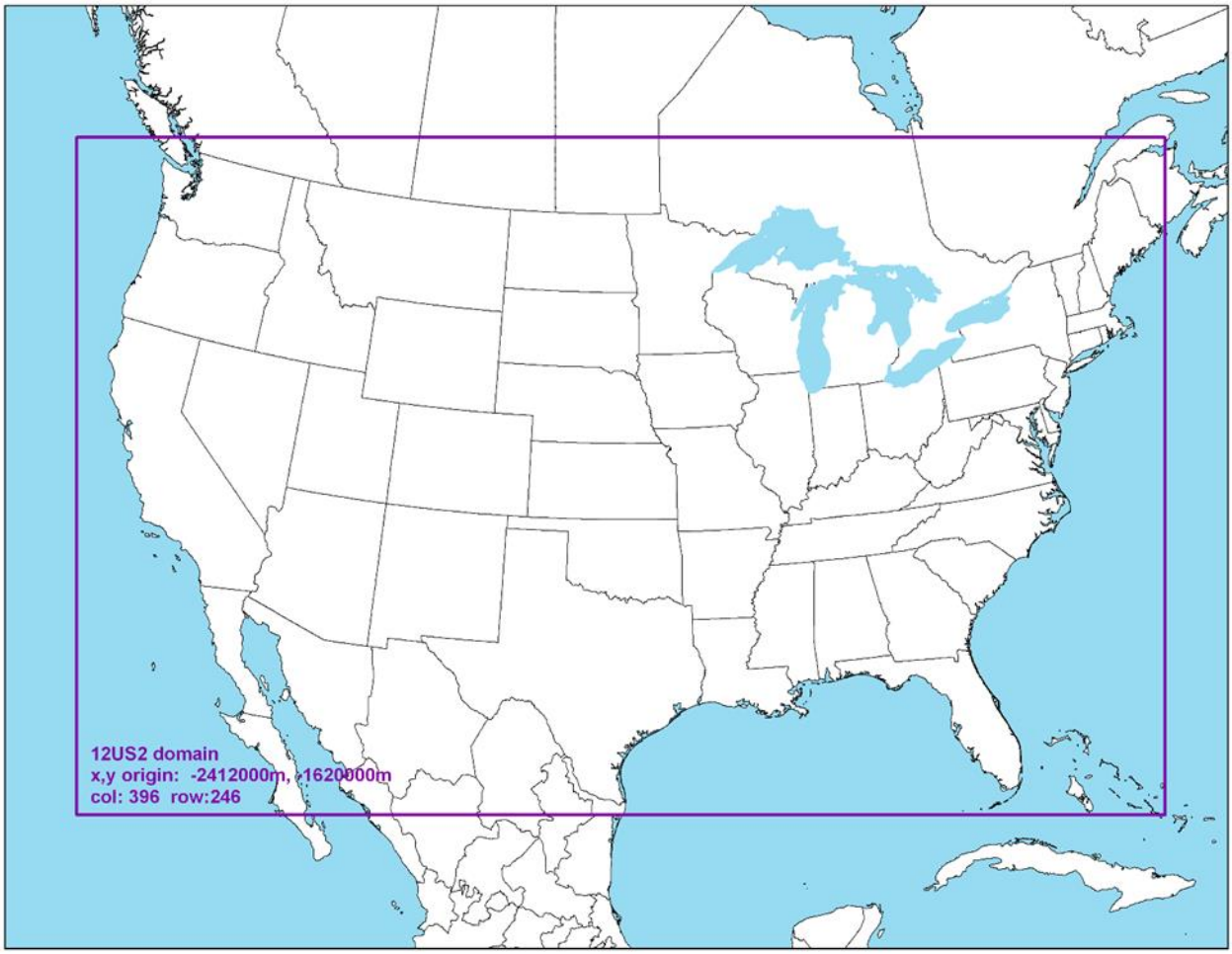

Figure 2-1. Air quality modeling domain

Table 2-9. Description of the platform grid

Common Name	Grid Cell Size	Description (see Figure 2-1)	Grid Name	Parameters Listed in SMOKE Grid Description (GRIDDESC) File: projection name, xorig, yorig, xcell, ycell, ncols, nrows, nthik
US 12 km or "smaller" CONUS-12	12 km	Smaller 12 km CONUS plus some of Mexico/Canada	12US2	'LAM_40N97W', -2412000, -1620000, 12.D3, 12.D3, 396, 246, 1

2.2.2. Sectors in the CMAQ NATA Platform

For the purposes of preparing the CMAQ model-ready emissions, the 2014 NEI v2 was split into finer-grained sectors used for emissions modeling. The significance of an emissions modeling or "platform sector" is that the data are run through all the SMOKE programs independently from the other sectors except the final merge program (Mrggrid). The sectors used for the NATA CMAQ platform are listed in Table 2-10.

Table 2-10. Platform sectors for the 2014v7.1 emissions modeling platform

Platform Sector: *abbreviation*	NEI Data Category	Description and Resolution of the Data Input to SMOKE
EGU units: *ptegu*	Point	2014 NEI v2 point source EGUs. The 2014 emissions are replaced with hourly 2014 continuous emissions monitoring system (CEMS) values for NO_X and SO_2 for any units that are matched to the NEI, and other pollutants for matched units are scaled from the 2014 NEI v2 using CEMS heat input. Emissions for all sources not matched to CEMS data come from the 2014 NEI v2. CEMS data come from EPA's Clean Air Markets data (http://ampd.epa.gov/ampd/). Annual resolution for sources not matched to CEMS data, hourly for CEMS sources.
Point source oil and gas: *pt_oilgas*	Point	2014 NEI v2 point sources that include oil and gas production and related processes based on facilities with the following NAICS: 2111, 21111, 211111, 211112 (Oil and Gas Extraction); 213111 (Drilling Oil and Gas Wells); 213112 (Support Activities for Oil and Gas Operations); 2212, 22121, 221210 (Natural Gas Distribution); 48611, 486110 (Pipeline Transportation of Crude Oil); 4862, 48621, 486210 (Pipeline Transportation of Natural Gas). Includes offshore oil and gas platforms in the Gulf of Mexico. Annual resolution.
Remaining non-EGU point: *ptnonipm*	Point	All 2014 NEI v2 point source records not matched to the ptegu or pt_oilgas sectors. Includes all aircraft and airport ground support emissions and some rail yard emissions. Annual resolution.
Agricultural: *ag*	Nonpoint	Nonpoint livestock and fertilizer application emissions. Livestock includes ammonia and other pollutants (except $PM_{2.5}$). Fertilizer includes only ammonia. County and daily resolution for livestock; county and annual resolution for fertilizer.
Agricultural fires with point resolution: *ptagfire*	Nonpoint	2014 NEI v2 agricultural fire sources that were developed by EPA as point sources with day-specific emissions or reported by S/L/T as county-level emissions and were apportioned to point sources. They are in the nonpoint NEI data category, but in the platform, they are treated as point sources.
Area fugitive dust: *afdust*	Nonpoint	PM_{10} and $PM_{2.5}$ fugitive dust sources from the 2014 NEI v2 nonpoint inventory; including building construction, road construction, agricultural dust and road dust. The NEI emissions are reduced during modeling according to a transport fraction and a meteorology-based (precipitation and snow/ice cover) zero-out. County and annual resolution.
Biogenic: *beis*	Nonpoint	Year 2014, hour-specific, grid cell-specific emissions generated from the BEIS3.61 model within SMOKE, including emissions in Canada and Mexico using BELD v4.1 land-use data (slightly updated from the BELDv4.1 used in 2014v7.0).
Category 1, 2 CMV: *cmv_c1c2*	Nonpoint	Category 1 (C1) and category 2 (C2) commercial marine vessel (CMV) emissions sources from the 2014 NEI v2 nonpoint inventory, except that it does not use C1/C2 from the 2014 NEI in federal waters. County and annual resolution; see othpt sector for all non-U.S. C3 emissions.
Category 3 CMV: *cmv_c3*	Nonpoint	Category 3 (C3) cmv emissions converted to point sources based on the center of the grid cells.
locomotives: *rail*	Nonpoint	Rail locomotives emissions from the 2014 NEI v2. County and annual resolution.

Platform Sector: *abbreviation*	NEI Data Category	Description and Resolution of the Data Input to SMOKE
Remaining nonpoint: *Nonpt*	Nonpoint	2014 NEI v2 nonpoint sources not included in other platform sectors, with adjustments to remove chromium from fugitive dust categories (paved and unpaved roads, construction and crops and livestock). County and annual resolution.
Nonpoint source oil and gas: *np_oilgas*	Nonpoint	2014 NEI v2 nonpoint sources from oil and gas-related processes. County and annual resolution.
Residential Wood Combustion: *Rwc*	Nonpoint	2014 NEI v2 nonpoint sources with residential wood combustion (RWC) processes. County and annual resolution.
Nonroad: *Nonroad*	Nonroad	2014 NEI v2 nonroad equipment emissions developed with the MOVES2014a using NONROAD2008 version NR08a with newer HAP emission factors than had been used in the 2011NEI. MOVES used for all states except California, which submitted their own emissions. County and monthly resolution.
On-road: *Onroad*	On-road	2014 on-road mobile source gasoline and diesel vehicles from moving and non-moving vehicles and vehicle refueling. Includes the following modes: exhaust, extended idle, auxiliary power units, evaporative, permeation, refueling and brake and tire wear. For all states except California, developed using winter and summer MOVES emission factor tables produced by MOVES2014a.
On-road California: *onroad_ca_adj*	On-road	2014 California-provided CAP and metal HAP on-road mobile source gasoline and diesel vehicles submitted to the NEI, gridded and temporalized using MOVES2014a. Volatile organic compound (VOC) HAP emissions derived from California-provided VOC emissions and MOVES-based speciation.
Point source fires: *ptfire*	Events	Point source day-specific wildfires and prescribed fires for 2014 computed using SMARTFIRE2 for both flaming and smoldering processes.
Non-US. fires: *ptfire_othna*	N/A	Point source day-specific wildfires and prescribed fires for 2014 for Canada and Mexico.
Other dust sources not from the 2014 NEI: *othafdust*	N/A	Fugitive dust sources from Canada's 2013 inventory. Transportable emissions are reduced via a transport fraction and a meteorology-based (precipitation and snow/ice cover) zero-out. County and annual resolution.
Other point sources not from the 2014 NEI: *othpt*	N/A	Point sources from Canada's 2013 inventory and Mexico's 2014 inventory, annual resolution. Also includes all non-U.S. C3 CMV.
Other non-NEI nonpoint and nonroad: *othar*	N/A	Year 2013 Canada emissions: monthly for agricultural ammonia and nonroad sources; annual for rail, CMV and other nonpoint Canada sectors. Year 2014 Mexico (municipio resolution): annual nonpoint and nonroad mobile inventories.
Other non-NEI on-road sources: *onroad_can*	N/A	Monthly year 2013 Canada on-road mobile inventory.
Other non-NEI on-road sources: *onroad_mex*	N/A	Monthly year 2014 Mexico (municipio resolution) on-road mobile inventory.

2.2.3. Fires and Biogenics

To approximate how much fires and biogenic primary emissions contribute to overall air toxics concentrations, we use a concept known as "zero-out" runs in CMAQ. This technique lets us split out the individual impacts from these source categories in the NATA results.

CMAQ can compute biogenic emissions during a run, and it has options to take multiple sets of point-source fire emission files as input. These features were used in this study to quantify the impacts of biogenic and fire emissions by running CMAQ three times:

1. The base-case run used all fire and anthropogenic emissions from the 2014fd_nata case with the option to generate biogenic emissions turned on.

2. The biogenic zero-out run used all fire and anthropogenic emissions from the 2014fd_nata case but with the option to generate biogenic emissions turned off.

3. The fire zero-out run used all anthropogenic emissions from the 2014fd_nata case and had the option to generate biogenic emissions turned on, but it excluded the input files for wild, prescribed and anthropogenic fires.

2.2.4. Speciation

The emissions modeling step for chemical speciation creates the "model species" needed by the air quality model for a specific chemical mechanism. These model species are either individual chemical compounds (i.e., "explicit species") or groups of species (i.e., "lumped species"). Model species are created in the emissions modeling process by directly mapping emissions from the emission inventory to the appropriate model species or by speciation of inventory species where a one-to-one match does not exist. For example, VOCs are speciated into numerous VOC-related model species defined by the chemical mechanism. The chemical mechanism used for the 2014 platform is the CB6 mechanism (Yarwood et al. 2010). We used a version of CB6 that we refer to as "CB6-CMAQ" that breaks out explicit naphthalene (NAPH) from the lumped CB6 model species XYL and PAR (resulting in model species NAPH, XYLMN and a revised PAR), and uses an additional VOC secondary organic aerosol tracer called SOAALK (Pye and Pouliot 2012). This platform generates the $PM_{2.5}$ model species associated with the CMAQ Aerosol Module version 6 (AE6).

In the NATA modeling platform, all CMAQ species that are explicit NATA HAPs were generated by directly mapping the NEI emissions for these HAPs; no HAPs in the United States were generated through speciation of VOC or $PM_{2.5}$ in the emissions modeling step.

Table 2-11 through Table 2-13 list the model species produced by SMOKE in the 2014 platform. Eight species (chloroprene, ethyl benzene, acrylic acid, styrene, acetonitrile, methyl chloride, carbonyl sulfide and hexane) were added to CMAQ for the 2014 NATA (these are shown with an asterisk in the below tables). The HAP metals, also from the inventory, are speciated within SMOKE into coarse and fine components used in CMAQ.

More information on speciation approach is available in the technical support document for the 2014 v2 modeling platform.

Table 2-11. Emission model species produced for CB6-CMAQ

Inventory Pollutant	Model Species[1]	Model Species Description
Cl_2	CL2	Atomic gas-phase chlorine
HCl	HCL	Hydrogen chloride (hydrochloric acid) gas
CO	CO	Carbon monoxide
NO_X	NO	Nitrogen oxide
	NO2	Nitrogen dioxide
	HONO	Nitrous acid
SO_2	SO2	Sulfur dioxide
	SULF	Sulfuric acid vapor
NH_3	NH3	Ammonia
VOC	ACET	Acetone
	ALD2	Acetaldehyde[2]
	ALDX	Propionaldehyde and higher aldehydes
	BENZ	Benzene[2]
	CH4	Methane[3]
	ETH	Ethene
	ETHA	Ethane
	ETHY	Ethyne
	ETOH	Ethanol
	FORM	Formaldehyde[2]
	KET	Ketone groups
	IOLE	Internal olefin carbon bond (R-C=C-R)
	ISOP	Isoprene
	MEOH	Methanol[2]
	NAPH	Naphthalene[2]
	OLE	Terminal olefin carbon bond (R-C=C)
	PAR	Paraffin carbon bond
	PRPA	Propane
	TOL	Toluene and other monoalkyl aromatics
	XYLMN	Xylene and other polyalkyl aromatics, minus naphthalene
	SOAALK	Lumped SOA tracer
Naphthalene	NAPH	Naphthalene from inventory
Benzene	BENZ	Benzene from inventory
Acetaldehyde	ALD2	Acetaldehyde from inventory
Formaldehyde	FORM	Formaldehyde from inventory
Methanol	MEOH	Methanol from inventory
VOC species from the biogenics model that do not map to model species above	SESQ	Sesquiterpenes
	TERP	Terpenes
PM_{10}	PMC	Coarse PM > 2.5 microns and ≤ 10 microns

Inventory Pollutant	Model Species[1]	Model Species Description
$PM_{2.5}$	PAL	Aluminum
	PCA	Calcium
	PCL	Chloride
	PEC	Particulate elemental carbon ≤ 2.5 microns
	PFE	Iron
	PK	Potassium
	PH2O	Water
	PMG	Magnesium
	PMN	Manganese
	PMOTHR	$PM_{2.5}$ not in other AE6 species
	PNA	Sodium
	PNCOM	Non-carbon organic matter
	PNO3	Particulate nitrate ≤ 2.5 microns
	PNH4	Ammonium
	POC	Particulate organic carbon (carbon only) ≤ 2.5 microns
	PSI	Silica
	PSO4	Particulate sulfate ≤ 2.5 microns
	PTI	Titanium
Sea-salt species (non-anthropogenic)[4]	PCL	Particulate chloride
	PNA	Particulate sodium

[1]Additional HAPs used outside of CB6-CMAQ for NATA are provided in Table 2-12.
[2]Naphthalene, benzene, acetaldehyde, formaldehyde and methanol (NBAFM) is produced via VOC speciation for Canada and Mexico, for other than on-road mobile sources in Mexico, or in very small quantities due to mixtures in the speciation profiles.
[3]Technically, CH_4 is not a VOC but part of TOG. Although emissions of CH_4 are derived, the AQ models do not use these emissions because the anthropogenic emissions are dwarfed by the CH_4 already in the atmosphere.
[4]These emissions are created outside of SMOKE.

Table 2-12. Additional HAP gaseous model species produced for CMAQ multipollutant specifically for NATA (not used within CB6)

Inventory Pollutant	Model Species
Acetaldehyde	ALD2_PRIMARY
Acetonitrile[1]	ACETONITRILE
Acrolein	ACROLEIN
Acrylic acid[1]	ACRYLICACID
Acrylonitrile	ACRYLONITRILE
1,3-Butadiene	BUTADIENE13
Carbon tetrachloride	CARBONTET
Carbonyl sulfide[1]	CARBSULFIDE
Chloroform	CHCL3
Chloroprene[1]	CHLOROPRENE
1,4-Dichlorobenzene(p)	DICHLOROBENZENE
1,3-Dichloropropene	DICHLOROPROPENE

Inventory Pollutant	Model Species
Ethylbenzene[1]	ETHYLBENZ
Ethylene dibromide (Dibromoethane)	BR2_C2_12
Ethylene dichloride (1,2-Dichloroethane)	CL2_C2_12
Ethylene oxide	ETOX
Formaldehyde	FORM_PRIMARY
Hexamethylene-1,6-diisocyanate	HEXAMETH_DIIS
Hexane[1]	HEXANE
Hydrazine	HYDRAZINE
Maleic anyhydride	MAL_ANYHYDRIDE
Methyl chloride[1]	METHCLORIDE
Methylene chloride (Dichloromethane)	CL2_ME
Specific PAHs assigned with URE =0	PAH_000E0
Specific PAHs assigned with URE =9.6E-06 (previously 1.76E-5)	PAH_176E5
Specific PAHs assigned with URE =4.8E-05 (previously 8.8E-5)	PAH_880E5
Specific PAHs assigned with URE =9.6E-05 (previously 1.76E-4)	PAH_176E4
Specific PAHs assigned with URE =9.6E-04 (previously 1.76E-3)	PAH_176E3
Specific PAHs assigned with URE =9.6E-03 (previously 1.76E-2)	PAH_176E2
Specific PAHs assigned with URE =0.01 (previously 1.01E-2)	PAH_101E2
Specific PAHs assigned with URE =1.14E-1	PAH_114E1
Specific PAHs assigned with URE =9.9E-04 (previously 1.92E-3)	PAH_192E3
Propylene dichloride (1,2-Dichloropropane)	PROPDICHLORIDE
Quinoline	QUINOLINE
Styrene[1]	STYRENE
1,1,2,2-Tetrachloroethane	CL4_ETHANE1122
Tetrachloroethylene (Perchloroethylene)	CL4_ETHE
Toluene	TOLU
2,4-Toluene diisocyanate	TOL_DIIS
Trichloroethylene	CL3_ETHE
Triethylamine	TRIETHYLAMINE
m-xylene, o-xylene, p-xylene, xylenes (mixed isomers)[2]	XYLENES
Vinyl chloride	CL_ETHE

[1]New to CMAQ5.2 – version of CMAQ used for 2011 NATA did not include these HAPs.
[2]In 2011 NATA, these were separated into three model species: MXYL, OXYL and PXYL; in 2014 they are combined into XYLENES.

Table 2-13. Additional HAP particulate model species produced for CMAQ multipollutant specifically for NATA

Inventory Pollutant	Model Species
Arsenic	ARSENIC_C, ARSENIC_F
Beryllium	BERYLLIUM_C, BERYLLIUM_F
Cadmium	CADMIUM_C, CADMIUM_F
Chromium VI, chromic acid (VI), chromium trioxide	CHROMHEX_C, CHROMHEX_F

Inventory Pollutant	Model Species
Chromium III	CHROMTRI_C, CHROMTRI_F
Lead	LEAD_C, LEAD_F
Manganese	MANGANESE_C, MANGANESE_F
Mercury[1]	HGIIGAS, HGNRVA, PHGI
Nickel, nickel oxide, nickel refinery dust	NICKEL_C, NICKEL_F
Diesel-PM10, diesel-PM25	DIESEL_PMC , DIESEL_PMFINE, DIESEL_PMEC, DIESEL_PMOC, DIESEL_PMNO3, DIESEL_PMSO4

[1]Mercury is multiphase.

2.2.5. Temporalization

While the total emissions are important, the timing of the occurrence of emissions is also essential for accurately simulating ozone, PM and other pollutant concentrations in the atmosphere. Temporal allocation (i.e., temporalization) is the process of distributing aggregated emissions to a finer temporal resolution, thereby converting annual emissions to hourly emissions as is required by CMAQ.

Temporalization takes these aggregated emissions and distributes them to the month, and then distributes the monthly emissions to the day and the daily emissions to the hours of each day. This process is typically done by applying temporal profiles to the inventories in this order: monthly, day of the week, and diurnal, with monthly and day-of-week profiles applied only if the inventory is not already at that level of detail.

The temporal factors applied to the inventory are selected using some combination of country, state, county, SCC and pollutant. Table 2-14 summarizes the temporal aspects of emissions modeling by comparing the key approaches used for temporal processing across the sectors. In the table, “Daily temporal approach” refers to the temporal approach for getting daily emissions from the inventory using the SMOKE Temporal program. The “Merge processing approach” refers to the days used to represent other days in the month for the merge step. If this is not “all,” then the SMOKE merge step runs only for representative days, which could include holidays as indicated by the rightmost column.

Table 2-14. Temporal settings used for the platform sectors in SMOKE

Platform Sector Short Name	Inventory Resolutions	Monthly Profiles Used?	Daily Temporal Approach	Merge Processing Approach	Process Holidays as Separate Days
afdust_adj	Annual	Yes	week	All	Yes
ag	Monthly	No	all	All	Yes
beis	Hourly	No	n/a	all	Yes
cmv_c1c2	Annual	Yes	aveday	aveday	No
cmv_c3	Annual	Yes	aveday	aveday	No
nonpt	Annual	Yes	week	week	Yes
nonroad	Monthly	No	mwdss	mwdss	Yes
np_oilgas	Annual	Yes	week	week	Yes
onroad	Annual & monthly[1]	No	all	all	Yes

Platform Sector Short Name	Inventory Resolutions	Monthly Profiles Used?	Daily Temporal Approach	Merge Processing Approach	Process Holidays as Separate Days
onroad_ca_adj	Annual & monthly[1]	No	all	all	Yes
othafdust_adj	Annual	Yes	week	all	No
othar	Annual & monthly	Yes	week	week	No
onroad_can	Monthly	No	week	week	No
onroad_mex	Monthly	No	week	week	No
othpt	Annual & monthly	Yes	mwdss	mwdss	No
pt_oilgas	Annual	Yes	mwdss	mwdss	Yes
ptegu	Annual & hourly	Yes[3]	all	all	Yes
ptnonipm	Annual	Yes	mwdss	mwdss	Yes
ptagfire	Daily	No	all	all	Yes
ptfire	Daily	No	all	all	Yes
ptfire_othna	Daily	No	all	all	Yes
rail	Annual	Yes	aveday	aveday	No
rwc	Annual	No[2]	met-based	all	Yes

[1]Note the annual and monthly "inventory" refers to the activity data (vehicle miles travelled and vehicle population) for onroad. The actual emissions are computed on an hourly basis.
[2]Except for 2 SCCs that do not use met-based speciation.
[3]Only units that do not have matching hourly CEMS data use monthly temporal profiles.

In the table, the value "all" means that hourly emissions are computed for every day of the year and that emissions potentially have day-of-year variation. The value "week" means that hourly emissions are computed for all days in one "representative" week, representing all weeks for each month. This means emissions have day-of-week variation, but not week-to-week variation within the month. The value "mwdss" means hourly emissions are computed for a representative Monday, representative weekday (Tuesday through Friday), representative Saturday, and representative Sunday for each month. This means emissions have variation between Mondays, other weekdays, Saturdays and Sundays within the month, but not week-to-week variation within the month. The value "aveday" means hourly emissions are computed for one representative day of each month, meaning emissions for all days within a month are the same. Sector-specific details, including meteorological-based temporal allocation, are provided in the 2014v7.1 platform TSD. Ancillary data are available at the emissions modeling platform ftp site.

2.2.6. Spatial Allocation

For CMAQ, all emissions were allocated to 12-km grid cells. Sources with geographic coordinates such as point sources and fires are mapped to the appropriate grid cell based on those coordinates. Sectors with county-level resolution were allocated to 12-km grid cells using spatial surrogates, which are developed based on shapefiles of data with spatial patterns expected for the emissions category.

Table 2-15 through Table 2-17 list the spatial surrogates available for the CONUS domain used by CMAQ. In Table 2-15, surrogate names and codes listed in *italics* are not directly assigned to any sources for the platform, but they are sometimes used to gap-fill other surrogates or as an input for merging two surrogates to create a new surrogate that is used.

Table 2-15. U.S. surrogates available for the 2014v7.1 modeling platform

Code	Surrogate Description	Code	Surrogate Description
N/A	Area-to-point approach (for jet refueling)	505	Industrial Land
100	Population	506	Education
110	*Housing*	*507*	*Heavy Light Construction Industrial Land*
131	*Urban Housing*	*510*	*Commercial plus Industrial*
132	*Suburban Housing*	*515*	*Commercial plus Institutional Land*
134	*Rural Housing*	*520*	*Commercial plus Industrial plus Institutional*
137	*Housing Change*	*525*	*Golf Courses plus Institutional plus Industrial plus Commercial*
140	*Housing Change and Population*	*526*	*Residential - Non-Institutional*
150	Residential Heating – Natural Gas	*527*	*Single Family Residential*
160	*Residential Heating – Wood*	535	Residential + Commercial + Industrial + Institutional + Government
170	Residential Heating – Distillate Oil	*540*	*Retail Trade (COM1)*
180	Residential Heating – Coal	*545*	*Personal Repair (COM3)*
190	Residential Heating – LP Gas	*555*	*Professional/Technical (COM4) plus General Government (GOV1)*
201	*Urban Restricted Road Miles*	560	Hospital (COM6)
202	Urban Restricted AADT	*575*	*Light and High Tech Industrial (IND2 + IND5)*
205	Extended Idle Locations	*580*	*Food Drug Chemical Industrial (IND3)*
211	*Rural Restricted Road Miles*	*585*	*Metals and Minerals Industrial (IND4)*
212	*Rural Restricted AADT*	*590*	*Heavy Industrial (IND1)*
221	*Urban Unrestricted Road Miles*	*595*	*Light Industrial (IND2)*
222	*Urban Unrestricted AADT*	*596*	*Industrial plus Institutional plus Hospitals*
231	*Rural Unrestricted Road Miles*	650	Refineries and Tank Farms
232	*Rural Unrestricted AADT*	670	Spud Count - CBM Wells
239	Total Road AADT	671	Spud Count - Gas Wells
240	Total Road Miles	672	Gas Production at Oil Wells
241	*Total Restricted Road Miles*	673	Oil Production at CBM Wells
242	All Restricted AADT	674	Unconventional Well Completion Counts
243	*Total Unrestricted Road Miles*	*676*	*Well Count - All Producing*
244	All Unrestricted AADT	*677*	*Well Count - All Exploratory*
258	Intercity Bus Terminals	678	Completions at Gas Wells
259	Transit Bus Terminals	679	Completions at CBM Wells
260	*Total Railroad Miles*	681	Spud Count - Oil Wells
261	NTAD Total Railroad Density	683	Produced Water at All Wells
271	NTAD Class 1 2 3 Railroad Density	685	Completions at Oil Wells
272	*NTAD Amtrak Railroad Density*	*686*	*Completions at All Wells*

Code	Surrogate Description	Code	Surrogate Description
273	*NTAD Commuter Railroad Density*	687	Feet Drilled at All Wells
275	*ERTAC Rail Yards*	691	Well Counts - CBM Wells
280	*Class 2 and 3 Railroad Miles*	692	Spud Count - All Wells
300	NLCD Low Intensity Development	693	Well Count - All Wells
301	*NLCD Med Intensity Development*	694	Oil Production at Oil Wells
302	*NLCD High Intensity Development*	695	Well Count - Oil Wells
303	*NLCD Open Space*	696	Gas Production at Gas Wells
304	NLCD Open + Low	697	Oil Production at Gas Wells
305	NLCD Low + Med	698	Well Count - Gas Wells
306	NLCD Med + High	699	Gas Production at CBM Wells
307	NLCD All Development	*710*	*Airport Points*
308	NLCD Low + Med + High	711	Airport Areas
309	NLCD Open + Low + Med	801	Port Areas
310	NLCD Total Agriculture	*805*	*Offshore Shipping Area*
318	*NLCD Pasture Land*	*806*	*Offshore Shipping NEI2014 Activity*
319	NLCD Crop Land	*807*	*Navigable Waterway Miles*
320	NLCD Forest Land	808	2013 Shipping Density
321	NLCD Recreational Land	820	Ports NEI2014 Activity
340	*NLCD Land*	850	Golf Courses
350	NLCD Water	860	Mines
500	*Commercial Land*	*890*	*Commercial Timber*

Land cover data from the 2011 National Land Cover Database (NLCD) were used to create several revised and new surrogates for the 2014 NATA modeling. We used the attributes in the NLCD that classify land as “Developed, Low Intensity,” “Developed, Medium Intensity,” “Developed, High Intensity,” and “Developed, Open Space,” along with combinations of these classifications.

In addition, we processed annual average daily traffic (AADT) data from the highway performance monitoring system (HPMS) to develop an activity-based on-network surrogate, and we updated Urban/Rural Restricted/Unrestricted road miles to use urban and rural distinctions consistent with the roadway classifications in MOVES.

Spatial surrogates were assigned to emissions sources based on SCC. Ancillary files providing the surrogate assignments and that describe the data used for the surrogates are available in the Supplemental Data provided with this TSD. Summaries of emissions by surrogate code are provided in the 2014v7.1 TSD.

For the onroad sector, the on-network (RPD) emissions were allocated differently from the off-network (RPP and RPV). On-network emissions were allocated based on AADT data and off network used land use surrogates as shown in Table 2-16. Emissions from the extended (i.e., overnight) idling of trucks were assigned to surrogate 205 that is based on locations of overnight truck parking spaces. This surrogate’s underlying data were updated for use in the 2014 NATA modeling to include additional data sources and corrections based on comments received on the 2011 NATA.

Table 2-16. Off-network mobile source surrogates

Source type	Source Type Name	Surrogate ID	Description
11	Motorcycle	307	NLCD All Development
21	Passenger Car	307	NLCD All Development
31	Passenger Truck	307	NLCD All Development
32	Light Commercial Truck	308	NLCD Low + Med + High
41	Intercity Bus	258	Intercity Bus Terminals
42	Transit Bus	259	Transit Bus Terminals
43	School Bus	506	Education
51	Refuse Truck	306	NLCD Med + High
52	Single Unit Short-haul Truck	306	NLCD Med + High
53	Single Unit Long-haul Truck	306	NLCD Med + High
54	Motor Home	304	NLCD Open + Low
61	Combination Short-haul Truck	306	NLCD Med + High
62	Combination Long-haul Truck	306	NLCD Med + High

For the oil and gas sources in the np_oilgas sector, the spatial surrogates were updated to those shown in Table 2-17 using 2014 data consistent with that used to develop the 2014 NEI nonpoint oil and gas emissions.

Table 2-17. Spatial surrogates for oil and gas sources

Surrogate Code	Surrogate Description
670	Spud Count - CBM Wells
671	Spud Count - Gas Wells
672	Gas Production at Oil Wells
673	Oil Production at CBM Wells
674	Unconventional Well Completion Counts
676	Well Count - All Producing
677	Well Count - All Exploratory
678	Completions at Gas Wells
679	Completions at CBM Wells
681	Spud Count - Oil Wells
683	Produced Water at All Wells
685	Completions at Oil Wells
686	Completions at All Wells
687	Feet Drilled at All Wells
691	Well Counts - CBM Wells
692	Spud Count - All Wells
693	Well Count - All Wells
694	Oil Production at Oil Wells
695	Well Count - Oil Wells
696	Gas Production at Gas Wells

Surrogate Code	Surrogate Description
697	Oil Production at Gas Wells
698	Well Count - Gas Wells
699	Gas Production at CBM Wells

2.3. Preparation of Emissions Inputs for AERMOD

Unlike emissions modeling for CMAQ, there were no tools[1] to perform emissions modeling for AERMOD until the 2014 NATA. For the 2014 NATA, we developed the capability in SMOKE to produce helper files that could be further post-processed to generate the source (SO) Pathway for AERMOD. The SO Pathway contains the source location and parameter information used by AERMOD. Helper files provide information about source location, release characteristics and temporal variability. They also provide source emissions. For sources in the CONUS, helper files also provide the column and row of the 12-km meteorological grid cell associated with the appropriate meteorological data (see also Section 3) to use for the emission source. Helper file formats and information vary by the type of source. For example, some emissions sources are point sources, some are gridded and some (like ports) are defined by polygon shapes. Gridded sources use different grid resolutions depending on their location (e.g., all Alaska gridded sources are 9 km^2) and/or the type of source.

The SMOKE interface for AERMOD models each source using a unit emissions rate rather than actual pollutant-specific emissions. The location, source parameter and temporal helper files join to produce the SO Pathway for each source's AERMOD run. AERMOD provides source-specific concentrations per unit emissions rate (also known as χ/Q, abbreviated here as X/Q) that are not pollutant specific (but are source specific). These concentrations are then combined with pollutant-specific emissions for each source, using the emissions helper file from the emissions modeling process, to create the pollutant- and source-specific concentrations as shown below.

$$C_{\text{pollutant i}} = \frac{X}{Q} \times \text{Emissions}_{\text{pollutant i}}$$

Because we are using a unit emission rate in AERMOD, we do not account for chemistry or deposition that would be specific to any individual pollutant.

The format and content of the helper files vary by type of source, and we have chosen to organize the creation of separate sets of helper files by "run group." A run group is a set of sources that use similar source characterization methods or parameters. Run groups allow us to combine sources with similar characteristics and run them in AERMOD together, even though they may have very different emissions. The emissions from the specific sources in the run group can then be applied to the source group X/Qs to create source-specific concentrations. We also combine the sources within the run group into source groups, which is the source-level resolution of concentration and risk results for NATA.

A difference from previous NATAs is the allocation of county-level emissions to grid cells, as opposed to census tract sources. This was done for both CONUS and non-CONUS (i.e., Alaska, Hawaii, Puerto Rico and the Virgin Islands) sources; however, different grid cell resolutions were used, as discussed below.

[1]EMS-HAP (EPA 454/B-03-006, 8/2004) is written in SAS and requires a SAS license. In addition, it was designed based on a previous inventory schema and would not be able to be used with the current NEI.

2.3.1. Source and Run Groups – Overview

Source and run groups are similar, but serve different functions in NATA. Source groups provide source attribution for the NATA census tract risk results.

Run groups organize sources for modeling in AERMOD to minimize the number of separate model runs. It would be resource prohibitive to run the thousands of different source classification codes separately in AERMOD, so we grouped them into a manageable number of run groups that all have the same spatial resolution, approach for temporal variation and release characteristics (height and sigma-z). Run groups typically have multiple source groups, though two of them (OILGAS and RWC) have the same source group as run group.

The inventory run groups are shown in Table 2-18. Those modeled in AERMOD as AREA sources using grid cells (i.e., "AREA (gridcell)") were gridded from county level to grid cells using the same underlying surrogate data (shape files) used in CMAQ.

Table 2-18. Run groups for AERMOD

Run Group	NEI Data Category	NATA Category	Resolution of Inventory Prior to Emissions Modeling	Modeled in AERMOD as:
Point	Point	Point, Nonroad[1]	Point	POINT, AREA (fugitive)
Airport	Point	Nonroad	Point	POINT, AREA (runway)
Onroad On-network LD (LDON)	Onroad	Onroad	County	AREA (gridcell)
Onroad Off-network LD (LDOFF)	Onroad	Onroad	County	AREA (gridcell)
Onroad On-network HD (HDON)	Onroad	Onroad	County	AREA (gridcell)
Onroad Off-network HD (HDOFF)	Onroad	Onroad	County	AREA (gridcell)
Onroad Off-network-hoteling (extended idling and auxiliary power units) (HOTEL)	Onroad	Onroad	County	AREA (gridcell)
Onroad On-network LD (LDON)	Onroad	Onroad	County	AREA (gridcell)
Nonroad (NONRD)	Nonroad	Onroad	County	AREA (gridcell)
Nonpoint 10-meter release height (NPHI)	Nonpoint	Nonpoint	County	AREA (gridcell)
Nonpoint low-level release height (NPLO)	Nonpoint	Nonpoint, Nonroad[2]	County	AREA (gridcell)
Nonpoint Oil and Gas (OILGAS)	Nonpoint	Nonpoint	County	AREA (gridcell)
Nonpoint Residential Wood Combustion (RWC)	Nonpoint	Nonpoint	County	AREA (gridcell)
Nonpoint Agricultural Livestock (AG)	Nonpoint	Nonpoint	County	AREA (gridcell)
Nonpoint Oil and Gas (OILGAS)	Nonpoint	Nonpoint	County	AREA (gridcell)
Commercial Marine Vessels (CMV)	Nonpoint	Nonroad	Shapes	POLYGON

[1]Rail yards.
[2]Locomotives.

The run groups modeled as grid cells have different resolutions: 3 kilometers for all grid cells in Hawaii, Puerto Rico and the Virgin Islands; 9 kilometers for all grid cells in Alaska, and either 12 or 4 kilometers for grid cells in the CONUS, depending on the run group. These are summarized in Table 2-19.

Table 2-19. Resolution of the run groups modeled as gridded sources

Run Group (resolution is the value of the number in the run group abbreviation)	CONUS GRID: 12US1	Alaska GRID: 9AK1	Hawaii GRID = 3HI1	Puerto Rico & Virgin Islands GRID = 3PR1
Onroad On-network LD (LDON)	LDON4	LDON9AK	LDON3HI	LDON3PR
Onroad Off-network LD (LDOFF)	LDOFF12	LDOFF9AK	LDOFF3HI	LDOFF3PR
Onroad On-network HD (HDON)	HDON4	HDON9AK	HDON3HI	HDON3PR
Onroad Off-network HD (HDOFF)	HDOFF12	HDOFF9AK	HDOFF3HI	HDOFF3PR
Onroad Off-network-hoteling (extended idling and auxiliary power units) (HOTEL)	HOTEL4	HOTEL9AK	N/A	N/A
Nonroad (NONRD)	NONRD12	NONRD9AK	NONRD3HI	NONRD3PR
Nonpoint 10-meter release height (NPHI)	NPHI12	NPHI9AK	NPHI3HI	NHI3PR
Nonpoint low-level release height (NPLO)	NPLO12	NPLO9AK	NPLO3HI	NPLO3PR
Nonpoint Oil and Gas (OILGAS)	OILGAS4	OILGAS9AK	OILGAS3HI	N/A
Nonpoint Residential Wood Combustion (RWC)	RWC12	RWC9AK	RWC3HI	N/A
Nonpoint Agricultural Livestock (AG)	AG12	N/A	N/A	N/A

N/A means there are no emissions for this run group in this grid.

Table 2-20 and Table 2-21 describe the source characteristics of these run groups and how they relate to the platform sectors used for CMAQ emissions modeling. Note that the run groups developed for the county-level emissions were treated differently for CONUS versus non-CONUS domains. For the CONUS, we allocated to grid cells using the spatial resolution in the table. For the non-CONUS areas (AK, HI, PR, VI), we used these same run groups but allocated to tracts rather than grid cells. Design documents for the generation of the helper files for on-road, nonroad and nonpoint sources in CONUS and non-CONUS areas are provided in the Supplemental Data files.

Table 2-20. Non-gridded AERMOD run groups

Run Group	NEI Category and NATA CMAQ Sector	AERMOD Modeling Features: Release Height (RH; meters), Initial Vertical Dispersion (σ_z; meters) and Temporal Approach	Description of Sources
POINT	**NEI:** point **Platform:** ptegu, pt_oilgas, ptnonipm	Release parameters for individual release points at each facility are taken from the 2014 NEI, with defaulting done for missing or out-of-range parameters. **Spatial**: Use specific geographic coordinates for stacks (“POINT”) and geographic coordinates along with fugitive length and width for fugitives (“AREA”). **Temporal**: Temporal profiles based on SCC codes for ptnonipm; based on continuous emissions monitoring data for ptegu.	All NEI point sources containing NATA HAP emissions except for facility source type 100 (airports).

Run Group	NEI Category and NATA CMAQ Sector	AERMOD Modeling Features: Release Height (RH; meters), Initial Vertical Dispersion (σ_z; meters) and Temporal Approach	Description of Sources
AIRPORTS	**NEI:** point Platform: ptnonipm	**RH**=3 σ_z =0 **Spatial:** For runway-area (line) sources: length based on a database containing runway endpoint coordinates; 50-m width for the major airports, 25-m width for the OTAQ-provided (smaller) airports. All facility emissions (NEI) spread equally over the runway(s). For nonrunway sources: 10-m-square area centered on NEI coordinates. **Temporal:** monthly/day-of-week/hourly profiles. Different profiles for Alaska seaplanes.	Airport Facilities in the point inventory – all emissions where facility source type code = 100 (airports). Includes seaplane ports and heliports, Emissions used at the facility unit's process release point. For these facilities all sub-facility emissions (airplane landing and takeoffs, ground support equipment) are summed to the facility level, and are treated the same way with regards to spatial and temporal allocation.
CMV	**NEI:** Nonpoint Platform: cmv	C1/C2 uses **RH** = 8.4 and σ_z = RH/2.15. C3 uses RH = 20 and σ_z = 40.7 based on CMAQ vertical emissions. **Spatial**– polygon shapes updated from the 2014 NEI v1-inventory shapes (there could be multiple polygons per port). Underway shapes use the same simplified shapes developed for the 2011 NATA. **Temporal:** monthly profiles in the SMOKE ancillary file. C1/C2 is flat except for Great Lakes state in which the monthly profile varies by county. C3 uses a monthly profile that puts slightly more emissions in the summer months.	C1/C2 and C3 commercial marine vessels at ports or underway.

Table 2-21. AERMOD gridded run groups

Run Group	NEI Category and NATA CMAQ Sector	AERMOD Modeling Features: Release Height (RH; meters), Initial Vertical Dispersion (σ_z; meters) and Temporal Approach	Description of Sources
LDON4 LDON9AK LDON3HI LDON3PR	**NEI:** on-road **Platform:** on-road	**RH** = 1.3, σ_z = 1.2, Resolution is 4 km for CONUS, 9 km for AK and 3 km for HI, PR, VI. **Temporal:** monthly temporal variation is pollutant-specific and county-specific. County-specific hourly profiles are the same for all pollutants based on benzene hourly emissions from SMOKE-MOVES (aggregate only SCCs in this run group).	On-network light duty mobile emissions such as passenger car exhaust and light duty passenger truck brake and tire wear. Emissions derived from SMOKE-MOVES. Includes refueling since temporal profile and spatial surrogate for on-network is a better match for refueling than off-network.

Run Group	NEI Category and NATA CMAQ Sector	AERMOD Modeling Features: Release Height (RH; meters), Initial Vertical Dispersion (σ_z; meters) and Temporal Approach	Description of Sources
LDOFF12 LDOFF9AK LDOFF3HI LDOFF3PR	**NEI:** on-road **Platform:** on-road	**RH** = 0.5, σ_z = 0.5, Resolution is 12 km for CONUS, 9 km for AK and 3 km for HI, PR, VI. **Temporal:** same approach as LDON4, but aggregate only SCCs in the LDOFF run group to compute hourly profiles.	Off-network light duty mobile emissions such as passenger car and passenger light truck start emissions. Derived from SMOKE-MOVES. Tailpipe height (no turbulence).
HDON12 HDON9AK HDON3HI HDON3PR	**NEI:** on-road **Platform:** on-road	**RH** = 3.4, σ_z = 3.2, Resolution is 4 km for CONUS, 9 km for AK and 3 km for HI, PR, VI. **Temporal:** monthly temporal variation is pollutant-specific and county-specific. County-specific hourly profiles based on **$PM_{2.5}$** hourly emissions from SMOKE-MOVES (aggregate only SCCs in this run group).	On-network heavy duty mobile emissions such as running exhaust from combination long haul and short haul trucks and buses. Includes brake and tire wear. Derived from SMOKE-MOVES.
HDOFF12 HDOFF9AK HDOFF3HI HDOFF3PR	**NEI:** on-road **Platform:** on-road	**RH** = 3.4, σ_z = 0.5, Resolution is 12 km for CONUS, 9 km for AK and 3 km for HI, PR, VI. **Temporal:** same approach as HDON run groups, but use only SCCs in the HDOFF run groups to compute hourly profiles.	Off-network heavy duty mobile emissions such as start emissions from combination long haul and short haul trucks and buses: Derived from SMOKE-MOVES. Minimal dispersion for start emissions. Tailpipe height (no turbulence.
HOTEL4 HOTEL9AK	**NEI:** on-road **Platform:** on-road	**RH** = 3.4, σ_z = 0.5, Resolution is 4 km for CONUS, 9 km for AK and 3 km for HI, PR, VI. **Temporal:** same approach as HDON run groups, but use only SCCs in the HOTEL run groups to compute hourly profiles.	Extended idling and auxiliary power units (APU) that occur at truck stops. Minimal dispersion for hoteling (e.g., extended idling) emissions. Tailpipe height (no turbulence).
NONRD12 NONRD9AK NONRD3HI NONRD3PR	**NEI:** nonroad **Platform:** nonroad	**RH** = 2, σ_z = 1, Resolution is 12 km for CONUS, 9 km for AK and 3 km for HI, PR, VI. **Temporal:** monthly temporal variation is pollutant-specific and county-specific. County-specific diurnal scalars computed based on **benzene** hourly emissions for the aggregate of all SCCs in this run group summed across all days of the year.	Nonroad equipment such as lawn mowers, turf equipment, agriculture and construction equipment, commercial generators, power-washing equipment, pleasure craft, recreational off-road.
NPHI12 NPHI9AK NPHI3HI NPHI3PR	**NEI:** nonpoint **Platform:** some of nonpt	**RH**=10, σ_z = 4.7, Resolution is 12 km for CONUS, 9 km for AK and 3 km for HI, PR, VI **Temporal:** uniform monthly/day-of-week. diurnal: Use SMOKE hourly profile 26 – mostly daytime emissions-(use qflag HROFDY).	Industrial processes (e.g., chemical plants, refineries, mines, metals); fuel combustion – industrial, commercial, institutional and residential (except wood); waste disposal.

Run Group	NEI Category and NATA CMAQ Sector	AERMOD Modeling Features: Release Height (RH; meters), Initial Vertical Dispersion (σ_z; meters) and Temporal Approach	Description of Sources
NPLO12 NPLO9AK NPLO3LO NPLO3PR	**NEI:** nonpoint **Platform:** some of nonpt	**RH** = 3.9, σ_z = 3.6, Resolution is 12 km for CONUS, 9 km for AK and 3 km for HI, PR, VI. **Temporal:** same as NPHI run groups.	Solvents (consumer, commercial); surface coating; commercial cooking; locomotives, bulk terminals, gas stations (stage 1); miscellaneous non-industrial (portable gas cans, auto repair shops, structure fires, and nonpoint mercury categories such as human cremation, dental amalgam).
OILGAS4 OILGAS9AK OILGAS3HI	**NEI:** nonpoint **Platform:** np_oilgas	**RH**=10, σ_z =4.7, Resolution is 4 km for CONUS and 9 km for AK. There are no emissions in HI, PR or VI. **Temporal:** monthly profiles that align with the county/scc temporal profiles used in CMAQ v7.1 platform. Use qflag= MONTH and generate county-specific run group monthly profiles based on benzene emissions aggregated over all SCCs within each county.	Oil and gas sources reported in the nonpoint NEI data category (i.e., county-level emissions).
RWC12 RWC9AK RWC3HI	**NEI:** nonpoint **Platform:** rwc	**RH** = 6.4, σ_z = 3.2, Resolution is 12 km for CONUS, 9 km for AK and 3 km for HI. There are no emissions in PR or VI. **Temporal:** hourly by grid cell based on county-specific hourly emissions (created by SMOKE using year-to-day factors derived from meteorological data that are used for many SCCs in this sector)-for all 8760 hours in the year-based on benzene emissions summed by hour and county across all SCCs in the run group.	Fireplaces, woodstoves, hydronic heaters used for residential heating.
AG12	**NEI:** nonpoint **Platform:** ag	**RH** = 1, σ_z = RH/2.15 = 0.465 m. Resolution is 12 km. There are no emissions in AK, HI, PR or VI. **Temporal:** hourly profile based on ammonia hourly emissions for the Ag emissions sector (which includes both livestock and fertilizer).	Miscellaneous area sources; agriculture production – livestock, beef cattle – finishing operations, dairy cattle – drylot/pasture dairy-confinement; swine production – operations; poultry production.

Each run group contains one or more source groups for purposes of presenting the NATA results. There are no situations where a source group fits into multiple run groups. The 2014 NATA uses groups similar to the 2011 NATA. The key differences are that mobile source groups were expanded and some nonpoint source groups from the 2011 NATA were combined. Table 2-22 lists these source groups.

Table 2-22. NATA source groups

2014 NATA Source Group Name	NATA Category	Source Group Description	Source Group Definition Compared to 2011 NATA	2014 Run Group
PT-StationaryPoint	POINT	All facilities in the POINT data category that have geographic coordinates other than those with facility type = 100 (which are in the "Airport" source group) or facility type = 151 (which are in the "Railyard" source group)	Same as 2011 NATA	POINT
OR-LightDuty-OffNetwork-Gas	Onroad	On-road, light duty, nondiesel (i.e., gasoline & ethanol blends) vehicles – off network processes (e.g., "starts")	Different grouping	LDOFF
OR-LightDuty-OffNetwork-Diesel	Onroad	On-road, light duty, diesel vehicles – off network processes (e.g., "starts")	Different grouping	LDOFF
OR-HeavyDuty-OffNetwork-Gas	Onroad	On-road, heavy duty**, nondiesel** vehicles – off network processes (e.g., "starts")	Different grouping	HDOFF
OR-HeavyDuty-OffNetwork-Diesel	Onroad	On-road, heavy duty, diesel vehicles – off network processes (e.g., "starts")	Different grouping	HDOFF
OR-LightDuty-OnNetwork-Gas	Onroad	On-road, light duty, **nondiesel** vehicles – on network processes (e.g., running emissions)	Different grouping	LDON
OR-LightDuty-OnNetwork-Diesel	Onroad	On-road, light duty, diesel vehicles – on network processes (e.g., running emissions)	Different grouping	LDON
OR-HeavyDuty-OnNetwork-Gas	Onroad	On-road, heavy duty, **nondiesel** vehicles – on-network processes (e.g., "running")	Different grouping	HDON
OR-HeavyDuty-OnNetwork-Diesel	Onroad	On-road, heavy duty, diesel vehicles – on-network processes (e.g., "running")	Different grouping	HDON
OR-Refueling	Onroad	On-road refueling	Same as 2011 NATA	LDON
OR-HeavyDuty-Hoteling	Onroad	On-road, heavy duty diesel vehicle extended idling and auxiliary power units	Different grouping	HOTEL
NR-Recreational-inc-PleasureCraft	Nonroad	Off-road motorcycles, snow mobiles, golf carts, outboard pleasure craft, personal watercraft, inboard/sterndrive pleasure craft, etc.	New category – nonroad are broken out into equipment categories	NONRD
NR-Construction	Nonroad	Paving equipment, plate compactors, trenchers, tampers/rammers, tractors/loaders/backhoes, cranes, signal boards/light plants, etc.	Same as above	NONRD
NR-CommercialLawnGarden	Nonroad	Mowers, leaf blowers, turf equipment, chippers/ stump grinders, tillers, chainsaws, snow blowers, etc.	Same as above	NONRD

2014 NATA Source Group Name	NATA Category	Source Group Description	Source Group Definition Compared to 2011 NATA	2014 Run Group
NR-ResidentialLawnGarden	Nonroad	Mowers, leaf blowers, tillers, chainsaws, snow blowers, shredders, etc.	Same as above	NONRD
NR-Agriculture	Nonroad	Agricultural tractors, combines, sprayers, balers, tillers, irrigation sets, swathers, etc.	Same as above	NONRD
NR-CommercialEquipment	Nonroad	Generator sets, pressure washers, pumps, hydropower units, etc.	Same as above	NONRD
NR-AllOther	Nonroad	Industrial Equipment (Forklifts, sweepers/scrubbers, other oil field equipment), logging equipment, railroad maintenance, underground mining equipment	Same as above	NONRD
NR-CMV_C1C2_ports	Nonroad	Commercial marine vessel (CMV) emissions – C1/C2 while at ports	C1/C2 are separate from C3; in 2011 they were combined	NR-CMV
NR-CMV_C3_ports	Nonroad	CMV emissions – C3 while at ports	Same as above	NR-CMV
NR-CMV_C1C2C3_underway	Nonroad	CMV emissions – both C1/C2 and C3 marine – while underway	Same as 2011 NATA	NR-CMV
NR-Locomotives	Nonroad	Locomotive emissions	Same as 2011 NATA	NPLO12
NR-Point-Airports	Nonroad	Point source inventory where facility type = 100 "Airport"	Same as 2011 NATA	AIRPORT
NR- Point-Railyards	Nonroad	Point source inventory where facility type = 151 "Rail Yard"	Same as 2011 NATA	POINT
NP-industrial	Nonpoint	Nonpoint mining and quarrying, paved and unpaved roads, food and kindred products, mineral products, chemical manufacturing, non-ferrous metals and nonpoint industrial processes not elsewhere classified	Combines: NP refinery, NP chemical mfg, NP-nonferrous metals, NP- mining, NP NEC	NPHI
NP-CommercialCooking	Nonpoint	Commercial cooking (charbroiling, frying)	Same as 2011 NATA	NPLO
NP-OilGas	Nonpoint	Oil and gas operations (pumps, dehydrators, tanks, engines	Same as 2011 NATA	OILGAS
NP-SolventsCoatings	Nonpoint	Degreasing, dry cleaning, consumer and commercial solvents, industrial surface coating, non-industrial surface coating	Adds degreasing, dry cleaning, consumer and commercial solvents, industrial surface coating, non-industrial surface coating	NPLO

2014 NATA Source Group Name	NATA Category	Source Group Description	Source Group Definition Compared to 2011 NATA	2014 Run Group
NP-StorageTransfer_ BulkTerminals_GasStage 1	Nonpoint	Bulk terminals, petroleum, organic and inorganic chemical storage and transport – has gas station emissions of only stage 1 (tank refueling) not stage 2 (vehicle refueling)	Bulk terminals, storage and transport – has gas station emissions of only stage 1 (tank refueling) not stage 2 (vehicle refueling)	NPLO
NP-MiscellaneousNonindustrial	Nonpoint	Poultry/livestock, laboratories, dental alloy, motor vehicle fires, portable fuel containers, residential charcoal grilling	Same as 2011 NATA except that charcoal grilling is a new NEI category for 2014	NPLO
NP-FuelCombustion_not_RWC	Nonpoint	Residential, industrial, commercial and institutional (ICI) fuel combustion, but excludes residential wood combustion	Combines residential and ICI fuel combustion	NPHI
NP-ResidentialWoodCombustionRWC	Nonpoint	Residential wood combustion – woodstoves, fireplaces	Same as 2011 NATA	RWC
NP-WasteDisposal	Nonpoint	Open burning, yard and household waste, managed burning, slash (logging debris), onsite incineration, waste water treatment, composting, landfills, scrap materials	Combines landfills and other waste disposal	NPHI
NP- AgriculturalLivestock	Nonpoint	Emissions from livestock waste (HAPs only)	New for 2014	AG
FIRE	FIRE	CMAQ category only: wildfires, prescribed fires and agricultural burning; while the modeled results are not separated by type of fire, the tabular emissions summary breaks out the three fire types separately		
BIOGENICS	BIOGENICS	CMAQ category only: VOCs and particular HAPs (formaldehyde, acetaldehyde and methanol) emitted from vegetation (and NOX from soils)		
SECONDARY	SECONDARY	Not an emissions group: formed in the atmosphere due to photochemical reactions (CMAQ)		
BACKGROUND	BACKGROUND	Not an emissions group: concentrations due to ubiquitous nature of some HAPs with long residence time or coming into the modeling domain from outside the domain such as carbon tetrachloride		

The next section describes in more detail the development of emissions and characterization of the emissions for the run groups by NEI data category.

2.3.2. Point Sources Excluding Airports

Point sources used in AERMOD are all sources in the point data category in the NEI that are in the United States, Puerto Rico or Virgin Islands;[2] have geographic coordinates present in the NEI and emit at least one HAP. This section discusses the nonairport point sources; airports are discussed in Section 2.3.3.

The starting point for the emissions modeling for point sources is the SMOKE modeling file, or FF10 discussed in Section 2.1.3. The format of this point FF10 file is in the SMOKE User's Manual https://www.cmascenter.org/smoke/documentation/4.0/html/ch08s02s08.html#sect_input_ptinv_ff10 and the file is posted on the emissions modeling platform ftp site.

The SMOKE FF10 was split into the CMAQ platform sectors (see Table 2-10) ptnonipm, ptegu and pt_oilgas, and the ptnonipm sector was further split out into airports and nonairports using the FACILITY_SOURCE_TYPE field. The FACILITY_SOURCE_TYPE indicates the type of facility (where available) and a value of "100" is used for airports (including large and small airports, heliports and seaplanes).

For purposes of AERMOD, the ptnonipm (after removal of airports) and pt_oilgas were run in the same way and were not distinguished from one another. The ptegu sector was treated differently due to different temporalization. The ptegu sector allowed for hourly variation at the unit level, whereas the ptnonipm (including pt_oilgas) used the monthly, day-of-week and diurnal profiles used by SMOKE. Within the run, each ptegu unit was temporalized using hourly emission values as discussed in Section 2.3. Non-EGU units were modeled in AERMOD using temporal allocation factors derived from the temporal profiles used in SMOKE for CMAQ. Many facilities included a mixture of EGU and non-EGU processes. In such cases, all sources at a given facility were modeled in the same AERMOD run.[3] This ensured that ambient impacts were calculated for a consistent set of receptor locations for all sources at the facility.

2.3.2.1. Point source characterization for AERMOD

In the SMOKE FF10 modeling file, a source is a unique combination of EIS process id and EIS release point id. In AERMOD, we chose to group together sources with the same release point characteristics (geographic coordinates, release point type and release point parameters) and temporal profile since they will have the same X/Qs, and grouping them reduces the number of AERMOD runs needed. This is because many processes use the same temporal profiles, so there are fewer unique combinations of these parameters than process id/release point id combinations. In the 2014 NEI, there are 75 percent fewer unique HAP sources (based on temporal and release parameters) than process-id/release point id combinations. The FF10 fields that must be unique (when combined) are: FACILITY_ID, MONTHLY temporal profile code, WEEKLY temporal profile code, ALLDAY temporal profile, ERPTYPE (except that ERPTYPEs 3, 4 and 6 are treated as equivalent), STKHT, STKVEL, STKTEMP, STKDIAM, FUG_HEIGHT, FUG_WIDTH_YDIM, FUG_LENGTH_XDIM, FUG_ANGLE, LATITUDE and LONGITUDE. Sources within the

[2]Offshore platforms (i.e., FIPS = 85; meaning federal waters) are excluded.
[3]AERMOD temporalization is performed at the level of source IDs, so using different temporalization schemes at one facility is possible.

same facility were run together in AERMOD. To assign the proper meteorological data, each facility was assigned to a grid cell based on the geographic coordinates of the release points.

Helper files were developed for point locations, point source parameters, area source parameters, temporal parameters and emissions. Point locations were based on the latitude and longitudes in the FF10 (the release point coordinates) and were converted to UTM coordinates. Point source parameters used the release point type code (field name is ERPTYPE in the FF10 file) and associated stack or fugitive parameter information from the FF10.

Table 2-23 lists the release point types and how each is assigned an AERMOD type.

Table 2-23. Assignment of AERMOD source type for point sources

Emission Release Point Type Code (NEI)	Emission Release Point Type Description	AERMOD Source Type Code or Special Adjustment
1	Fugitive	AREA
2	Vertical	POINT
3	Horizontal	POINTHOR
4	Goose neck	POINTHOR
5	Vertical with rain cap	POINTCAP
6	Downward-facing vent	POINTHOR

For AERMOD area sources, the following fields are used to characterize a fugitive release (units in parentheses):

- Latitude and longitude (decimal degrees)
- FUG_HEIGHT – fugitive height (ft)
- FUG_WIDTH_YDIM[4] – fugitive width (east/west), (ft)
- FUG_LENGTH_XDIM[4] – fugitive length (north/south), (ft)
- FUG_ANGLE– fugitive angle (degrees)

The NEI allows fugitive release angles of 0 to 89 degrees. While the fugitive release point latitude and longitude are not specified to be any particular location in the area source in the emission inventory system, due to the limits on the angle and the general conventions for specifying the source in AERMOD, we interpret the release point as the follows: 1) the lat/lon is treated as the most western corner; 2) the angle is measured clockwise from true (geodetic) north (not magnetic north); 3) length is the measure along the side that would run in the north-south direction if the angle were 0 degrees and 4) width is the measure along the side that would run in the east-west direction if the angle were 0 degrees.

As shown in Figure 2-2, the release point is at the push pin, the width is 680 feet, the length is 1897 feet and the angle is 22 degrees.

Geographic coordinates were converted to UTM, with all release points within the same facility assigned to the same UTM zone. Release parameters are converted to meters in SMOKE as required by AERMOD.

[4]These SMOKEFF10 variables will be renamed to FUG_WIDTH_XDIM and FUG_LENGTH_YDIM to keep with the convention of X as the east-west direction and Y as the north-south direction.

The initial vertical dispersion (σ_z) was set to FUG_HEIGHT/4.3 if the FUG_HEIGHT was greater than 10 meters, and 0 m if otherwise.

For AERMOD point sources, the following fields are used to characterize a stack release. The SMOKE FF10 units are listed below; they are converted to metric (m, m/s, Kelvin) as required by AERMOD.

- Latitude and longitude (decimal degrees)
- STKHGT– height of stack (ft)
- STKDIAM – diameter of stack (ft)
- STKTEMP – temperature of stream exiting stack (°F)
- STKVEL – velocity of stream exiting stack (ft/s)

Separate helper files are derived for AREA versus POINT AERMOD source types because the source parameters required for these two types differ.

Figure 2-2. Example fugitive source characterization: NEI length = 1897 feet, width = 680 feet and angle = 22

2.3.2.2. Point source temporalization

As in CMAQ, point sources in the ptnonipm sector of the NATA CMAQ platform were modeled differently in AERMOD from those in the ptegu sector with respect to the temporalization of the emissions. The ptegu sectors were temporalized allowing for hourly variation at the unit level, whereas the ptnonipm and pt_oilgas sectors used the monthly, day-of-week and diurnal profiles used by SMOKE for the CMAQ platform. Within the run, each ptegu unit was temporalized using hourly emission values

as discussed below. Non-EGU units were modeled in AERMOD using temporal allocation factors derived from the temporal profiles used in SMOKE for CMAQ. Many facilities included a mixture of EGU and non-EGU processes. In such cases, all sources at a given facility were modeled in the same AERMOD run.[5] This ensured that ambient impacts were calculated for a consistent set of receptor locations for all sources at the facility.

For non-EGUs, temporal helper files were prepared based on the temporal cross reference file for point sources (PTREF) and the temporal profile files (TPRO) used by SMOKE (same data as are used for CMAQ). The AERMOD scalars reflect diurnal, day-of-week and/or monthly variability and are determined from the SMOKE diurnal, weekly and monthly temporal profile values. Table 2-24 shows the temporal variability options for non-EGUs.

Table 2-24. Options for temporal variation specification in helper files

Temporal Variability	TPRO	Qflag (for AERMOD)	Number of Scalars	Notes and Calculation of Scalar Using SMOKE TPRO Fractions1
Uniform – every hour of every day emits the same amount	Monthly profile code 262, daily profile code 7, hourly profile code 24	MONTH	12	AERMOD Scalar value is equal to 1/12 for each of the 12 months (identical to profile code 262)
Monthly Variation only	Day-of-week profile code 7, hourly profile code 24	MONTH	12	AERMOD Scalar value month is $monthfrac_m$ Where $monthfrac_m$ is monthly fraction from the TPRO monthly profile assigned to the source
Diurnal Variation Only	Monthly profile code 262, day-of-week profile code 7	HROFDAY	24	AERMOD Scalar value month is $dayfrac_d$ Where $dayfrac_d$ is the diurnal fraction from the TPRO diurnal profile assigned to the source
Month and hour of day type variation in which M-F is the same, but Sat and Sunday can be different	Diurnal profile code same for all weekdays	MHRDOW	864 (=24hrs*3day types*12 months)	AERMOD Scalar value = $monthfrac_m * dayfrac_d * hourfrac_h$ Where $monthfrac_m$ is the monthly fraction, $dayfrac_d$ is the day-of-week fraction and $hourfrac_h$ is the diurnal fraction for each hour for weekdays, Saturday and Sunday from the TPRO 5 × sum of weekday scalars + sum of Saturday scalars + sum of Sunday scalars = 1

[5]AERMOD temporalization is performed at the level of source IDs, so using different temporalization schemes at one facility is possible.

Temporal Variability	TPRO	Qflag (for AERMOD)	Number of Scalars	Notes and Calculation of Scalar Using SMOKE TPRO Fractions1
Month and hour of day variation and every day of the week could be different	Diurnal profile code varies by day-of-week	MHRDOW7	2016 (=24 hrs*7 day types * 12 months)	AERMOD Scalar value = $monthfrac_m * dayfrac_d * hourfrac_h$ Where $monthfrac_m$ is the monthly fraction, $dayfrac_d$ is the day-of-week fraction and $hourfrac_h$ is the diurnal fraction for each hour every day of the week from the TPRO Sum of scalars is 1

For EGUs, hourly temporalization was used, based on continuous emission monitoring data for heat input. The approach is the same as used in CMAQ and is described in more detail in the 2014v7.1 modeling platform TSD. For AERMOD, separate facility-specific helper files were developed with the hourly scalars for each hour of the year.

2.3.3. Airport Point Sources

Airports are in the SMOKE point FF10 file and can be identified by the FACILITY_SOURCE_TYPE field "100" (for an airport facility). We modeled airports as one of two types: runway line sources or small (10- by 10-meter) area sources. The runway airports are those for which we have geographic coordinates for the runway endpoints from either the 2014 National Transportation Atlas Database or the OTAQ-supplied database used for the 2011 NATA. The nonrunway airports have no runway information and were modeled as small area sources. These include smaller airports, seaplanes and heliports. Although there may be multiple processes at an airport (e.g., commercial aircraft emissions and ground support equipment emissions), we did not treat them differently with respect to source characterization. Emissions at an airport were summed and apportioned equally among the runways or to the small area source. Airports have multiple sources in the AERMOD helper files only if the airport had more than one runway.

Runway information is not in the NEI. The NEI has a site latitude and longitude, and all release points (fugitives) use the site coordinates. To get runway endpoints, we matched the NTAD/OTAQ databases with the NEI emissions. Non-matches (NEI facilities with no match to NTAD/OTAQ based on airport identifiers, or NEI facilities with coordinates inconsistent with the runway locations) were modeled as area sources based on the NEI coordinates. Matches were done using the airport location id (typically a 3- or 4-character field), which is an alternate facility id in EIS and is the id used for the NTAD/OTAQ airports. The starting-point airport facilities and final runway airports resulting from the matching effort, and detailed set of process steps taken to do the matching, are available in the Supplemental Data folder. This process resulted in 7,384 nonrunway airports and 11,991 runway airports.

2.3.3.1. Airport characterization for AERMOD

For runway airports, an airport source is a runway at an airport facility; for nonrunway airports, an airport source is a 10-by-10-meter area source at an airport facility. Runways are modeled as AERMOD "LINE" sources, using the coordinates of the runway endpoints, which are assumed to be in the center of the runway width. All runways are assumed to be 50 meters wide (NTAD-based runways) or 25 meters wide (OTAQ-based runways) and have a release height and initial vertical dispersion of 3 meters. All pollutant emissions are divided equally across all runways at the airport.

Airports without runway characterization are modeled as 10m by 10 m area sources with the same release height and vertical dispersion as runway airports. The NEI airport coordinates are used as the southwest corner of the area source and the angle is 0.

2.3.3.2. Airport temporalization

Airports used a single set of temporal profiles for all processes within the airport, since the emissions from all processes are combined on the airport runways or as the small area sources.

All airports use the same set of monthly, day-of-week and diurnal profiles except for Alaska seaplanes.

For airports other than Alaska seaplanes, weekly and monthly temporal profiles are based on 2014 data from the FAA Operations Network Air Traffic Activity System (Figure 2-3) (http://aspm.faa.gov/opsnet/sys/Terminal.asp). A report of all airport operations (takeoffs and landings) by day for 2014 was generated. These data were then summed to month and day-of-week to derive the monthly and weekly temporal profiles. An overview of the Operations Network data system is at http://aspmhelp.faa.gov/index.php/Operations_Network_%28OPSNET%29. These are profile codes 727 (monthly) and 747 (weekly). For Alaska seaplanes, we used the flat weekday profile and spring/summer weighted profile as used in the 2011 NATA. The Alaska sea plane profile codes are 8888 (monthly) and 7 (weekly).

For airports other than Alaska seaplanes, hourly airport operations data were obtained from the Aviation System Performance Metrics (ASPM) Airport Analysis website (https://aspm.faa.gov/opsnet/sys/airport.asp). A report of 2014 hourly Departures and Arrivals for Metric Computation was generated. An overview of the ASPM metrics is at http://aspmhelp.faa.gov/index.php/Aviation_Performance_Metrics_%28APM%29. For Alaska seaplanes, we used the same spring/summer-weighted monthly profile that was developed in the 2011 NATA. The profile code is 777. For Alaska seaplanes, we used the same diurnal profile as 2011 NATA, which zeroes out emissions prior to 6 am or after 10 pm (see Figure 2-4).

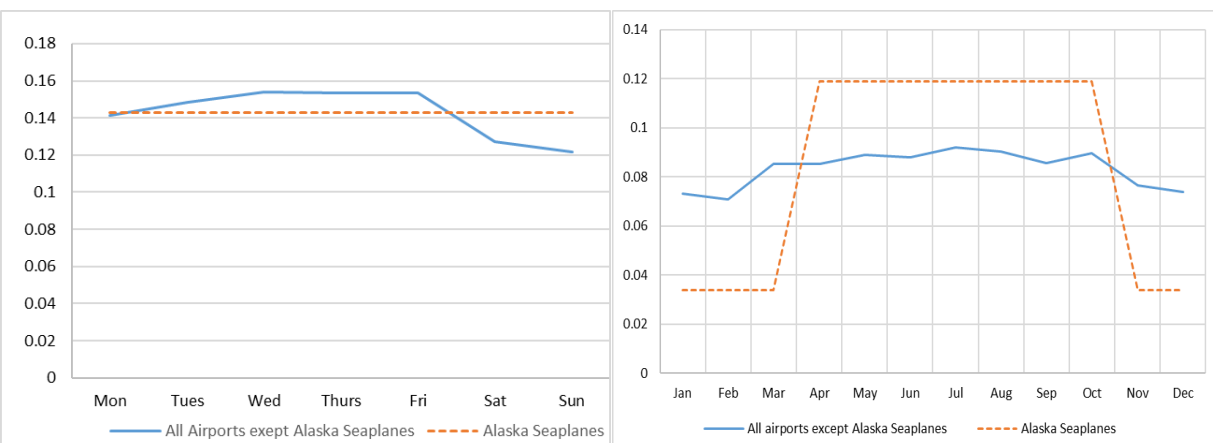

Figure 2-3. Airport weekly and monthly temporal profiles

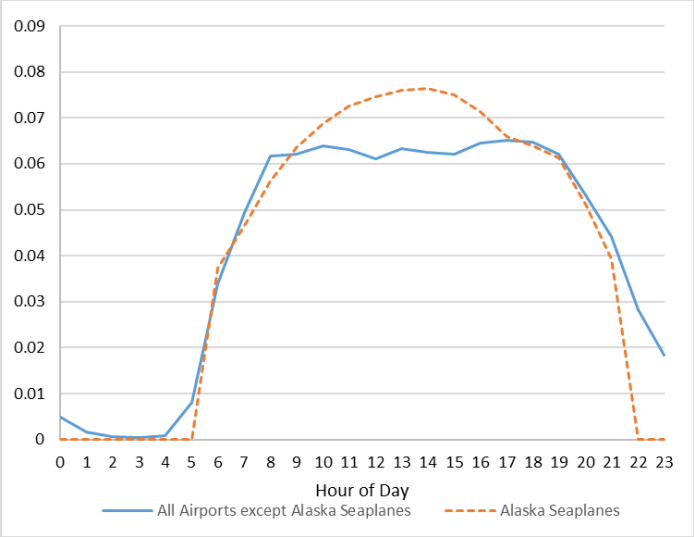

Figure 2-4. Airport diurnal temporal profiles

2.3.3.3. Airport emissions

Emissions are applied to X/Qs for airports differently than other point sources. Instead of multiplying the source-based emissions to the X/Qs, we multiply the *total facility* emissions to a facility-aggregated X/Q, which for runway airports is the aggregate across all runways. In creating the emissions inputs to AERMOD, the unit emission rate, 1000 g/s, is the unit emission rate for the entire airport, not each runway. To apportion the 1000 g/s to each runway, the 1000 g/s is divided by the number of runways. AERMOD then outputs the annual average concentration for the entire airport, not each runway. The annual average concentrations reflect the apportionment between the different runways. Because it can be assumed that each runway will get the same share of actual HAP emissions as the unit emission rate based on the fraction variable, the specific HAP emissions for the entire airport can be used instead of runway-specific emissions. This approach reduces the number of records in both the emissions helper file used for X/Q and the AERMOD annual average concentration output file based on the unit emission rate.

The NEI estimated that lead emissions from piston aircraft totaled 456 TPY, nationally. Of these emissions, the NEI estimated that lead emitted during several modes of operation at and near airports totaled 228 TPY. These estimates were used in NATA. The NEI also estimated in-flight lead emissions at the state level, which happened to equal the lead emitted from the piston aircraft (228 TPY). In-flight lead emissions were not included in NATA. Lead emissions near airports included lead emitted during the climb-out and approach modes, which occur at altitude and are not included in NATA. To account for this, we adjusted the NEI-specific lead[6] emissions estimates used in AERMOD down by 50 percent, based on previous modeling conducted at the Santa Monica (SMO) airport indicating that nearly 50 percent of emissions occurred in these higher-altitude modes (see Table 2-25).

[6]We designed the programs to reduce all metals from the following 2 SCCs: 2275050011=General Aviation /Piston and 2275060011=Air Taxi /Piston by 50%; however, the only metal emissions from these 2 SCCs are lead, so only lead was reduced.

Table 2-25. Lead emissions (kg/yr) at SMO in 2008 by aircraft operation mode

Mode	Emissions (% of Total)
Taxi to runway	20.4 (17.6%)
Run-up	13.5 (11.4%)
Takeoff roll	10.0 (8.4%)
Climb-out	37.9 (32.7%)
Approach	17.9 (15.8%)
Landing	9.4 (7.9%)
Taxi to apron	9.5 (8.4%)

The emissions helper file format for runway and nonrunway airports is the same and is shown in Table 2-26.

Table 2-26. Airport emissions file format

Field Name	Description
State abbrev	2-character abbrev. Use TB for tribe
Facility id	Identifer for facility (i.e., EIS ID)
Facility name	Facility name
FAC_SOURCE_TYPE	Code indicating facility type (from SMOKEFF)
pollutant name	Use SMOKE shortname
Emissions (tons)	Emissions from the SrcID multiplied by the Metal/CN speciation factor (column AI) from the NATA_Pollutants.xslx) For airports, for metals only, multiply metal pollutant emissions from (2275050011=General Aviation /Piston; 2275060011=Air Taxi /Piston) by 0.5

2.3.4. Nonroad, On-road and Nonpoint – County-level Sources

Nonroad, on-road and nonpoint (other than CMVs and locomotives) sources in the NEI are estimated at the county level and use various levels of temporal variation. For AERMOD, we characterize these as "AREAPOLY" sources, which provide an emission flux over a defined polygon shape. We also characterize the temporal variability based on the various options available in AERMOD.

The main steps needed to prepare county-level sources for AERMOD are spatial allocation, assignment of temporal scalar factors and assignment of release parameters. County-level sources must undergo spatial allocation prior to being input into AERMOD. All county-level sources are allocated to finer resolution using spatial surrogates. For CONUS domain sources, they are allocated to 4-km or 12-km resolution, and the size is primarily based on our confidence in the surrogate data at fine resolution and its representativeness of the source category for which it is being used. For non-CONUS county-level sources, they are allocated to 9-km resolution (Alaska) or 3-km resolution (Hawaii, Puerto Rico and the Virgin Islands). This is a major difference from the 2011 NATA approach, which allocated county-level emissions to census tracts. Mostly, the same underlying surrogate data are used for AERMOD as CMAQ and are discussed in detail in the TSD developed for CMAQ emissions (2014v7.1 Emissions TSD).

Table 2-15 through Table 2-17 provide the available surrogates. One difference is that the National Land Cover (NLCD) data are not available for Hawaii, Puerto Rico and the Virgin Islands (i.e., grids 3HI and 3PR), so an alternative land cover database, the Coastal Change Analysis Program (C-CAP) database was used for the land cover categories. C-CAP does not have as many categories as the NLCD; low and medium intensity land was not available and other land categories were substituted. For example, if the surrogate called for open+low, then only open was used in the 3HI and 3PR grids. Another difference is that CMAQ uses 12 km for all gridded emissions whereas AERMOD uses 4 km for some of the source groups in the CONUS; also, CMAQ does not cover non-CONUS areas. As in CMAQ, the spatial surrogates are assigned according to SCC codes. The SCC-to-surrogate cross reference and surrogate documentation workbook is provided in the Supplemental Data folder.

In addition to spatial allocation, the emissions are temporally allocated to capture the temporal variability of emissions throughout the year, day and/or hour of day. Temporal allocation is done because not all emissions are emitted uniformly throughout the year. Ideally each specific SCC (and in some cases SCC and county) would be given a different temporal profile as is done when preparing emissions for CMAQ. But because all sources in the same run group must have the same scalars, we need temporal scalars that best represent the aggregation of the individual SCCs. In addition, these scalars, apart from onroad and nonroad mobile run groups, do not vary by pollutant because AERMOD is run at a unit emissions rate and the pollutant-specific emissions are applied after the model is run. The scalars can vary by county. For the onroad and nonroad mobile categories, AERMOD preserves the pollutant-specific monthly variation.

For each run group, SMOKE is used to produce AERMOD helper files that provide the locations and coordinates of the gridded sources, the area source parameters, the temporal scalars and the emissions by source and pollutant, broken out by run group.

The subsections below provide more information on how the emissions are developed and modeled in AERMOD. Detailed information on the development of the emissions at county level is provided in the 2014 NEI v2 TSD.

2.3.4.1. On-road

On-road uses 5 run groups: LDON4, LDOFF12, HDON4, HDOFF12 and HOTEL4, as described in Table 2-21. These run groups distinguish on-network (ON) versus off-network (OFF) sources, heavy-duty versus light-duty sources, and hoteling (extended idling and auxiliary power units).

For characterization, the release height of LD ON vs OFF is different (1.3 m vs. 0.5 m) to account for added dispersion from the vehicle wake. Sigma-z is also different (1.2 vs. 0.5) to account for more dispersion on the roads. Off-network sources use minimal dispersion associated with start emissions (no turbulence). HD on and off and hoteling (which is pertinent only to HD vehicles) use the same release height based on average tailpipe height (3.4 m) but different dispersion. Sigma-z for on-network is 3.2 m, but for off-network and hoteling it is 0.5 m to account for less dispersion during idling.

On-network sources and hoteling use finer resolution (4 km vs 12 km) in the CONUS domain than for off-network. This is because we have more confidence in the spatial surrogates used to allocate the county-level emissions. The on-network sources use AADT data, whereas the off-network emissions are allocated to broad classes of land use data. Off-network exhaust and evaporative emissions from passenger cars are allocated to the “all development” land category, which consists of the sum of the following land categories: developed, open space; developed, low intensity; developed, medium

intensity; and developed, high intensity. This is land with greater than zero percent impervious surface. For HI, PR and VI, which use C-CAP, there is no low or medium intensity, so it is the sum of open space and high intensity. Hoteling uses a set of truck stops that have been updated since the 2011 NATA.

The temporal resolution for onroad run groups is hourly across the year. Different profiles were developed for off-network than on-network due to the types of mobile processes (running vs. starts, for example) that occur. They are also different for heavy duty versus light duty because of the different vehicle mixes (trucks vs. cars). For the v2 modeling platform, more refined temporal profiles were developed for the diurnal variation in vehicle miles travelled based on telematics data analyzed under the CRC Project A-100 (ERG 2017).

In developing the hourly scalars for CONUS areas, we used the SMOKE-MOVES hourly emissions reports by county and SCC for a key pollutant for each run group. We chose $PM_{2.5}$ for HD run groups and benzene for LD run groups. We then aggregated emissions across all SCCs in that run group. Hourly emissions were converted to local time (considering daylight saving time where appropriate). SMOKE-MOVES was run only for the CONUS. National averages were used for non-CONUS temporal profiles.

Because we run grid cells (and not counties) in AERMOD, we assigned each grid cell to a county for purposes of assigning county-specific hourly emissions. Due to the unit emissions rate, we could not account for differences across pollutants in temporal variation, which can occur due to different temperature impacts on EFs that vary by pollutant, except at the monthly level. We imparted monthly variation to on-road run groups by pollutant by running unit emissions rates by SEASON to get season-specific X/Q values, and then by post-processing the X/Q by at the seasonal level (i.e., applying seasonal emissions). This is further discussed in Section 3.4.

The temporal variability of on-road mobile sources varies by emissions process (e.g., running vs. idling), vehicle type, road type and pollutant. Different pollutants can have different temporal variation because some pollutants' emission factors depend on meteorology, which has diurnal variation.

Figure 2-5 and Figure 2-6 show example Wednesday and Sunday diurnal profiles in April for King County, WA (55033), Cook County, IL (17031) and Wake County, NC (37183). The single-unit short-haul starts appear to peak in the morning, and that peak is particularly pronounced for $PM_{2.5}$. Other pollutants do not show such a large gradient.

For non-CONUS areas, we used hourly scalars by run group that were developed by taking a national average of the hourly scalars in the CONUS area.

2.3.4.2. Nonroad

Nonroad equipment, i.e., emissions other than planes, trains and ships that are generated by MOVES, are put into a single run group. While there are differences in types of equipment and therefore emissions characterization, for this national study we chose to use a more simplified approach by characterizing equipment with the same spatial resolution, temporal profile and release characteristics.

The release characteristics are a release height of 2 meters and an initial vertical dispersion of 1 meter, the same as used for the 2011 NATA. We chose a spatial resolution of 12 km for the CONUS domain; however, we used a variety of spatial surrogates for different SCCs. For example, for agricultural nonroad SCCs such as combines, tractors and balers, agricultural land from NLCD was used, whereas for

pleasure craft, water (also from NLCD) was used. For non-CONUS, we also used land use surrogates and allocated to grid cells.

For the 2014 NATA, we revised the temporal allocation approach used in the 2011 NATA to be more consistent with changes made for the 2014 modeling platform for the diurnal variation. We changed the diurnal profile from profile 26, which puts a considerable portion of emissions at night (as shown in Figure 2-7), to county-specific nonroad average profiles based on the equipment-specific profiles shown in Figure 2-7. These profiles remove the nighttime emissions from lawn & garden and agriculture (profile code 25a), remove night time and early morning emissions from residential lawn and garden (profile code 27), and reduce the nighttime emissions from construction (profile code 26a). County-specific profiles enable us to account for the different mix of nonroad equipment in different counties. We used benzene to create the county-specific averages. The county-specific profiles are represented by the gray band in Figure 2-8; selected counties are provided for reference. Similar to the 2011 NATA, we did not use the weekday variation used in the modeling platform, which is less important than diurnal variation in terms of impact of emissions/meteorological iterations.

We revised the seasonal variation to run AERMOD monthly by applying pollutant specific monthly emissions to the X/Q. Note that the month-specific emissions applied were at source group resolution, not SCC-level resolution.

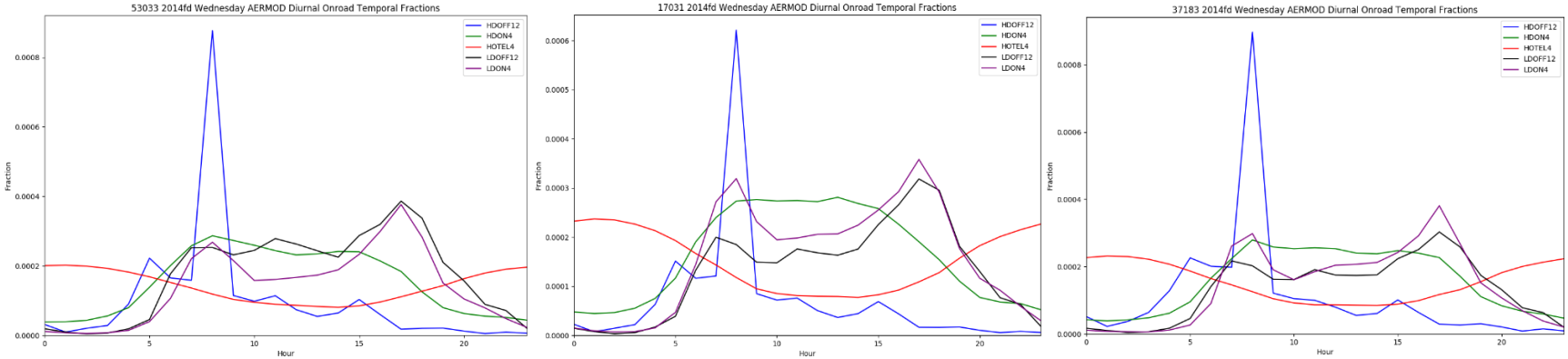

Figure 2-5. On-road weekday diurnal temporal profiles for King County, WA (55033); Cook County, IL (17031) and Wake County, NC (37183)

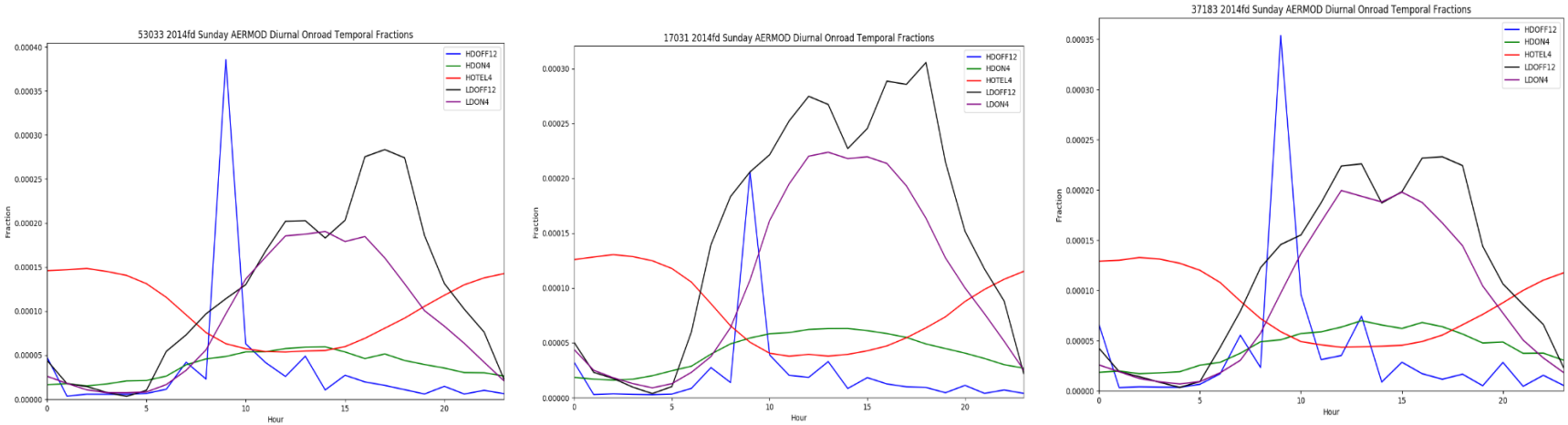

Figure 2-6. On-road Sunday diurnal temporal profiles for King County, WA (55033); Cook County, IL (17031); and Wake County, NC (37183)

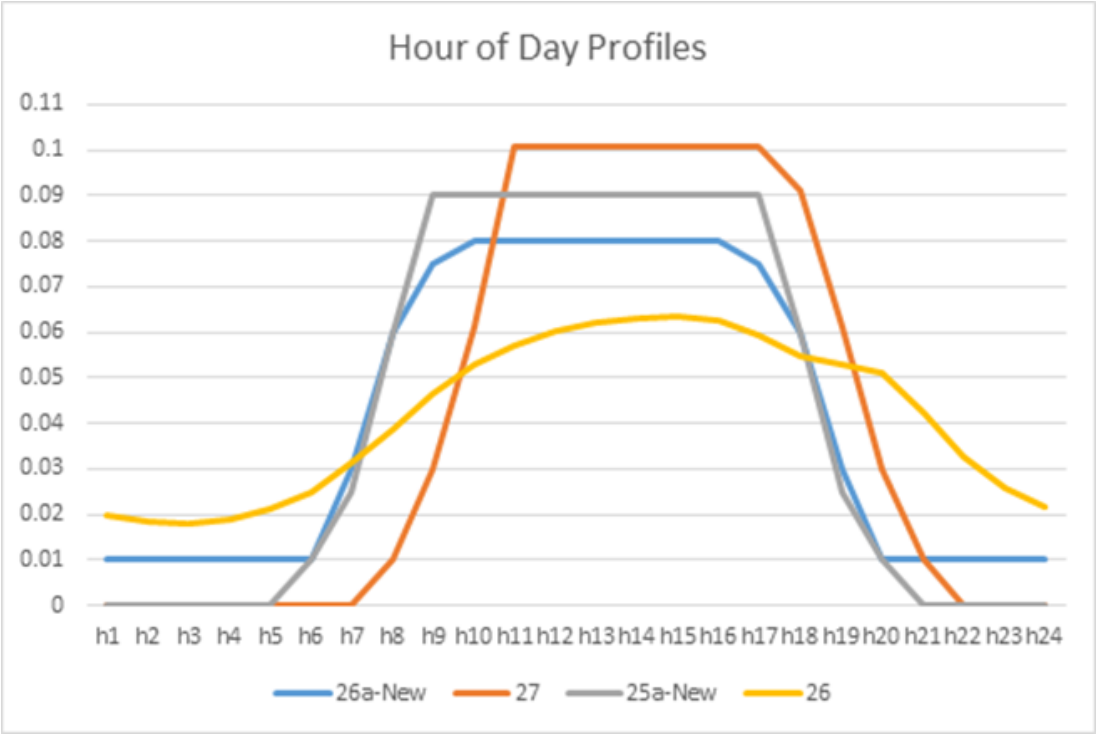

Figure 2-7. Hourly pattern of activity for SMOKE Profile 26

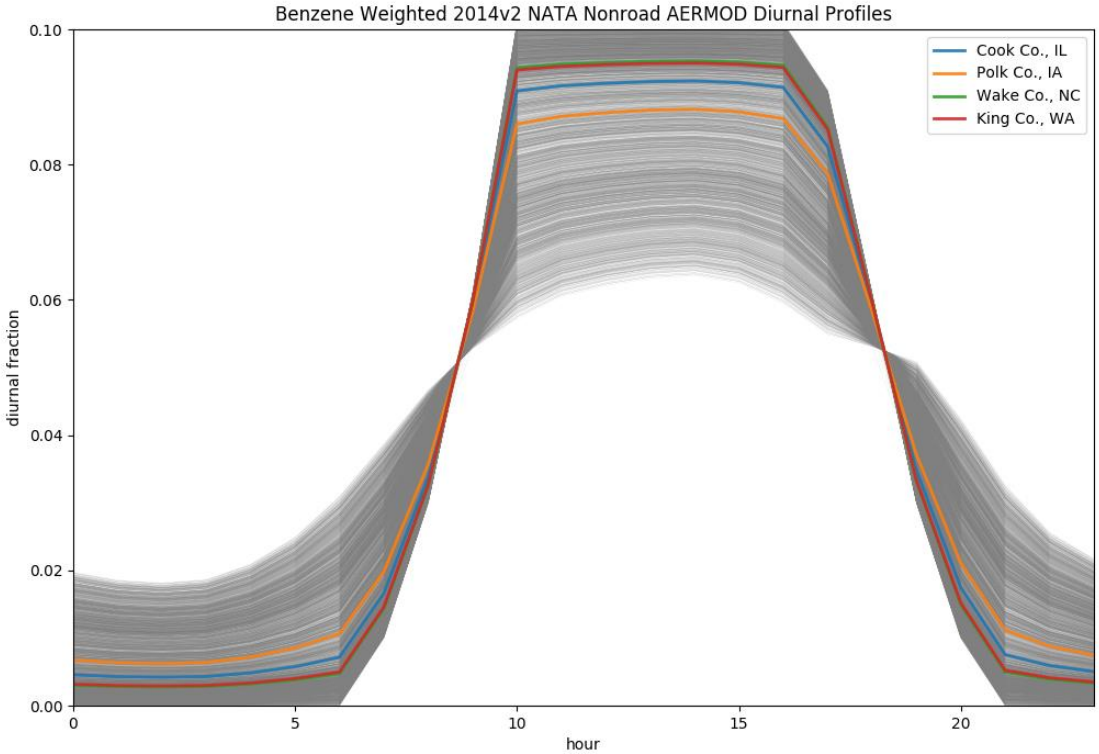

Figure 2-8. Hourly pattern of activity for county-average profiles used for the nonroad run group in AERMOD modeling

2.3.4.3. Nonpoint – NPHI12 and NPLO12

Nonpoint stationary sources are broken out into several run groups: NPHI, NPLO, RWC and OILGAS. NPHI and NPLO are very similar; they use the same temporal profile (diurnal profile 26, which is shown in Figure 2-7 and uniform weekday and monthly profiles. They are allocated to a 12-km spatial resolution (12 km for CONUS sources and a 9- or 3-km resolution for non-CONUS). NPHI uses a release height of 10 meters and an initial vertical dispersion of 4.7 meters, which is based on release height/2.15. NPLO uses a release height of 3.9 meters and an initial vertical dispersion of 3.6 meters. Because we combined all fuel combustion other than Residential Wood Combustion (RWC) into a single run group, we had to move residential nonwood combustion, which had been characterized with the lower release height/vertical dispersion in the 2011 NATA, to the NPHI12, which uses the same release height as industrial, commercial and institutional (ICI) fuel combustion.

Other than locomotive emissions, the two nonpoint run groups are the same as the CMAQ "nonpt" sector. The CMAQ "nonpt" sector excludes locomotive emissions, which are in the NPLO run group.

2.3.5. Residential Wood Combustion

As in the 2011 NATA, this is a source group that has its own run group; i.e., the run group and source group are identical. It is separate from other run groups because its temporalization, which depends on daily temperature, is unique. This run group comprises wood stoves (indoor and outdoor) and fireplaces. The NEI SCC codes are 2104008* (includes wood stoves and fireplaces, fire pits/chimneas and hydronic heaters) and 2104009000 (fire logs).

We used the same release height and initial vertical dispersion as in the 2011 NATA – 6.4 m height and 3.2 m vertical dispersion. All SCCs in the source group used the same spatial surrogate: NLCD Low Intensity Development.

The temporal approach is the same as used in 2011, which used temperature data to assign emissions to days of the year. This was done using the "Gentpro" feature of SMOKE that was developed specifically for this sector, as the level of residential wood combustion activity depends on the daily minimum temperature. For 2014, we took the same approach using 2014 meteorological data. Diurnal profiles based on device type were also applied. For AERMOD, we took the SMOKE-generated hourly emissions by SCC and created the temporal scalars using benzene emissions for all SCCs by hour of the year. Hourly scalars were computed by county as:

$$Scalar_{hour\text{-}i} = 8760 * (Benzene)_{county,hour\text{-}i} / \Sigma_{all\ hours,county}(Benzene)$$

To assign grid cells to counties, we used the county having the most RWC HAP emissions.

Puerto Rico and the Virgin Islands do not have any emissions for this source group. For Alaska and Hawaii, the hourly scalars were computed in the same way as the CONUS scalars. However, the underlying data SMOKE used for generating the hourly benzene emissions were not based on day-specific meteorological data. Instead, monthly temporal profiles for Alaska and Hawaii were calculated from the national average of the 2014 meteorology-based profiles, and SMOKE SCC-to-profile mappings were used for daily and diurnal variation.

2.3.6. Oil and Gas

This run group covers all nonpoint oil and gas sector emissions in the NEI. It contains only one source group – the oil and gas source group. The main purpose for breaking nonpoint oil and gas sources out of the NPHI run group (as they were characterized in the 2011 NATA modeling) was to allow a finer spatial allocation resolution – 4 km as opposed to 12 km in the CONUS. A finer spatial resolution was chosen because the surrogates are based on well locations from a commercially available database called HPDI that compiles oil and gas data (such as individual well locations, production information, drilling information and well completion data) from state databases – the same underlying data used by the Oil and Gas tool during the creation of the NEI. Because of the different types of activity data underlying the tool, there are numerous spatial surrogates applied to the various SCCs that make up the nonpoint oil and gas category. The same source of data (HPDI) was used to develop temporal profiles by county and SCC. This run group uses only monthly variation. County-specific monthly scalars were computed from benzene monthly emissions across all SCCs from the run group in the county (as shown below). If for a certain county there are no benzene emissions, then the sum of all HAPs was used.

$$\text{Scalar}_i = \frac{\text{Benzene}_i}{\#\text{ of days}_i} \times \frac{1}{\sum \frac{\text{Benzene}_i}{\#\text{ of days}_i}}$$

Where:

Benzene$_i$	=	the tons of benzene in month i for the county associated with the met grid cell across all SCCs in OILGAS
# of days$_i$	=	the number of days in month i

The release height chosen is the same as NPHI – 10 m height and 4.7 m for the initial vertical dispersion.

2.3.7. Agricultural Livestock

Like oil and gas, this run group contains just the one source group – agricultural livestock. These emissions are new to the 2014 NEI v2, as previously neither VOC nor the HAP components were estimated. We kept this run group separate due to the different temporal nature of livestock emissions from other nonpoint run groups and to be consistent with the temporal allocation used in CMAQ. In CMAQ, these emissions were modeled in the “ag” sector and use a meteorologically based temporalization. For AERMOD, a separate run group was created for consistent temporalization across the two models. For AERMOD, hourly scalars were computed from hourly ammonia emissions. The release height chosen was 1 m, and 0.465 m for the initial vertical dispersion.

2.3.8. Commercial Marine Vessels – County/Shape-level Sources

This run group has the same sources as the cmv_c1c2 and cmv_c3 CMAQ modeling sectors except that for AERMOD, we include only sources in U.S. state or territory waters, whereas in CMAQ, ships in federal waters were also included. The NEI inventory uses different SCCs to distinguish between ships that are at ports (hoteling or maneuvering) versus ships that are moving along waterways, or “underway” (cruising or in low speed zones), and uses different SCCs for diesel versus residual oil ships. The NEI provides emissions by port or underway “shape,” which are drawn to provide sub-county geographic resolution of the cmv emissions. In all, there are four SCCs in this run group. Table 2-27 lists the SCCs in the CMV run group.

Table 2-27. 2014NEI SCCs covered in the CMV run group

SCC	Sector	Description: Mobile Sources Prefix for All
2280002100	cmv	Marine Vessels; Commercial; Diesel; Port
2280002200	cmv	Marine Vessels; Commercial; Diesel; Underway
2280003100	cmv	Marine Vessels, Commercial; Residual; Port emissions
2280003200	cmv	Marine Vessels, Commercial; Residual; Underway emissions

For AERMOD, each source is characterized by a polygon shape with multiple vertices and SCC. The polygon shape is based on the NEI shape. It is assumed that the emissions are homogeneous in each polygon. The port polygon shapes are identical to the NEI port shapes; these were updated for the 2014 NEI v2. Note that in the NEI, a single port may be characterized by multiple NEI polygon port shapes. The polygon emissions for all polygons within a single port are proportional to the total port emissions based on the shape's area compared to the total area of all polygons for that port. The underway shapes were the same as used in the 2011 NATA except for a few new shapes in Puerto Rico and a few other areas. The NATA underway polygons were simplified from the NEI underway shapes such that multiple simplified polygons were constructed to represent complex NEI underway shapes. For underway shapes, the emissions of the simplified shape are assumed proportional to the NEI shape based on the simplified shape area. An example of a port shape is shown in Figure 2-9.

Figure 2-9. Port shapes for Los Angeles and Long Beach, California

One change from the NEI was to correct the county FIPS that were inadvertently used in the NEI but were no longer valid for year 2014 due to census changes. For NATA, these emissions were re-allocated to the valid counties as follows:

shape_id	old_fips	new_fips
20171	02280	02198
20190	02232	02105
20191	02232	02105
20192	02232	02105
20336	02232	02230
20539	02280	02195
20598	02201	02198
20599	02280	02275
20601	02232	02105
20602	02201	02198
20603	02201	02198
20604	02201	02275
20605	02201	02198
20619	02201	02198
20837	02232	02105

Each source's temporal profile was based on the SCC code and/or county; CMV uses only monthly variation; daily and diurnal profiles are uniform.

For the 2014 NATA, release characteristics are different for C1/C2 vessels than for C3. For C1/C2, we used a release height of 8.4 meters and an initial vertical dispersion of 3.907 meters. Category 3 vessels are larger and different release parameters were used for consistency with CMAQ. In CMAQ, C3 vessels were characterized as point sources so the model would compute plume rise. We developed the C3 AERMOD release height and initial vertical dispersion to be consistent with the characterization in CMAQ. We used the same release height, 20 m. For the initial vertical dispersion, we examined summaries of plume rise of C3 from CMAQ; in particular, we looked at a SMOKE report of the annual NO_X vertical distribution by county for the CMAQ cmv_c3 sector. For every county, we found that 50 percent of the emissions were above layer 3 and 50 percent were below. The midpoint of layer 3 is 60.7 meters. Therefore, we computed sigma-z as 60.7-20 = 40.7 m.

2.3.9. Urban/Rural Determination for All Emission Sources

The urban/rural determination for all emissions sources was based on the urban/rural classification of nearby census blocks. We classified each populated census block in the United States as urban if its centroid falls within an "urbanized area." For the 2010 Census, an urbanized area comprises a densely settled core of census tracts or census blocks, or both, that meet minimum population density requirements (50,000 or more people), along with adjacent territory. The adjacent territory generally is also densely settled, but it may also contain some lower-density areas as well as nonresidential urban land uses. About 500 such areas are included in the 2010 Census.

For point sources, each facility was designated as urban or rural based on the urban/rural classification of the nearest census-block centroid receptor to the average facility latitude/longitude (averaged across

all release points emitting HAPs). Each gridded source was designated based on the urban/rural classification of the nearest block receptor to the center of the 12-km grid cell (so all 4-km sources within the same 12-km grid cell are treated the same, based on the center of the 12-km grid cell). There were 353 grid cells on the borders of the United States that were inadvertently excluded from the approach; these were assigned a classification of rural, which would be expected based on their locations.

For CMV ports, each individual port shape was designated based on the urban/rural classification of the census block nearest to the center of the port shape. All CMV underway sources were designated as rural.

3. Air Quality Modeling and Characterization

The NATA emission estimates described in Section 2 are used as inputs to EPA air quality models to estimate ambient concentrations of emitted air toxics. An air quality model is a set of mathematical equations that uses emissions, meteorological and other information to simulate the behavior and movement of air toxics in the atmosphere. Air quality models estimate outdoor concentrations of air toxics at specified locations. The modeling approach for the HAPs in the NATA includes development and application of a hybrid approach blending a chemical transport model (CMAQ) with a dispersion model (AERMOD) to estimate ambient concentrations of about 50 of the more prevalent and higher risk HAPs as described in Section 3.5. The HAPs modeled in the hybrid approach capture a vast majority of the total risk nationally. Treatment for the remaining "non-hybrid" HAPs are described in Section 3.1.2.

3.1. Modeling Overview

3.1.1. Photochemical Model Selection

For 2014 NATA photochemical modeling, we used CMAQv5.2 (Appel et al., 2018) with the Carbon-Bond 6 (CB6-CMAQ) chemical mechanism. CMAQ is a comprehensive, three-dimensional grid-based Eulerian air quality model designed to simulate the formation and fate of gaseous and particulate species, including ozone, oxidant precursors, primary and secondary PM concentrations, and sulfur and nitrogen deposition over urban and regional spatial scales. CMAQ includes numerous science modules that simulate the emission, production, decay, deposition and transport of organic and inorganic gas-phase and pollutants in the atmosphere. CMAQv5.2 includes many updates from the previous version 5.1. The model enhancements in version 5.2 include updates to the organic aerosol treatment (via new source pathways and updated properties of secondary organic aerosol (SOA)), updates to the gas-phase photochemistry (improved treatment of rural and remote chemistry and oceanic halogen chemistry), as well as various updates to the cloud treatment. While most compounds are grouped when model chemistry is applied, the CB6-CMAQ chemical mechanism treats formaldehyde, acetaldehyde, benzene, methanol and naphthalene explicitly within the chemistry. In this version, xylene concentrations are aggregated across the xylene isomers rather than separately generating concentrations for each isomer. For more information on CMAQ, see https://www.epa.gov/air-research/community-multi-scale-air-quality-cmaq-modeling-system-air-quality-management or http://www.cmascenter.org.

Table 3-1 lists HAPs included in the multipollutant version of CMAQv5.2 used for the 2014 NATA. The table also identifies the HAPs not run in CMAQ for the 2011 NATA that are included in this assessment.

Table 3-1. CMAQ HAPs

Air Toxic	Added for 2014	2014 CMAQ Species Name(s)
1,1,2,2-Tetrachloroethane	-	CL4_ETHANE1122
1,3-Butadiene	-	BUTADIENE13
1,3-Dichloropropene	-	DICHLOROPROPENE
1,4-Dichlorobenzene(p)	-	DICHLOROBENZENE
2,4-Toluene diisocyanate	-	TOL_DIIS
Acetaldehyde	-	ALD2, ALD2_PRIMARY
Acetonitrile	YES	ACETONITRILE

Air Toxic	Added for 2014	2014 CMAQ Species Name(s)
Acrolein	-	ACROLEIN, ACROLEIN_PRIMARY
Acrylic acid	YES	ACRYLICACID
Acrylonitrile	-	ACRYLONITRILE
Arsenic	-	AASI, AASJ, ASSK
Benzene (including benzene from gasoline)	-	BENZENE
Beryllium	-	ABEK, ABEI, ABEJ
Cadmium	-	ACDI, ACDJ, ACDK
Carbon tetrachloride	-	CARBONTET
Carbon tetrachloride (without background) *	YES	CARBONTET_NOBC
Carbonyl sulfide	YES	CARBONYLSULFIDE
Chlorine	-	CL2
Chloroform	-	CHCL3
Chloroprene	YES	CHLOROPRENE
Chromium Compounds	-	ACR_VIK, ACR_VIJ, ACR_VII
Chromium Compounds	-	ACR_IIIK, ACR_IIII, ACR_IIIJ
Diesel PM *	-	ADE_ECI, ADE_ECJ, ADE_OCI, ADE_OCJ, ADE_SO4J, ADE_NO3J, ADE_OTHRI, ADE_OTHRK, ADE_K
Ethyl benzene	YES	ETHYLBENZ
Ethylene dibromide (Dibromoethane)	-	BR2_C2_12
Ethylene dichloride (1,2-Dichloroethane)	-	CL2_C2_12
Ethylene oxide	-	ETOX
Formaldehyde	-	FORM, FORM_PRIMARY
Hexamethylene-1,6-diisocyanate	-	HEXAMETHY_DIIS
Hexane	YES	HEXANE
Hydrazine	-	HYDRAZINE
Hydrochloric acid	-	HCL
Lead Compounds	-	APBK, APBJ, APBI
Maleic anhydride	-	MAL_ANHYDRIDE
Manganese Compounds	-	AMN_HAPSK, AMN_HAPSJ, AMN_HAPSI
Mercury Compounds	-	HG,HGIIGAS, APHGI, APHGJ (there is no APHGK)
Methanol	-	MEOH
Methyl chloride (Chloromethane)	YES	METHYLCHLORIDE
Methylene chloride (Dichloromethane)	-	CL2_ME
m-xylene, p-xylene, o-xylene and xylenes (isomers and mixture)	-	XYLENES
Naphthalene	-	NAPHTHALENE
Nickel Compounds	-	ANIK, ANII, ANIJ
Polycyclic Organic Matter	-	PAH_000E0
Polycyclic Organic Matter	-	PAH_176E5
Polycyclic Organic Matter	-	PAH_880E5

Air Toxic	Added for 2014	2014 CMAQ Species Name(s)
Polycyclic Organic Matter	-	PAH_176E4
Polycyclic Organic Matter	-	PAH_176E3
Polycyclic Organic Matter	-	PAH_192E3
Polycyclic Organic Matter	-	PAH_101E2
Polycyclic Organic Matter	-	PAH_176E2
Polycyclic Organic Matter	-	PAH_114E1
Propylene dichloride (1,2-Dichloropropane)	-	PROPDICHLORIDE
Quinoline	-	QUINOLINE
Styrene	YES	STYRENE
Tetrachloroethylene (Perchloroethylene)	-	CL4_ETHE
Toluene	-	TOLU
Trichloroethylene	-	CL3_ETHE
Triethylamine	-	TRIETHYLAMINE
Vinyl chloride	-	CL_ETHE

3.1.2. Dispersion Model Selection

For 2014 NATA air dispersion modeling, we used AERMOD (Cimorelli et al. 2005; EPA 2015e), a steady-state plume model that incorporates air dispersion based on planetary boundary layer turbulence structure and scaling concepts. AERMOD is EPA's preferred near-field modeling system of emissions for distances up to 50 km (EPA 2017). AERMOD version 15181 was used for all NATA rungroups except CMV due to a bug related to polygon sources in version 15181. For CMV sources, AERMOD version 16216 was used to take advantage of the bug fix for polygon sources.

3.2. Meteorological Data

3.2.1. Input WRF Data

For use in all NATA modeling, we derived gridded meteorological data for all of year 2014 for the contiguous United States from version 3.8 of the Weather Research and Forecasting Model (WRF), Advanced Research WRF (ARW) core (Skamarock et al. 2008). The WRF Model is a state-of-the-science mesoscale numerical weather prediction system developed for both operational forecasting and atmospheric research applications (https://www.mmm.ucar.edu/weather-research-and-forecasting-model). The WRF simulation used the same CMAQ map projection, a Lambert Conformal projection centered at coordinates (-97, 40) with true latitudes at 33 and 45 degrees north. The 12-km WRF domain consisted of 396 by 246 grid cells and 35 vertical layers up to 50 millibars.

3.2.2. MCIP Processing for CMAQ

The 2014 WRF meteorological outputs were processed using the Meteorology-Chemistry Interface Processor (MCIP) package (Otte and Pleim 2010), version 4.2.5, to derive the specific inputs to CMAQ: horizontal wind components (i.e., speed and direction), temperature, moisture, vertical diffusion rates and rainfall rates for each grid cell in each vertical layer. Table 3-2 shows the vertical layer structure

used in WRF and the layer-collapsing approach used to generate the CMAQ meteorological inputs. CMAQ resolved the vertical atmosphere with 25 layers, preserving greater resolution in the planetary boundary layer.

Table 3-2. Vertical layer structure for WRF and CMAQ (heights are layer top)

CMAQ Layers	WRF Layers	Sigma P	Approximate Height (m)
25	35	0.0000	17,556
	34	0.0500	14,780
24	33	0.1000	12,822
	32	0.1500	11,282
23	31	0.2000	10,002
	30	0.2500	8,901
22	29	0.3000	7,932
	28	0.3500	7,064
21	27	0.4000	6,275
	26	0.4500	5,553
20	25	0.5000	4,885
	24	0.5500	4,264
19	23	0.6000	3,683
18	22	0.6500	3,136
17	21	0.7000	2,619
16	20	0.7400	2,226
15	19	0.7700	1,941
14	18	0.8000	1,665
13	17	0.8200	1,485
12	16	0.8400	1,308
11	15	0.8600	1,134
10	14	0.8800	964
9	13	0.9000	797
	12	0.9100	714
8	11	0.9200	632
	10	0.9300	551
7	9	0.9400	470
	8	0.9500	390
6	7	0.9600	311
5	6	0.9700	232
4	5	0.9800	154
	4	0.9850	115
3	3	0.9900	77
2	2	0.9950	38
1	1	0.9975	19
Surface		1.0000	0

3.2.3. MMIF Processing for AERMOD

WRF output was processed through the Mesoscale Model Interface (MMIF) program to create AERMOD-ready meteorological input data. The MMIF produces the surface and profile files used by AERMOD. MMIF was processed for AERMOD in accordance with EPA guidance, Guidance on the Use of the Mesoscale Model Interface Program (MMIF) for AERMOD Applications (U.S. EPA 2016). As options, we used the default FLM layers (see MMIF User's Guide for details), TOP for vertical interpolation and MMIF-calculated mixing heights.

3.2.4. Meteorological Data Outside the Contiguous States

For meteorological data covering areas outside the contiguous states (Alaska, Hawaii, Puerto Rico and the U.S. Virgin Islands), we used National Weather Service observations processed through the AERMET program (version 15181). AERMET is a general purpose meteorological preprocessor that organizes meteorological data into a format compatible with AERMOD. In AERMET, we included the adjusted surface friction velocity option.

3.3. CMAQ Setup

3.3.1. Sources Modeled in CMAQ

The 2014 NATA CMAQ modeling included a 2014 base year run (primary and secondary annual average concentrations) and "zero-out" runs for biogenics and fires (primary annual average concentrations). The 2014 annual simulations included a "ramp-up" period of 10 days to mitigate the effects of initial concentrations. All 365 model days were used in the annual average levels of air toxics modeled.

The 2014 CMAQ model runs were performed for a domain covering the contiguous United States (CONUS), as shown in Figure 3-1. This single domain covers the entire CONUS and large portions of Canada and Mexico using 12-km by 12-km horizontal grid spacing. The model extends vertically from the surface to 50 millibars (approximately 17,600 meters) using a sigma-pressure coordinate system. Air quality conditions at the outer boundary of the 12-km domain were taken from a global model. Table 3-3 provides some basic geographic information regarding the 12-km CMAQ domain.

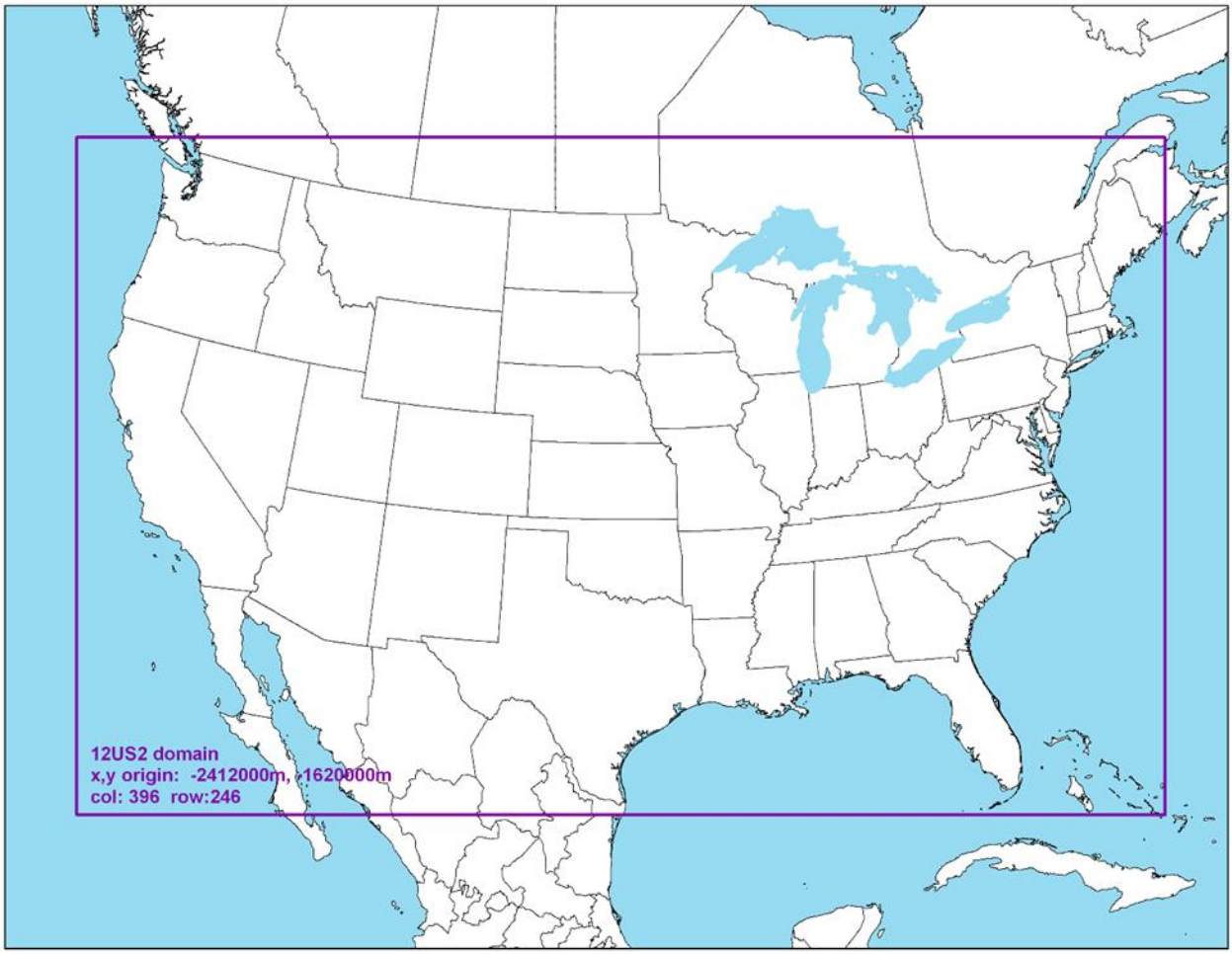

Figure 3-1. Map of the CMAQ modeling domain; the purple box denotes the 12-km national modeling domain

Table 3-3. Geographic information for the 12-km CMAQ modeling domain

12-km CMAQ Modeling Configuration	
Map Projection	Lambert Conformal Projection
Grid Resolution	12 km
Coordinate Center	97 W, 40 N
True Latitudes	33 and 45 N
Dimensions	396 x 246 x 25
Vertical Extent	25 Layers: Surface to 50 mb level (see Table 3-2)

3.3.2. Boundary and Initial Conditions

The lateral boundary and initial species concentrations are provided by a three-dimensional global atmospheric chemistry model, the GEOS-Chem (Bey et al. 2001) model version 11-01, with the SOA chemistry option and updates for lightning NOx inputs from Murray et al. (personal communication 2017-09-28). The global GEOS-Chem model simulates atmospheric chemical and physical processes

driven by assimilated meteorological observations from NASA's Goddard Earth Observing System (GEOS-5). This model was run for 2014 with a grid resolution of 4.0 degrees x 45 degrees (latitude-longitude) and 47 vertical layers. The predictions were processed using pseudonetcdf (Akhtar et al. 2012) using chemical translations comparable to Henderson et al. (2014) at three-hour intervals. Boundary conditions of formaldehyde, acetaldehyde and benzene were explicitly provided from the 2014 GEOS-Chem run. More information is available about the GEOS-Chem model and other applications using this tool at: http://gmao.gsfc.nasa.gov/GEOS/ and http://wiki.seas.harvard.edu/geos-chem/index.php/GEOS-5.

Because GEOS-Chem does not include all modeled HAPs, we also used remote concentration estimates as nonvarying background (in space and time). These were computed based on data from the five NOAA GMD sites: Cape Kumukahi, Hawaii (KUM); Mauna Loa, Hawaii (MLO); Niwot Ridge, Colo. (NWR); Barrow, Alaska (BRW); and Alert, Canada (ALT) and the Trinidad Head Site (AGAGE). More information on how these were derived is in Appendix D.

For the remaining CMAQ HAP BCs not provided by GEOS-Chem nor estimated using remote concentrations listed in Table 3-4, a value of zero was applied (shown in Table 3-5) due to a lack of data.

Table 3-4. Boundary conditions from 2014 remote concentration estimates

Pollutant	2014 Remote Concentration at STP (µg/m3)	RCE (pptv) 2014	Remote Network	Location(s)	CMAQ HAP
Chloroform	0.070	0.072	AGAGE	Trinidad Head	x
Methyl chloride (chloromethane)	1.16	0.99	NOAA GMD	KUM, MLO, NWR, BRW, ALT	x
Carbon tetrachloride	0.530	84.4	NOAA GMD	KUM, MLO, NWR, BRW, ALT	x
Methyl bromide (bromomethane)	0.028	7.2	NOAA GMD	KUM, MLO, NWR, BRW, ALT	
Methyl chloroform (1,1,1-trichloroethane)	0.020	3.7	NOAA GMD	KUM, MLO, NWR, BRW, ALT	
Dichloromethane (methylene chloride)	0.20	58.3	NOAA GMD	KUM, MLO, NWR, BRW, ALT	x
Tetrachloroethene (perchloroethylene, tetrachloroethylene)	0.013	1.9	NOAA GMD	KUM, MLO, NWR, BRW, ALT	x

Table 3-5. CMAQ HAP boundary conditions applied as zero value

Air Toxic	2014 CMAQ Species Name(s)
1,3-Butadiene	BUTADIENE13
1,3-Dichloropropene	DICHLOROPROPENE
1,4-Dichlorobenzene(p)	DICHLOROBENZENE
2,4-Toluene diisocyanate	TOL_DIIS
Acetonitrile	ACETONITRILE
Acrolein	ACROLEIN, ACROLEIN_PRIMARY
Acrylic acid	ACRYLICACID

Air Toxic	2014 CMAQ Species Name(s)
Acrylonitrile	ACRYLONITRILE
Arsenic	AASI, AASJ, ASSK
Beryllium	ABEK, ABEI, ABEJ
Cadmium	ACDI, ACDJ, ACDK
Carbon tetrachloride	CARBONTET_NOBC
Carbonyl sulfide	CARBONYLSULFIDE
Chlorine	CL2
Chloroprene	CHLOROPRENE
Chromium Compounds	ACR_VIK, ACR_VIJ, ACR_VII
Chromium Compounds	ACR_IIIK, ACR_IIII, ACR_IIIJ
Diesel PM*	ADE_ECI, ADE_ECJ, ADE_OCI, ADE_OCJ, ADE_SO4J, ADE_NO3J, ADE_OTHRI, ADE_OTHRK, ADE_K
Ethyl benzene	ETHYLBENZ
Ethylene dibromide (Dibromoethane)	BR2_C2_12
Ethylene dichloride (1,2-Dichloroethane)	CL2_C2_12
Ethylene oxide	ETOX
Hexamethylene-1,6-diisocyanate	HEXAMETHY_DIIS
Hexane	HEXANE
Hydrazine	HYDRAZINE
Hydrochloric acid	HCL
Lead Compounds	APBK, APBJ, APBI
Maleic anhydride	MAL_ANHYDRIDE
Manganese Compounds	AMN_HAPSK, AMN_HAPSJ, AMN_HAPSI
Mercury Compounds	HG,HGIIGAS, APHGI, APHGJ (there is no APHGK)
Methanol	MEOH
m-xylene, p-xylene, o-xylene and xylenes (isomers and mixture)	XYLENES
Naphthalene	NAPHTHALENE
Nickel Compounds	ANIK, ANII, ANIJ
Polycyclic Organic Matter	PAH_000E0
Polycyclic Organic Matter	PAH_176E5
Polycyclic Organic Matter	PAH_880E5
Polycyclic Organic Matter	PAH_176E4
Polycyclic Organic Matter	PAH_176E3
Polycyclic Organic Matter	PAH_192E3
Polycyclic Organic Matter	PAH_101E2
Polycyclic Organic Matter	PAH_176E2
Polycyclic Organic Matter	PAH_114E1
Propylene dichloride (1,2-Dichloropropane)	PROPDICHLORIDE
Quinoline	QUINOLINE
Styrene	STYRENE
Toluene	TOLU

Air Toxic	2014 CMAQ Species Name(s)
Trichloroethylene	CL3_ETHE
Triethylamine	TRIETHYLAMINE
Vinyl chloride	CL_ETHE

3.4. AERMOD Setup

3.4.1. Sources Modeled in AERMOD

AERMOD modeling comprised point, nonpoint, on-road and nonroad sources. We excluded fires (agricultural burning, wildfires and prescribed fires) and biogenic emissions.

3.4.2. Receptor Placement

For the CONUS domain, we used the following receptors:

1. Equally spaced "gridded" receptors (1 km in highly populated areas, 4 km otherwise)

2. 2010 populated census-block centroid receptors (discussed in Section 3.4.2.2)

3. 2014 monitoring site receptors (discussed in Section 3.4.2.3)

To facilitate the CMAQ/AERMOD hybrid modeling, we used these receptors to compute an AERMOD average concentration corresponding to each CMAQ grid cell. These concentrations could then be used in the hybrid equation. Gridded receptors were also used for interpolating to block receptors and monitor receptors. Receptors at the monitoring locations were used in the model evaluation.

For non-CONUS areas (AK, HI, PR, VI), where we do not run CMAQ, we used:

1. Census-block centroid receptors (both non-populated and populated)

2. Monitoring site receptors

3.4.2.1. Gridded receptors

We used gridded receptors throughout the CONUS area. The purposes of the gridded receptors were to provide a uniform grid in the CMAQ grid cells to adequately capture near-field concentration gradients of sources in and surrounding the grid cells and to provide a grid used to interpolate census block and monitor receptors post-modeling. We based spacing of the gridded receptors on the 2013 populations of Core Base Statistical Areas (CBSA). For CMAQ grid cells that intersected a CBSA with a population of 1 million people or more (Figure 3-2), the receptors were placed 1 km apart, resulting in 144 receptors per 12-km CMAQ grid cell. Otherwise, the receptors were placed 4 km apart, resulting in nine receptors per 12-km CMAQ grid cell. This resulted in 1.4 million receptors nationwide, with 1-km spacing used in 6,935 12-km cells and 4-km spacing used in 49,490 12-km cells. Correct receptor placement was verified by overlaying receptors with CBSA's in ArcGIS.

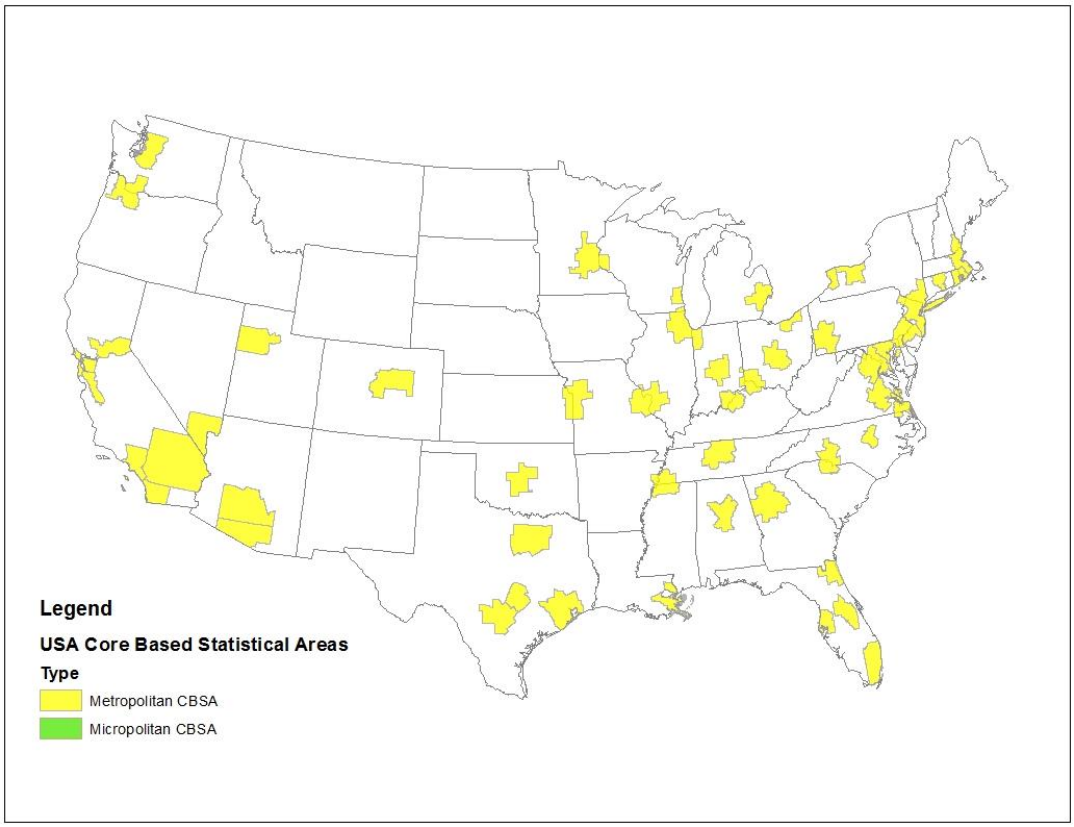

Figure 3-2. CBSAs exceeding 1 million people

Each gridded receptor, with either 1- or 4-km spacing, represented the center of a subgrid cell within the 12-km CMAQ grid cells (Figure 3-3). These gridded receptors, plus populated block and monitor receptors when available within a subgrid cell, were averaged (Figure 3-4). These subgrid-cell averages were then used to calculate the overall AERMOD average of the 12-km grid cell, which was then used in the hybrid equation that combines CMAQ and AERMOD results. Receptor elevations and hill heights were determined using AERMAP (version 11103).

0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0

0	0	0
0	0	0
0	0	0

Figure 3-3. Dense (left) and coarse (right) receptor grid layout in CMAQ Lambert Projection

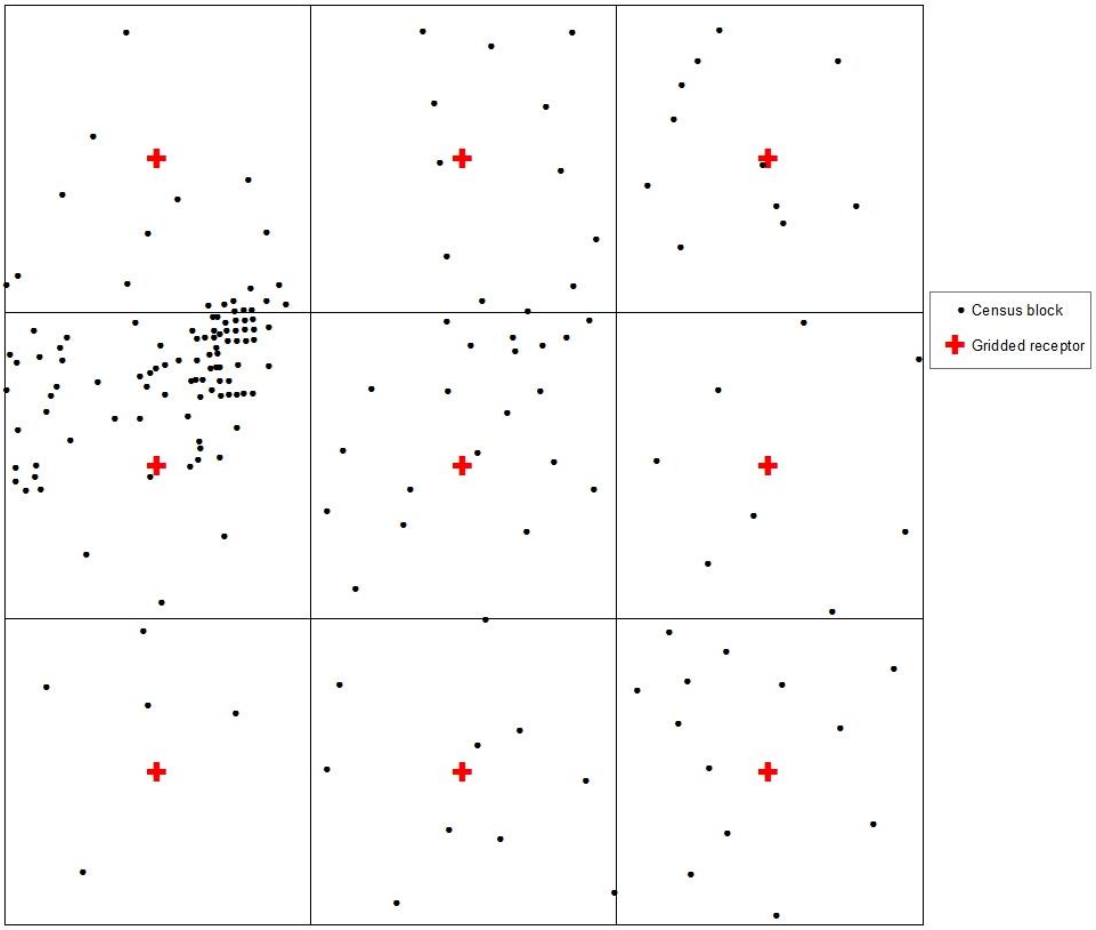

Figure 3-4. Example grid cell with subgrid cells and census blocks

When performing the dispersion modeling for point sources, gridded receptors within 50 km of any emission point at the facility were explicitly modeled in AERMOD. For airports, any gridded receptor within 50 km of any point along a runway or within 50 km of any part of the 100-by-100 m area sources was explicitly modeled. For CONUS gridded sources, any gridded receptor within 50 km of the center of the 12-km or 4-km gridded source was explicitly modeled. For ports and underway sources, any gridded receptor that was within 50 km of a side of the polygon or within 50 km of the center of the source was explicitly modeled. Gridded receptors were not modeled for the non-CONUS grid sources.

3.4.2.2. Census-block centroid receptors

The locations of census-block centroids were based on the 2010 U.S. Census (2010). When performing the dispersion modeling for point sources in the CONUS area, populated block receptors within 10 km of any emission point at the facility were explicitly modeled in AERMOD. For non-CONUS point sources, the distance was 50 km. For airports in the CONUS area, any populated block receptor within 10 km of any point along a runway or 10 km from any point of the 100-by-100 m area sources was modeled. For airports in the non-CONUS areas, the distance was 50 km. For gridded CONUS sources, census blocks were not modeled; these were later interpolated from gridded receptors during model post-processing. For ports and underway sources in the CONUS area, any block receptor within 10 km of a side of the polygon or within 10 km of the center of the source was explicitly modeled. For ports and underway emissions in the non-CONUS areas, the distance was 50 km. For the non-CONUS gridded emissions, we

used the same methods as used for CONUS gridded emissions, except the distance was 50 km instead of 10 km. For all non-CONUS sources, point, airports, etc., non-populated blocks were modeled as receptors as well using the same methodology and distance criteria as used for populated blocks. Non-populated blocks were not modeled in the CONUS area.

3.4.2.3. AERMOD receptors at monitoring sites

The Air Toxics Archive of monitoring data sites was used for the model evaluation (Section 3.7.1). Therefore, we obtained a unique set of geographic coordinates for all monitors to include as receptors in the AERMOD modeling. AERMAP (version 11103) was used to generate receptor elevations and hill heights for input into AERMOD. The modeling distance criteria used for census blocks was used for the monitor receptors.

3.4.3. Model Options

For all AERMOD runs, the FASTALL option was used to decrease model runtimes, especially for gridded, airport, CMV shapes and tract sources. For all AERMOD runs excluding point and airport sources, the FLAT option was used (terrain ignored).

For sources determined to be urban, the AERMOD urban option was used.

3.4.4. AERMOD Simulations

We ran AERMOD for each of the run groups described in Table 2-20. For the run groups that included the gridded source types in the CONUS area, gridded sources were also used as the sources in the non-CONUS areas. Receptor placement was as described in Section 3.4.2, and each source was assigned the meteorological files corresponding to the WRF grid cells in which they were located for the CONUS gridded sources. For all non-CONUS sources, the closest meteorological station to the source was used.

For the point sources and airports, each facility or airport was run in its own AERMOD run. For the point sources, each AERMOD source in the facility was its own AERMOD source group with the source group name corresponding to the AERMOD source ID. For each airport, all emissions sources were assigned to a total group (group ALL). Similarly, for the CMV runs and 12 gridded sources, each CMV shape or 12-km grid cell was run in its own AERMOD run. The CMV emissions sources in each AERMOD run were assigned to groups based on the source. For underway emissions, a single group representing all three ship types was used. For the port emissions, groups were assigned: 1) a group for C1 and C2 and 2) a C3 group. . For the 12-km gridded sources and non-CONUS gridded sources, the source was assigned to source group with the same name as the AERMOD source ID. For the 4-km gridded sources, all sources that shared the same parent 12-km grid cell and thus the same meteorological data were run together in one AERMOD run. Each 4-km source was given its own source group in the AERMOD output.

As discussed in Section 2.3 for the various run groups, different temporalization resolutions were used (hourly, monthly, etc.). The scalars from the temporal helper files were used in conjunction with the unit emission rate of 10,000 tons/year to develop hourly unit emissions for the modeled sources. For hourly emissions, this was simply the product of the hourly scalar and 10,000 tons/year, then applying a

conversion factor of 251.9957[7] to yield an emission rate in g/s. If a source was an hourly source, the resulting emission rate was divided by the area of the source to yield the correct units for AERMOD.

For sources using monthly emission factors, a weighting factor was calculated by multiplying each monthly scalar by the number of days for the month. These products were summed across all 12 months. The hourly emission rate *E* for each month *i* was then calculated as:

$$E_i = \frac{10000 \times \left({}^{EF_i}/_{Weight} \right)}{24} \times 251.9957$$

Where EF_i is the monthly scalar factor from the temporal helper file and 10,000 is the unit emission rate in tons/year. If the source was an area source, E_i was divided by the area of the source. Since each hour for a particular month has the same emission rate, the AERMOD EMISFACT keyword was used to represent the hourly emissions. The emission rate calculated above was used for the factor, and the base emission rate on the SRCPARAM line was set to 1.0 g/s or 1.0 g/s/m^2 for area sources. For emissions that varied by hour of day only, the AERMOD EMISFACT HROFDY was used and the hourly emission rate E_i for hour *i* (1–24) was calculated as:

$$E_i = \frac{10000 \times EF_i}{365} \times 251.9957$$

Where 365 represents the number of days per year.

Area sources' emission rates were divided by the area of the source.

For emissions that varied by month, day of the week, MHRDOW or MHRDOW7, and hour of day, the month weighting factor was applied in the temporal helper file. The hourly emission rate applied in AERMOD was calculated as the product of 10,000 tons/year, the emission factor, and the conversion factor of 215.9957. As with the other emission factors, area sources' emission rates were divided by the area of the source.

3.4.5. Post-processing of AERMOD Results

Post-processing of the AERMOD runs consisted of two steps: 1) interpolation of populated census blocks and monitors from gridded receptors in the CONUS domain and 2) calculation of HAP-specific concentrations. For all NATA run groups except the gridded sources, interpolation of concentrations to census blocks and monitors occurred at blocks and monitors from 10 to 50 km from the source in the CONUS domain. For the CONUS gridded source types, census blocks and monitors were interpolated 0 to 50 km from the sources. Interpolation was done for each individual facility (point source, airport, CMV shape) or gridded source. Note that interpolation was not done for the non-CONUS AERMOD runs, as all census blocks and monitors within 50 km of a source were explicitly modeled.

For a receptor located between four gridded receptors, the concentration at the receptor was based on linear interpolation between the four gridded receptors. For receptors near the 50-km edge of the

[7] 215.9957 is the conversion factor from tons/hr to g/s.

modeling domain and thus without four receptors around it, the interpolated receptor's concentration was the average of the nearest gridded receptors.

For nonmobile NATA run groups (point, airports, CMV, nonpoint, RWC, oil and gas, non-CONUS nonroad) the HAP/source group-specific concentrations at each receptor were calculated by dividing the HAP emissions (tons/year) for each source group at each AERMOD source by 10,000 tons/year.

For the mobile run groups (excluding nonroad in non-CONUS areas), the HAP/source group-specific concentrations were calculated based on monthly emissions. The AERMOD output for these rungroups was average concentrations by month. AERMOD also output the hours that had missing or calm meteorological data. Only hours that were noncalm and not missing in the meteorological data were included in the averaging, consistent with the calculation of long-term concentrations in AERMOD. The following methodology was used to calculate the annual average HAP/source group specific concentrations at each receptor:

1. Multiply the concentration from the monthly output file by the number of valid hours for the particular month based on review of the AERMOD errors file. Add the resulting product to a running total of concentration for each month and modeled source group.

2. Interpolate the results from step 1 to unmodeled census/blocks and monitors within 50 km for each facility or gridded source.

3. For each season, multiply the total calculated in step 1 and 2 by the ratio of the source group's monthly HAP emissions (tons/month) to the modeled monthly emissions (based on 10,000 tons/year) listed in the AERMOD output file.

4. Add the result from step 3 to a running total across all months. Also for each month, loop through the months to determine the total number of valid hours for the year. If all meteorological data hours were noncalm and not missing, this results in a total of 8,760 hours. The number may be less if calms and missing data are present in the meteorological data.

5. Divide running total concentration from step 4 by the running total of hours from step 4 to calculate an annual average HAP/source group-specific concentration. This division of concentration by hours is equivalent to how AERMOD calculates annual average concentrations in a simulation, a sum of hourly concentrations divided by the number of noncalm and nonmissing hours.

Once HAP/source group-specific concentrations are calculated for each gridded receptor, block receptor and monitor receptor, the resulting concentrations were output for input into the hybrid program.

3.5. Hybrid Modeling

The hybrid approach combines the annual concentration results from the AERMOD and CMAQ models to compute ambient concentrations at census block receptors. The 2014 NATA used largely the same approach used for the 2011 NATA. The main differences are the computation of the average AERMOD concentration for each grid cell, the inclusion of more HAPs in CMAQ (and thus the hybrid and the treatment of carbon tetrachloride, a HAP present mainly in background concentrations). The subsections below contain discussions on the hybrid air modeling approach used for the 2014 NATA.

3.5.1. Overview

For 52 of the most prevalent and highest risk air toxics (see Table 3-1), we used a hybrid air quality modeling method combining the fine spatial scale and source attributions of AERMOD (Cimorelli et al. 2005; EPA 2015e) with the full treatment of chemistry and transport afforded by CMAQ. In this application, AERMOD treated all species as chemically nonreactive. The emissions and meteorological data sets used in CMAQ were processed further to generate AERMOD inputs consistent with CMAQ. AERMOD receptor locations were based on the centroids of populated census blocks, monitoring-site positions, and evenly distributed points within each 12-km horizontal CMAQ grid cell in the CONUS (see Figure 3-1 and Figure 3-5), resulting in at least nine, and sometimes more than 10,000, receptors per cell and 6.5 million receptors nationwide.

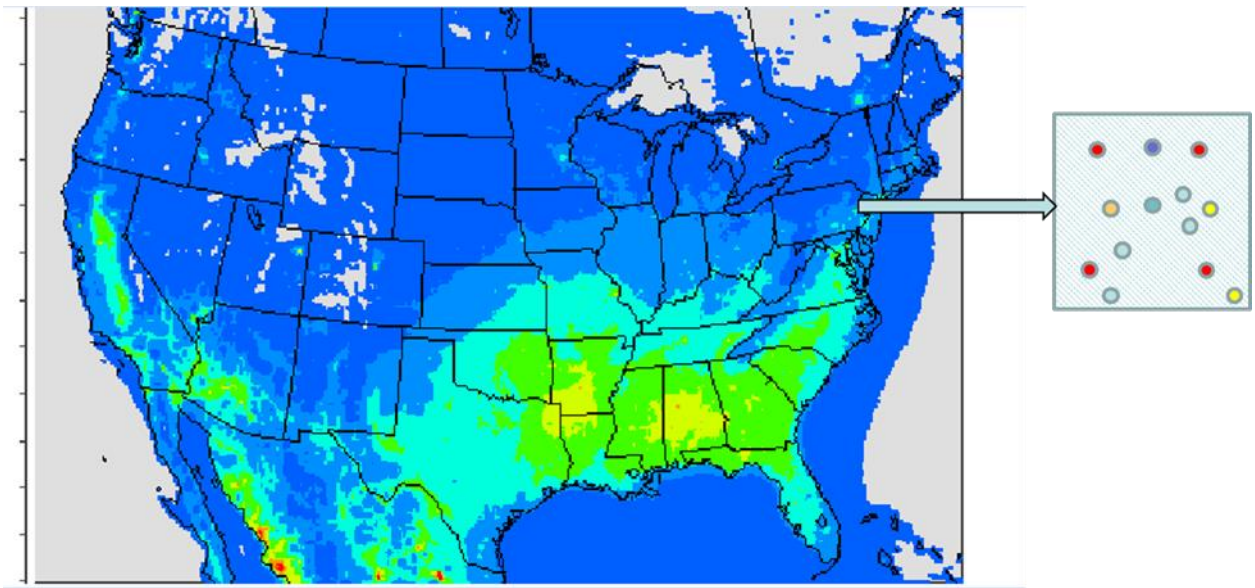

Figure 3-5. CMAQ domain with expanded cell showing hybrid receptors; colors indicate modeled concentrations; dots in inset show locations of receptors within a grid cell

The equation below was used to calculate the 2014 annual average estimates of air concentrations at receptor locations, which were constrained to CMAQ-grid-average values, with AERMOD providing subgrid-scale spatial texture.

$$C = AERMOD_{REC} \times \left(\frac{CMAQ_{PNFB}}{AERMOD_{GRIDAVG}}\right) + CMAQ_{SEC} + CMAQ_{PFIRES} + CMAQ_{PBIOGENICS} + CMAQ_{BACKGROUND}$$

Where:

C	=	concentration at a receptor
$CMAQ_{PNFB}$	=	concentration in CMAQ grid cell, contributed by primary emissions, excluding fires and biogenics
$AERMOD_{REC}$	=	concentration at AERMOD receptor

$AERMOD_{GRIDAVG}$	=	average of all AERMOD results within a CMAQ grid, calculated through averaging the receptors in each of the nine 4-km cells in a CMAQ grid cell, and then taking the average of the nine grid cells
$CMAQ_{SEC}$	=	contribution from atmospheric reactions in CMAQ grid cell
$CMAQ_{PFIRES}$	=	contribution from primary emissions of fires in CMAQ grid cell
$CMAQ_{PBIOGENICS}$	=	contribution from primary emissions of biogenics in CMAQ grid cell
$CMAQ_{BACKGROUND}$	=	contribution from background in CMAQ grid cell for carbon tetrachloride

This hybrid approach, which builds on earlier area-specific applications to Philadelphia, Pa. (Isakov et al. 2007) and Detroit, Mich. (Wesson et al. 2010), attempts to characterize nonreactive and reactive species across multiple spatial scales. However, the blending of two different modeling platforms challenges adherence to basic mass-conservation principles. To address this issue, CMAQ tracks primary and secondary contributions by source type, enabling the AERMOD estimate at each receptor location to be normalized to the CMAQ primary contribution. Anchoring concentration averages to CMAQ largely retains mass conservation. The constraint to CMAQ average grid values imposed by the above equation minimized possible redundancies and allows us to combine results from these two very different models.

3.5.2. Treatment of Species

As noted above, we applied the hybrid model to 52 of the highest risk air toxics (shown in Table 3-1) among the 181 air toxics included in the 2014 NATA. CMAQ bases its treatment of atmospheric chemistry on gas-phase reaction processes optimized to characterize ozone, linked with heterogeneous and thermodynamic processes for PM formation. This structure allows us to model explicit chemical species. For example, formaldehyde and acetaldehyde generate significant amounts of peroxy radicals, which lead to enhanced ozone production and secondary PM formation. This demonstrates the multipollutant linkages driven by atmospheric processes that CMAQ can simulate.

Chemical species not incorporated as explicit species in chemical mechanisms are added as nonreactive tracers (e.g., several halogenates) or included in simple reaction schemes, such as 1,3-butadiene decay and subsequent acrolein generation, decoupled from the chemical mechanism. The emissions mass of several less reactive VOCs, such as the prevalent benzene, toluene and xylene species, are tracked as nonreactive tracers. CMAQ treats these as lumped carbon bond species in its reaction calculations, assuming that atmospheric chemistry minimally influences air concentrations. AERMOD, which treats all pollutants as nonreactive, was applied to the remaining air toxics not incorporated within CMAQ.

The calculation of the AERMOD grid cell average, $AERMOD_{GRIDAVG}$ in the hybrid equation is a three-step process:

1. Calculate a total AERMOD concentration at each gridded receptor, block receptor and monitor receptor by reading the individual post-processed run group concentrations and adding to a running total.

2. Calculate the average concentration at each subgrid cell centered on each gridded receptor in each CMAQ grid cell (see Section 3.4.2.1 for details on gridded receptors and example subgrid cells). This results in either 9 or 144 subgrid-cell averages in each CMAQ cell.

3. Average the 9 or 144 averages in each grid cell to calculate an overall average for the grid cell, $AERMOD_{GRIDAVG}$.

After calculating $AERMOD_{GRIDAVG}$ the following steps are taken:

1. For secondary HAPs (acetaldehyde, formaldehyde and acrolein), calculate the secondary concentration by subtracting the CMAQ primary concentration from the total CMAQ concentration at each grid cell. For nonsecondary HAPs, secondary concentrations are zero.

2. For fire and biogenic HAPs, calculate the primary concentration at each grid cell by subtracting the no-fire/no-biogenic CMAQ concentration from the base CMAQ concentration, where base concentration includes all sources. For nonfire and nonbiogenic HAPs, secondary concentrations are zero.

3. At each grid cell, calculate the primary anthropogenic concentrations by subtracting primary fire and primary secondary concentrations from the total primary concentration from the base CMAQ results.

4. Divide the CMAQ primary concentration from step 3 by the $AERMOD_{GRIDAVG}$ and multiply by the AERMOD total concentration at each receptor in the CMAQ grid cell. This is the primary hybrid concentration.

5. To yield the individual source groups' hybrid concentrations (e.g., nonroad construction equipment), multiply each receptor's hybrid primary concentration by the ratio of the receptor's source group concentration to its total AERMOD concentration.

6. For carbon tetrachloride, two CMAQ species were used, one for which boundary conditions and initial conditions were set to zero (CARBONTET_NOBC) and one with non-zero initial and boundary conditions (CARBONTET). Then calculate background concentrations for carbon tetrachloride for each CMAQ grid cell by subtracting CARBONTET_NOBC from CARBONTET. Set total primary concentrations equal to the CARBONTET_NOBC concentrations.

7. Calculate total hybrid concentrations at each receptor by adding the total primary hybrid from step 4 with the secondary, fire and biogenic concentrations from steps 1 and 2.

For CMAQ HAPs in non-CONUS areas, the hybrid program calculated the background, fire, secondary and biogenic concentrations as discussed in Section 3.6 and added them to the total AERMOD concentrations. For non-CMAQ HAPs in all areas, relevant background was added to the total AERMOD concentrations. The hybrid program then output hybrid concentrations for each run group for each HAP. Separate files were created for gridded receptors, block receptors and monitors. The block and monitor files contained all areas, including non-CONUS areas comprising the AERMOD concentrations with relevant background, fire, secondary and biogenic concentrations. The program output the AERMOD results for the non-CMAQ HAPs in a similar format.

Hybrid concentrations for the non-populated blocks in the CONUS area were interpolated from the hybrid concentrations for the gridded receptors using methods similar to those used for the post-AERMOD interpolation of populated blocks (described in Section 3.4.5). For NATA, the hybrid ambient concentrations at the block level were used to estimate exposures. However, they were also summarized at the tract level. After calculating concentrations for the non-populated blocks, tract-average concentrations for the entire United States, Puerto Rico and the Virgin Islands were calculated by area-weighting the block (populated and non-populated) hybrid concentrations in each tract.

3.6. Other Source Characterizations

3.6.1. Background Concentrations Used for non-CMAQ Areas and Pollutants

For non-CMAQ HAPs and non-CMAQ areas, background concentrations were included with the hybrid results. Table 3-6 lists the pollutants for which 2014 background was included in non-CONUS areas. For methyl bromide and methyl chloroform, the background was also included in the CONUS area, as these two HAPs were not CMAQ HAPs.

For background, we used the remote concentration estimates from five NOAA GMD sites: Cape Kumukahi, Hawaii (KUM); Mauna Loa, Hawaii (MLO); Niwot Ridge, Colo. (NWR); Barrow, Alaska (BRW); Alert, Canada (ALT); and the Trinidad Head Site (AGAGE). These are the same values used for CMAQ boundary conditions for pollutants not estimated by GEOS-Chem. Appendix D details how these were developed.

Table 3-6. Background Concentrations used for non-CMAQ areas and pollutants

Pollutant	2014 Remote Concentration at STP (μg/m^3)	RCE (pptv) 2014	Remote Network	Location(s)
Chloroform	0.070	0.072	AGAGE	Trinidad Head
Methyl chloride (chloromethane)	1.16	0.99	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Benzene	0.109	0.096	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Carbon tetrachloride	0.530	84.4	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Methyl bromide (bromomethane)	0.028	7.2	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Methyl chloroform (1,1,1-trichloroethane)	0.020	3.7	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Dichloromethane (methylene chloride)	0.20	58.3	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Tetrachloroethene (perchloroethylene, tetrachloroethylene)	0.013	1.9	NOAA GMD	KUM, MLO, NWR, BRW, ALT

For background, we used the remote concentration estimates from five NOAA GMD sites: Cape Kumukahi, Hawaii (KUM); Mauna Loa, Hawaii (MLO); Niwot Ridge, Colo. (NWR); Barrow, Alaska (BRW); Alert, Canada (ALT); and the Trinidad Head Site (AGAGE). These are the same values used for CMAQ boundary conditions for pollutants not estimated by Geos-Chem. Appendix D details how these were developed.

3.6.2. Fires, Biogenics and Secondary Concentrations Used for Non-CMAQ Situations

In the CONUS, fires, biogenics and secondary concentrations are determined by CMAQ. For non-CONUS areas, we developed an approach to estimate these components based on available information, including hemispheric CMAQ concentrations for formaldehyde and acetaldehyde for secondary concentrations.

3.6.3. Non-CONUS Fires

For the HAPs that include fire contributions, an approach for the non-CONUS areas was developed using average CMAQ fire concentrations of states with similar fire emission densities in the CONUS area. For example, North Dakota had a similar emissions density for formaldehyde and acrolein as Alaska. North Dakota's formaldehyde density was 75 and Alaska's 89. For acrolein, North Dakota's formaldehyde density was 11 and Alaska's was 13. For Hawaii (formaldehyde density = 685, acrolein density = 118), the state with the closest densities was Louisiana (formaldehyde density = 557, acrolein density = 99). For Puerto Rico (formaldehyde density = 74, acrolein density = 13), Maryland was chosen as the representative state (formaldehyde density = 79, acrolein density = 13). For the Virgin Islands, fire emissions were assumed zero.

To calculate the fire concentrations for fire HAPs in Alaska, Hawaii and Puerto Rico, the average primary fire concentration was calculated for each of the representative states based on the CMAQ gridded results that overlapped the states. The resulting averages were then applied to the appropriate non-CONUS areas. Table 3-7 lists the fire HAPs with the Alaska, Hawaii and Puerto Rico fire concentrations.

Table 3-7. Fire concentrations (µg/m^3) for selected HAPs in Alaska, Hawaii and Puerto Rico

HAP	Alaska	Hawaii	Puerto Rico
Acetaldehyde (primary)	9.3×10^{-3}	1.1×10^{-2}	6.0×10^{-2}
Acetonitrile	2.9×10^{-3}	4.1×10^{-3}	1.1×10^{-2}
Acrolein (primary)	3.8×10^{-3}	5.6×10^{-3}	3.4×10^{-2}
Acrylic acid	2.2×10^{-4}	3.5×10^{-4}	2.1×10^{-3}
PAH_00E0	2.0×10^{-5}	2.9×10^{-5}	1.1×10^{-4}
PAH_176E4	1.5×10^{-5}	2.2×10^{-5}	8.1×10^{-5}
Benzene	9.9×10^{-3}	1.6×10^{-2}	5.3×10^{-2}
PAH_880E5	9.6×10^{-5}	1.4×10^{-4}	5.1×10^{-4}
PAH_176E3	1.5×10^{-5}	2.2×10^{-5}	8.1×10^{-5}
1,3-butadiene	1.1×10^{-3}	1.4×10^{-3}	1.6×10^{-2}
Carbonyl sulfide	4.3×10^{-7}	8.9×10^{-7}	6.7×10^{-6}
PAH_176E5	1.5×10^{-5}	2.2×10^{-5}	8.1×10^{-5}
Formaldehyde (primary)	1.3×10^{-2}	1.8×10^{-2}	1.1×10^{-1}
Hexane	4.6×10^{-4}	5.2×10^{-4}	2.3×10^{-3}
Methanol	3.9×10^{-2}	3.3×10^{-2}	1.3×10^{-1}
Methyl chloride	2.3×10^{-3}	3.4×10^{-3}	1.2×10^{-2}
Naphthalene	2.9×10^{-3}	4.2×10^{-3}	2.4×10^{-2}
Styrene	6.8×10^{-11}	2.3×10^{-6}	4.8×10^{-5}
Toluene	4.3×10^{-3}	6.3×10^{-3}	2.8×10^{-2}
Xylene	1.3×10^{-3}	9.2×10^{-4}	8.0×10^{-3}

3.6.4. Secondary Concentrations

For formaldehyde and acetaldehyde in non-CONUS areas, secondary concentrations were based on results from a 2011 hemispheric CMAQ simulation. This simulation did not include HAPs other than formaldehyde and acetaldehyde, which are explicit model species in the CB05 chemical mechanism. The simulation used a 108-km resolution hemispheric grid that included these areas, and emission inputs for these areas used the 2011 NEI v2 (Eyth et al. 2011). Hemispheric CMAQ results were used to determine a representative secondary concentration for formaldehyde and acetaldehyde for non-CONUS areas. For each area, the secondary concentration was assumed to be 75 percent of the total concentration from the hemispheric CMAQ simulations. The total concentration used for the calculations was based on visual inspections of the modeled concentrations over each area.

Acrolein was processed differently than formaldehyde and acetaldehyde, as hemispheric CMAQ results were not available for acrolein. To determine the secondary concentration for acrolein, the statewide primary acrolein concentrations averages for Alaska and Hawaii (territory averages for Puerto Rico and Virgin Islands) were calculated based on the AERMOD results. Averages were based on modeled census blocks and monitor receptors. The acrolein secondary concentration was assumed to be 25 percent of the primary concentration, as 25 percent is the average ratio of secondary to primary concentrations in the CONUS.

Table 3-8 lists the secondary concentrations for acetaldehyde, acrolein and formaldehyde, and Figure 3-6 and Figure 3-7 show the spatial distribution of the total formaldehyde and acetaldehyde hemispheric CMAQ concentrations. For Alaska and Puerto Rico, the chosen values were based on an average of the range of concentrations across each area. For Alaska, this was the mainland area. The value chosen for Hawaii was based on the areas with populated areas, and the value for the Virgin Islands was the CMAQ grid cell value.

Table 3-8. Concentrations (µg/m^3) used to derive secondary concentrations for formaldehyde, acetaldehyde and acrolein; acrolein is primary concentrations only

HAP	Alaska	Hawaii	Puerto Rico	Virgin Islands
Acetaldehyde (hemispheric average)	0.2	0.225	0.45	0.37
Formaldehyde (hemispheric average)	0.1	0.225	0.60	0.30
Acrolein (non-CONUS average)	0.007	0.007	0.01	0.005

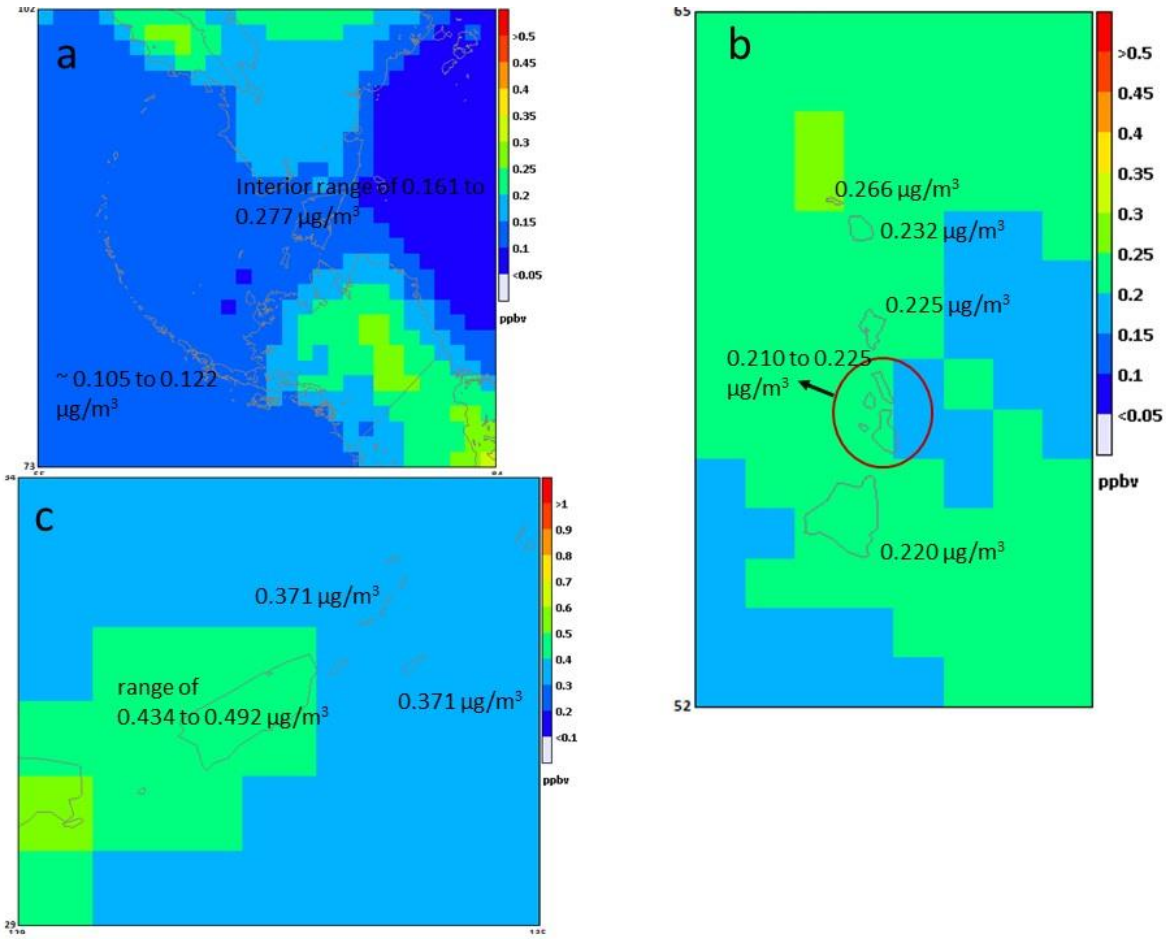

Figure 3-6. Acetaldehyde total concentrations for a) Alaska, b) Hawaii and c) Puerto Rico/Virgin Islands

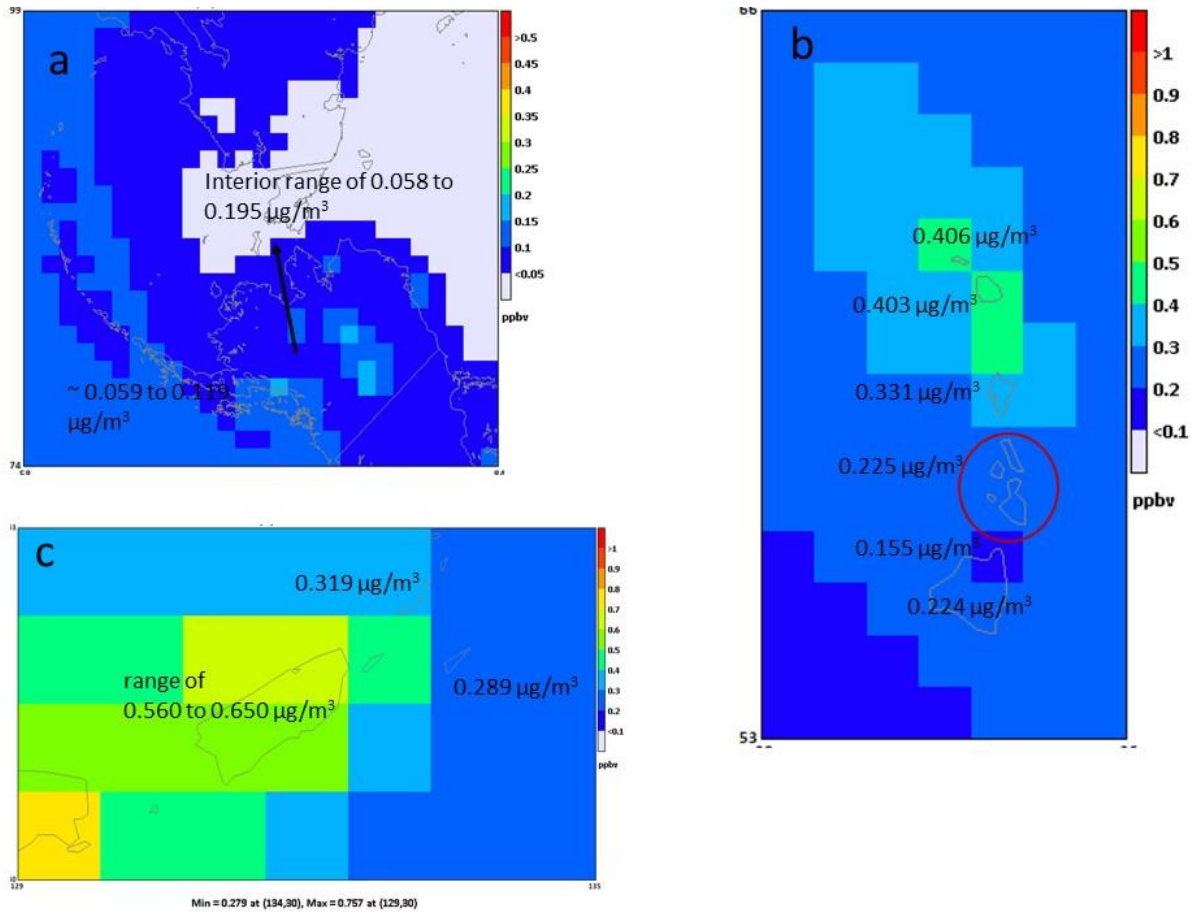

Figure 3-7. Formaldehyde total concentrations for a) Alaska, b) Hawaii and c) Puerto Rico/Virgin Islands

3.6.5. Biogenics

To calculate formaldehyde and acetaldehyde biogenic concentrations for non-CONUS areas, we used the total hemispheric CMAQ concentrations shown in Table 3-6. Biogenic concentrations were assumed to be 20 percent of the total concentrations. For methanol, biogenic concentrations in the non-CONUS areas were assumed to be zero.

3.7. Model Evaluation

An operational model performance evaluation of the HAPs simulated for this 2014 NATA was conducted using the Air Toxics Archive Phase12 for the year 2014 (https://www3.epa.gov/ttnamti1/toxdat.html#data); more details found in Section 3.7.1 below). The model evaluation included both the hybrid air toxics and non-hybrid air toxics. The hybrid evaluation compared the HAPs for which there are valid ambient data (i.e., completeness criteria protocol) to compare against CMAQ, AERMOD and the hybrid model predictions. Likewise, the HAP non-hybrid evaluation used similar observational completeness criteria constraints to compare against HAPs estimated by adding AERMOD to remote ambient concentrations (where available) that are assumed to reflect background conditions.

Note that when pairing observed to model data, there are spatial-scale differences between CMAQ, AERMOD and the hybrid model predictions. A CMAQ concentration represents a 12-km grid-cell volume-averaged value. The AERMOD model concentration represents a specific point within the modeled domain. The hybrid model concentration combines the AERMOD point concentration gradients with the 12-km CMAQ grid-cell volume average. The ambient observed measurements are made at specific spatial locations (latitude/longitude). Several annual graphical presentations and statistics of model performance were calculated and prepared. Graphical presentations include:

1. Box and whisker plots that show the distribution and the bias of the predicted and observed data, and

2. Regional maps that show the mean bias and error calculated at individual monitoring sites.

3.7.1. Ambient Monitoring Data Preparation

EPA has created annual average concentrations for year 2014 using data in the Air Toxics Archive Phase12 (https://www3.epa.gov/ttnamti1/toxdat.html#data). These data primarily come from AQS; however, they may also come directly from special studies that may not have been included in AQS. In addition, these data have been converted to micrograms per cubic meter (µg/m^3) from the unit they were originally reported in (typically parts per billion) using local meteorological data where available or standard conditions otherwise. To create annual averages, EPA used the following procedures:

1. Separated out (did not mix) data with different duration description at a monitoring site (e.g., hourly, 3-hour, 5-hour, 24-hour are not averaged together)

2. Averaged subdaily data (hourly) to create daily averages

3. Required 70 percent of expected days to be present (a nondetect [“ND”] is counted as present) for each quarter

4. Required 3 of 4 quarters to be 70 percent complete

5. Used the regression on order statistics (ROS) for creating annual averages where less than 80 percent of the data were ND; removed site/pollutants where greater than 80 percent of the data were ND

6. Removed site/pollutant data where the difference between the ROS-computed mean and the zero-substituted mean was more than 30 percent

7. The value we used to compare to the modeled value is the median for the year 2014. We computed site/pollutant medians using ROS so data that were ND would be treated as censored values rather than zero. The ROS requires the detection limit to be used as the censor value. Because the instrument detection limit was not available, we chose the minimum measured value for the year or the method detection limit (MDL) as the censor value. The MDL is not the instrument detection limit, but rather is defined as the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. MDLs are determined through statistical procedures. For this the model evaluation, we used data below the MDL in the computation of the annual statistics if the data were not ND (i.e., equal to zero).

8. For some monitors, we summed annual medians because NATA models the sum of the monitored components as the NATA modeled pollutant and not the individual components. This occurred, for example, for PAH groups (summed individual PAHs belonging to the PAH groups), xylenes (summed m/p with o-xylene) and 1,3-dichloropropylene (summed cis and trans).

9. For some monitors, the same NATA pollutant had multiple 2014 median values to use for the evaluation (for example, if there were 1-hour and 24-hour sampling durations and both met the data completeness criteria). These multiple 2014 median observation data are noted in Tables 3-6 and 3-8 as compared to the model HAPs (e.g., modeled 1,3-butadiene is evaluated against median observations for BUTADIENE13_1_HOUR and BUTADIENE13_24_HOUR).

The data used in the model evaluation are provided in the Supplemental Data folder.

3.7.2. Model Performance Statistics

The Atmospheric Model Evaluation Tool (AMET) was used to conduct the 2014 NATA HAP evaluation (Appel et al., 2011). There are various statistical metrics used by the science community for model performance evaluation. For a robust evaluation, the principal evaluation statistics used to evaluate model performance are based on the following metrics: two-bias metrics (mean bias and normalized mean bias); three-error metrics (mean error, normalized mean error and root mean square error) and correlation coefficient.

Common Variables:

M = predicted concentration

O = observed concentration

X = predicted or observed concentration

σ = standard deviation

I. Mean Bias, Mean Error and Root Mean Square Error (µg/m^3)

$$\textit{Mean Bias} = \frac{1}{n}\sum_{1}^{n}(M - O)$$

$$\textit{Mean Error} = \frac{1}{n}\sum_{1}^{n}|M - O|$$

$$\textit{Root Mean Square Error} = \sqrt{\frac{\sum_{1}^{n}(M - O)^2}{n}}$$

Mean Bias (MB) quantifies the tendency of the model to overestimate or underestimate values, while Mean Error (ME) and Root Mean Square Error (RMSE) measure the magnitude of the difference

between modeled and observe values regardless of whether the modeled values are higher or lower than observations.

II. Normalized Mean Bias and Error (unitless)

$$\textit{Normalized Mean Bias} = \frac{\sum_{1}^{n}(M - O)}{\sum_{1}^{n}(O)}$$

Normalized mean bias (NMB) is used as a normalization to facilitate a range of concentration magnitudes. This statistic averages the difference (modeled minus observed) over the sum of observed values. NMB is a useful model performance indicator because it avoids overinflating the observed range of values, especially at low concentrations.

$$\textit{Normalized Mean Error} = \frac{\sum_{1}^{n}|M - O|}{\sum_{1}^{n}(O)}$$

Normalized mean error (NME) is similar to NMB, where the performance statistic is used as a normalization of the mean error. NME calculates the absolute value of the difference (model minus observed) over the sum of observed values.

III. Correlation Coefficient (unitless)

$$\textit{Correlation} = \frac{1}{(n-1)}\sum_{1}^{n}\left(\left(\frac{O - \overline{O}}{\sigma_o}\right) * \left(\frac{M - \overline{M}}{\sigma_m}\right)\right)$$

Correlation coefficient (r) provides an indication of the strength of linear relationship and is signed positive or negative based on the slope of the linear regression.

3.7.3. Hybrid Evaluation

An annual operational model performance evaluation for HAPs used in the hybrid model calculation was conducted to estimate the ability of the hybrid model as well as to compare to the predictions from the CMAQ and AERMOD modeling systems to replicate the 2014 HAP observed ambient concentrations. Inclusion of all three model results is intended to demonstrate the merged attributes of the hybrid model used for this 2014 NATA. Statistical assessments of each model versus observed pairs were paired in time and space and aggregated on an annual basis. Table 3-9 provides a list of HAPs evaluated in the hybrid model performance evaluation and the number of observed monitoring sites (based on completeness criteria of observations, Section 3.7.2). Figure 3-8 shows the 2014 HAP monitoring locations.

Table 3-9. List of hybrid HAPs evaluated

Model Air Toxic	Measured Air Toxic	No. of Sites
Acetonitrile	ACETONITRILE_24_HOURS	51
Acrolein	ACROLEIN_24_HOURS	30
Acrylonitrile	ACRYLONITRILE_24_HOURS	18
Acetaldehyde	ALD2_24_HOURS	111
Arsenic	ARSENIC_PM10_24_HOURS	39
	ARSENIC_PM25_24_HOURS	213
	ARSENIC_TSP_24_HOURS	44
Benzene	BENZENE_1_HOUR	15
	BENZENE_24_HOURS	211
	BENZENE_5_MINUTES	12
Beryllium	BERYLLIUM_PM10_24_HOURS	32
	BERYLLIUM_TSP_24_HOURS	43
Ethylene dibromide	BR2_C2_12_24_HOURS	9
1,3-Butadiene	BUTADIENE13_1_HOUR	14
	BUTADIENE13_24_HOURS	154
Cadmium	CADMIUM_PM10_24_HOURS	38
	CADMIUM_PM25_24_HOURS	99
	CADMIUM_TSP_24_HOURS	53
Carbon tetrachloride	CARBONTET_24_HOURS	184
	CARBONTET_5_MINUTES	11
Chloroform	CHCL3_24_HOURS	170
Vinyl chloride	CL_ETHE_24_HOURS	48
Chlorine	CL2_24_HOURS	324
Ethylene dichloride	CL2_C2_12_24_HOURS	109
Methylene chloride	CL2_ME_24_HOURS	184
	CL2_ME_5_MINUTES	12
Trichloroethylene	CL3_ETHE_24_HOURS	53
1,1,2,2-Tetrachloroethane	CL4_ETHANE1122_24_HOURS	10
Tetrachloroethylene	CL4_ETHE_24_HOURS	134
	CL4_ETHE_5_MINUTES	12
Chromium Compounds	CR_VI_PM10_24_HOURS	4
1,4-Dichlorobenzene(p)	DICHLOROBENZENE_24_HOURS	49
1,3-Dichloropropene	DICHLOROPROPENE_24_HOURS	26
Ethyl benzene	ETHYLBENZENE_1_HOUR	15
	ETHYLBENZENE_24_HOURS	184
Formaldehyde	FORM_24_HOURS	111
Hexane	HEXANE_1_HOUR	15
	HEXANE_24_HOURS	130
Lead Compounds	LEAD_NON_FEM_TSP_24_HOURS	161
	LEAD_PM10_24_HOURS	56

Model Air Toxic	Measured Air Toxic	No. of Sites
	LEAD_PM25_24_HOURS	320
	LEAD_TSP_24_HOURS	29
Manganese Compounds	MANGANESE_PM10_24_HOURS	43
	MANGANESE_PM25_24_HOURS	322
	MANGANESE_TSP_24_HOURS	73
Methyl chloride	METHCHLORIDE_24_HOURS	161
	METHCHLORIDE_5_MINUTES	12
Naphthalene	NAPHTHALENE_24_HOURS	35
Nickel Compounds	NICKEL_PM10_24_HOURS	39
	NICKEL_PM25_24_HOURS	266
	NICKEL_TSP_24_HOURS	59
Polycyclic Organic Matter	PAH_000E0_NA	31
Polycyclic Organic Matter	PAH_176E3_NA	20
Polycyclic Organic Matter	PAH_176E4_NA	23
Polycyclic Organic Matter	PAH_176E5_NA	27
Polycyclic Organic Matter	PAH_880E5_NA	28
Propylene dichloride	PROPDICHLORIDE_24_HOURS	22
Styrene	STYRENE_1_HOUR	15
	STYRENE_24_HOURS	132
Toluene	TOLU_1_HOUR	15
	TOLU_24_HOURS	215
Xylene	XYLENE_24_HOURS	194
	XYLENE_1_HOUR	7

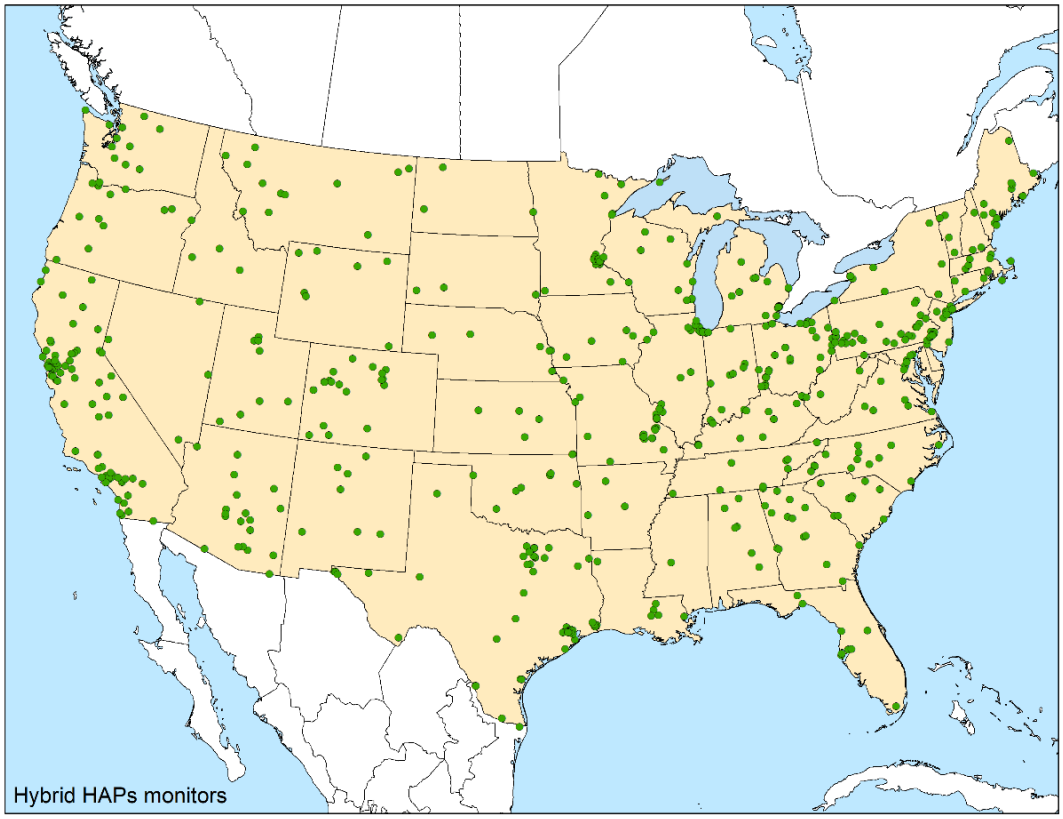

Figure 3-8. 2014 monitoring locations for the hybrid HAPs evaluation

In this section, we present paired annual model-to-monitor site comparisons for the hybrid model, along with CMAQ and AERMOD, for three key HAPs: acetaldehyde, formaldehyde and benzene. The annual model performance statistical results for these three HAPs are presented below in Table 3-10. Boxplots showing model distribution (units of $\mu g/m^3$) and bias differences (units of $\mu g/m^3$) as compared to ambient observations are presented in this statistical analysis. These boxplots display boxed interquartile ranges of 25th to 75th, along with whiskers from the 5th to 95th, quartiles. Also plotted on these boxplots are summary statistics of correlation (r), RMSE, NMB, NME, MB and ME. Regional spatial maps that show the mean bias and error calculated at individual monitoring sites are also provided for acetaldehyde, formaldehyde and benzene. Appendix E presents more details of the hybrid evaluation.

Both CMAQ and hybrid model predictions of annual formaldehyde, acetaldehyde and benzene showed relatively small to moderate bias and error percentages when compared to observations. AERMOD showed larger biases and errors; these underestimates are expected for secondarily formed HAPs (e.g., -84.8% for acetaldehyde and -83.9% for formaldehyde) given the exclusion of atmospheric chemistry in AERMOD. Differences in bias and error statistics between the hybrid and CMAQ models were negligible for formaldehyde and acetaldehyde. Technical issues in the HAPs data consist of (1) uncertainties in monitoring methods; (2) limited measurements in time/space to characterize ambient concentrations ("local in nature"); (3) commensurability issues between measurements and model predictions; (4) emissions and science uncertainty issues may also affect model performance and (5) limited data for estimating intercontinental transport that effects the estimation of boundary conditions (i.e., boundary estimates for some species are much higher than predicted values inside the domain).

Table 3-10. 2014 annual air toxics performance statistics for the Hybrid, CMAQ and AERMOD models

Air Toxic Species	Model	MB (µg/m3)	ME (µg/m3)	NMB (%)	NME (%)
Acetaldehyde (ALD2_24_HOURS)	Hybrid	-0.3	0.5	-21.0	35.2
	CMAQ	-0.3	0.5	-21.8	35.5
	AERMOD	-1.2	1.2	-84.8	84.8
Formaldehyde (FORM_24_HOURS)	Hybrid	-0.9	1.0	-40.6	44.7
	CMAQ	-0.9	1.0	-41.5	45.2
	AERMOD	-1.9	1.9	-83.9	85.2
Benzene (BENZENE_24_HOURS)	Hybrid	-0.1	0.2	-14.5	38.8
	CMAQ	-0.2	0.2	-26.9	39.1
	AERMOD	-0.2	0.3	-38.3	48.6

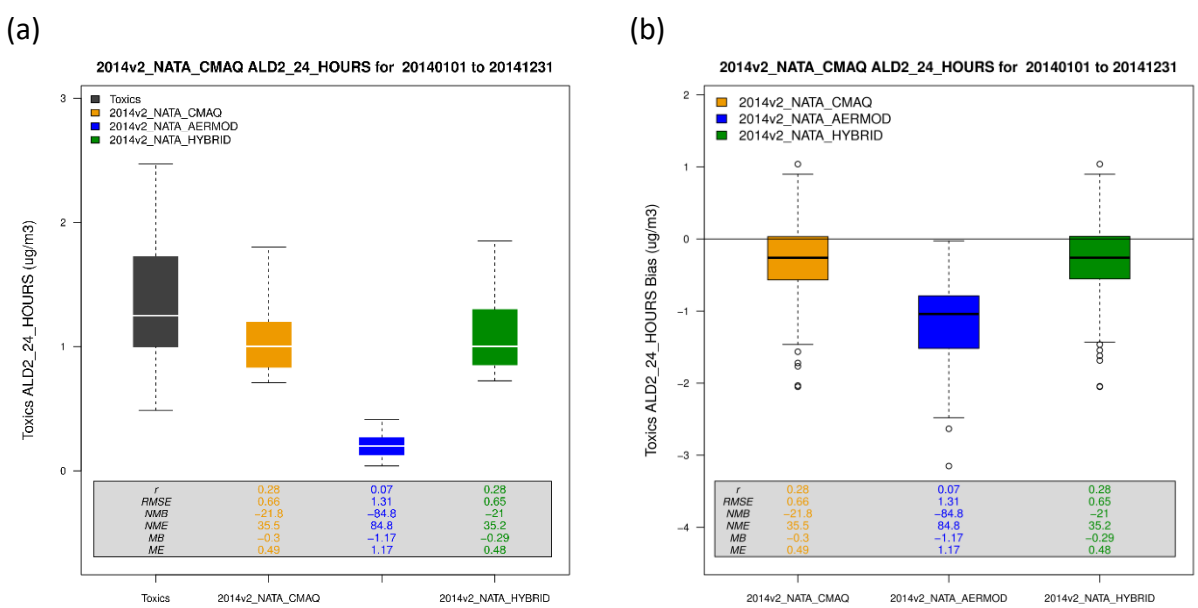

Figure 3-9. Acetaldehyde boxplots of (a) distribution (µg/m^3) and (b) bias difference (µg/m^3) for CMAQ, AERMOD and Hybrid models compared to ambient observations

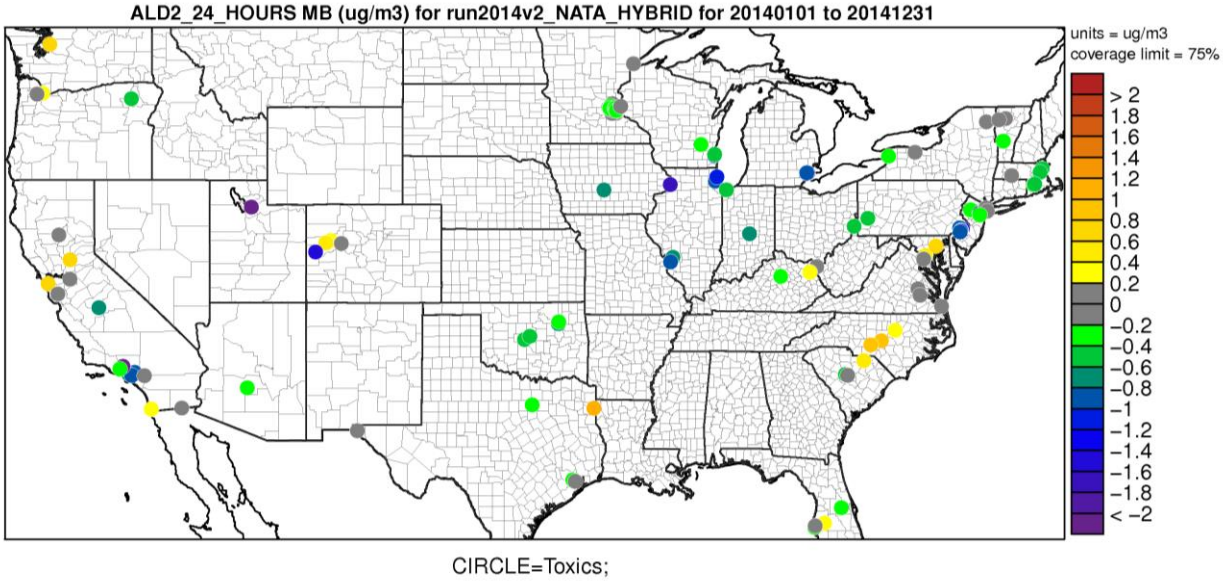

Figure 3-10. Mean bias (%) for acetaldehyde at 2014 monitoring sites in the Hybrid modeling domain

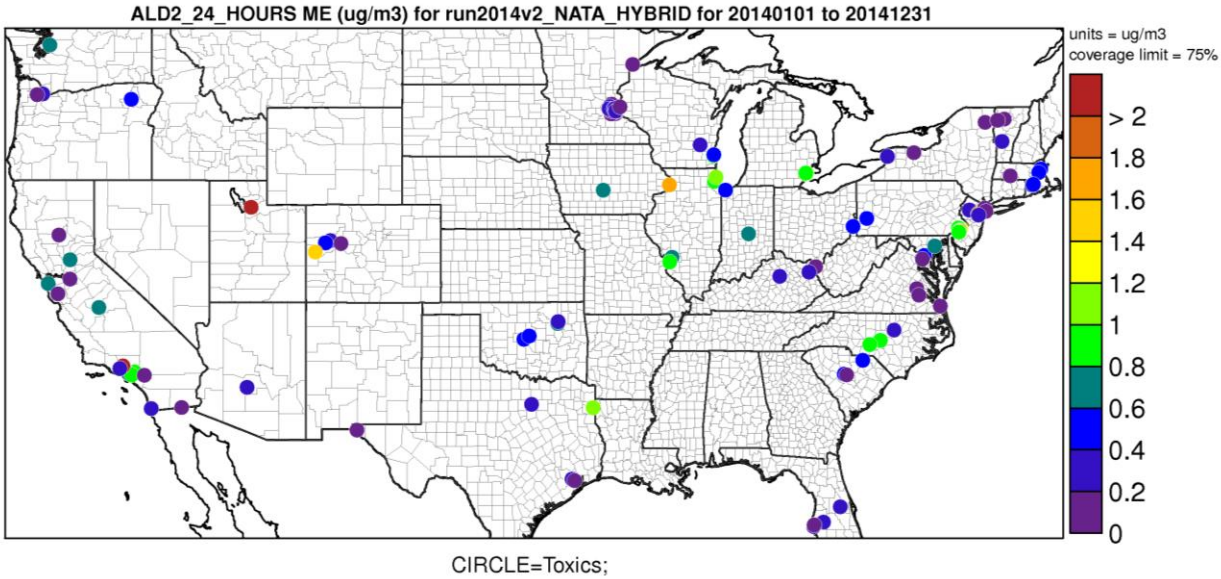

Figure 3-11. Mean error (%) for acetaldehyde at 2014 monitoring sites in the Hybrid modeling domain

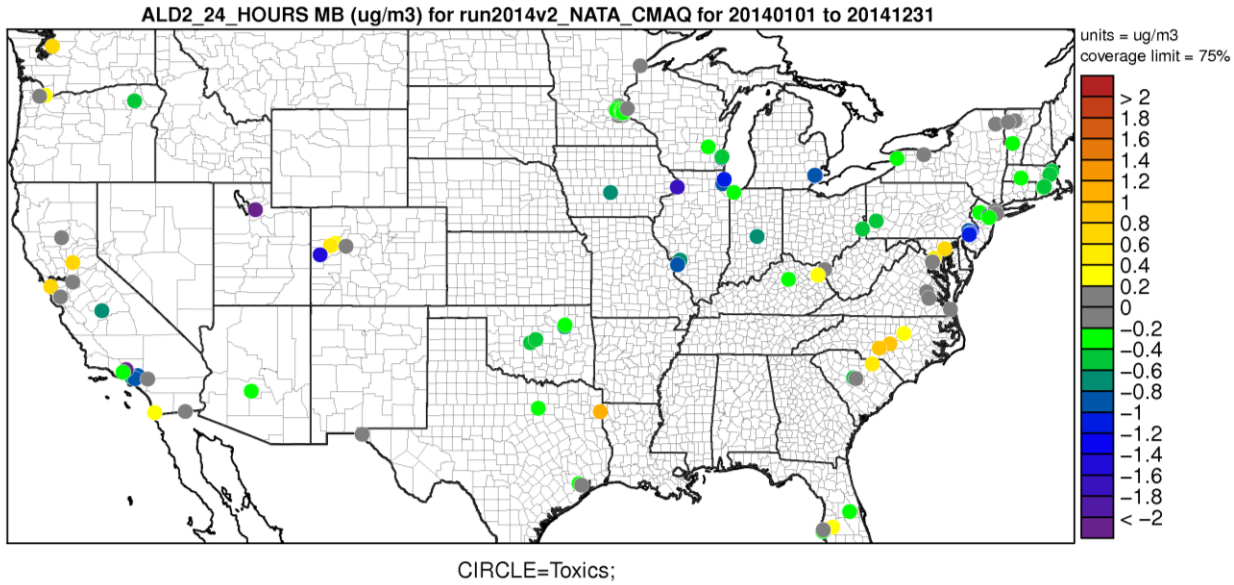

Figure 3-12. Mean bias (%) for acetaldehyde at 2014 monitoring sites in the CMAQ modeling domain

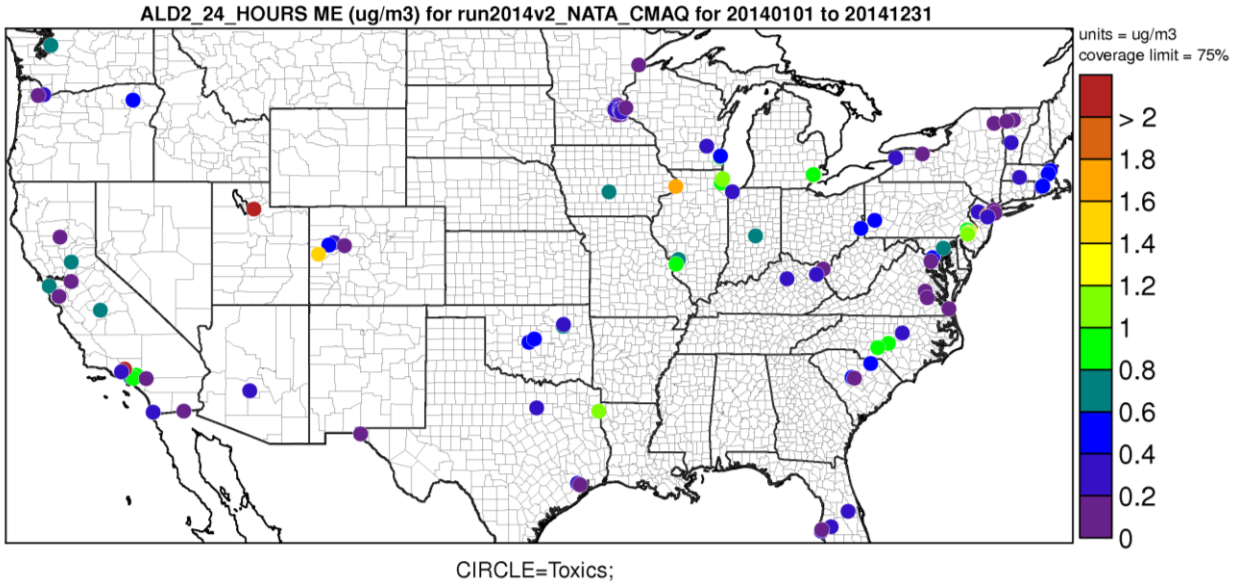

Figure 3-13. Mean error (%) for acetaldehyde at 2014 monitoring sites in the CMAQ modeling domain

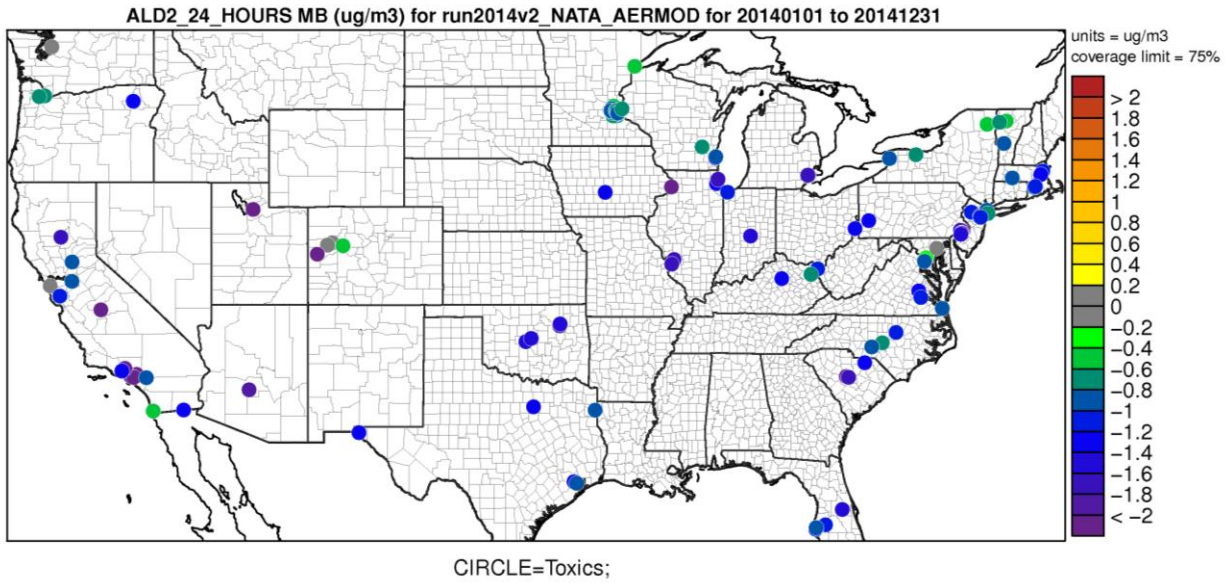

Figure 3-14. Mean bias (%) for acetaldehyde at 2014 monitoring sites in the AERMOD modeling domain

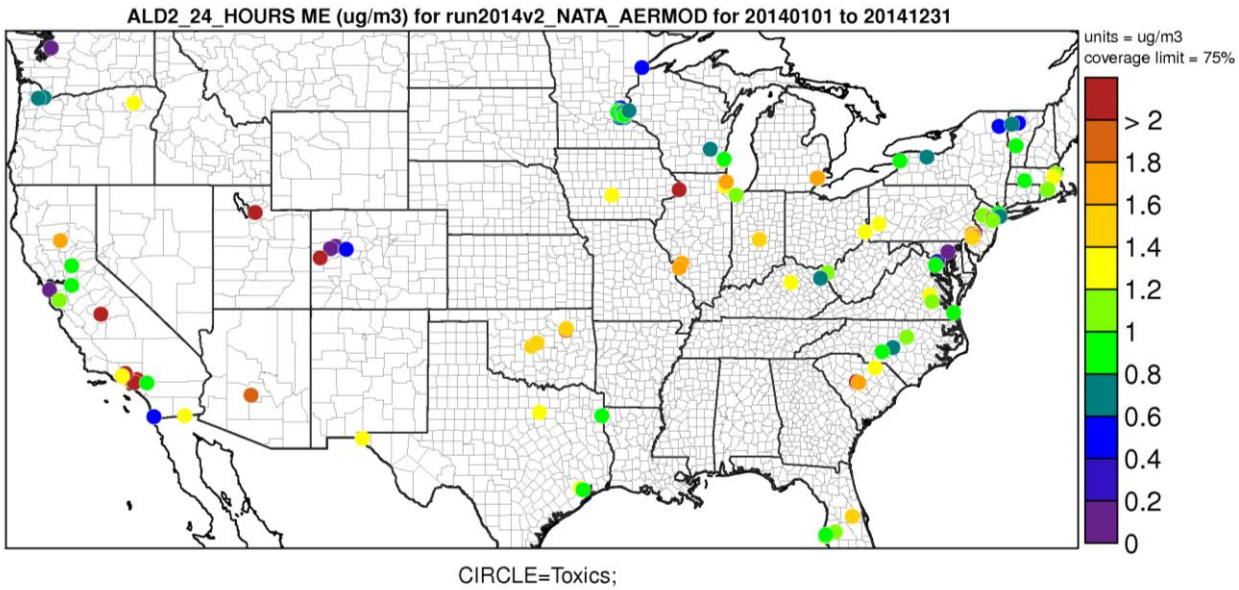

Figure 3-15. Mean error (%) for acetaldehyde at 2014 monitoring sites in the AERMOD modeling domain

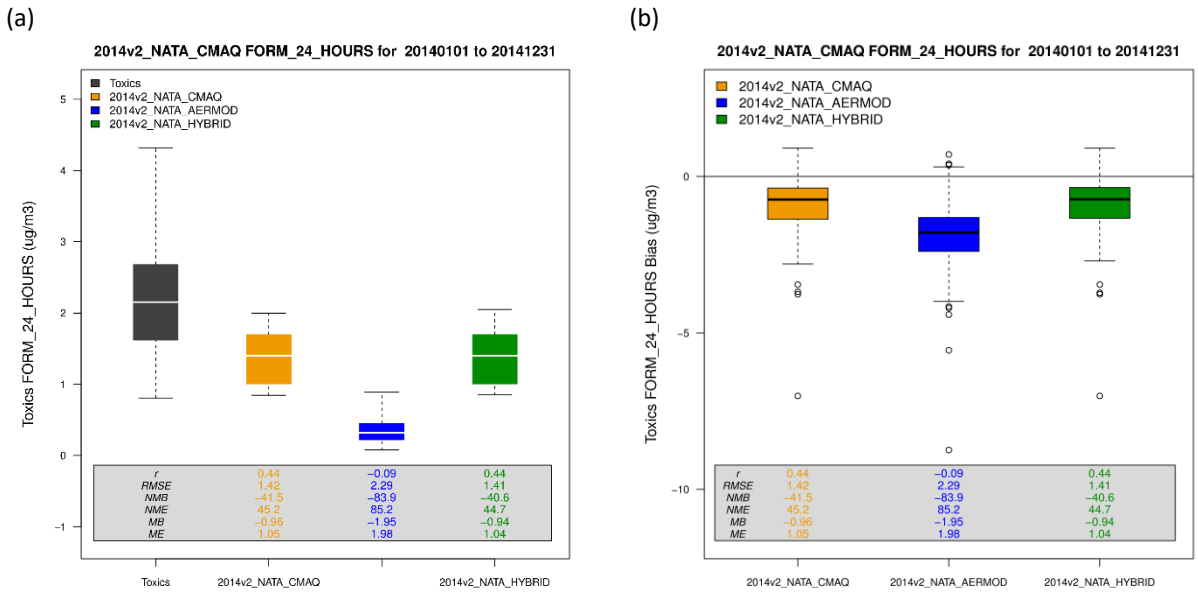

Figure 3-16. Formaldehyde boxplots of (a) distribution (μg/m^3) and (b) bias difference (μg/m^3) for CMAQ, AERMOD and Hybrid models compared to ambient observations

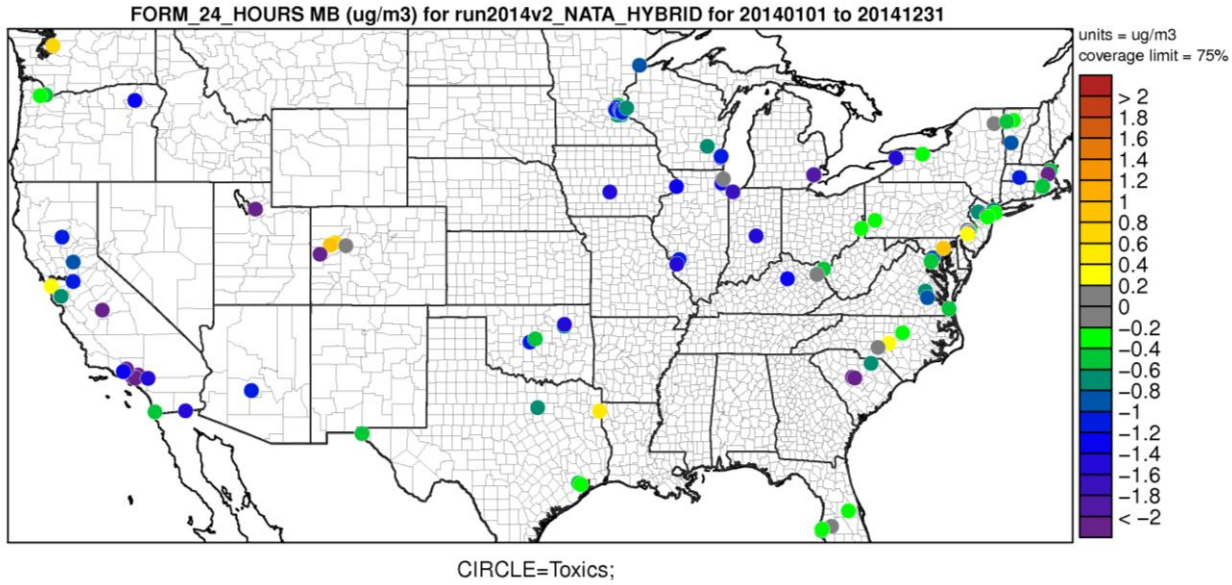

Figure 3-17. Mean bias (%) for formaldehyde at 2014 monitoring sites in the Hybrid modeling domain

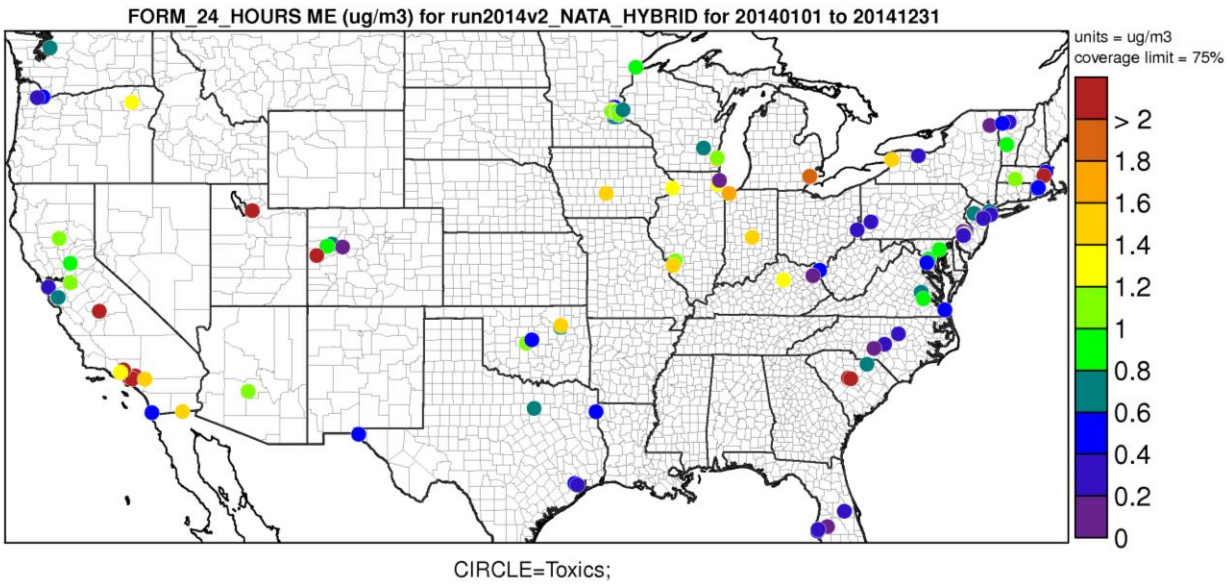

Figure 3-18. Mean error (%) for formaldehyde at 2014 monitoring sites in the Hybrid modeling domain

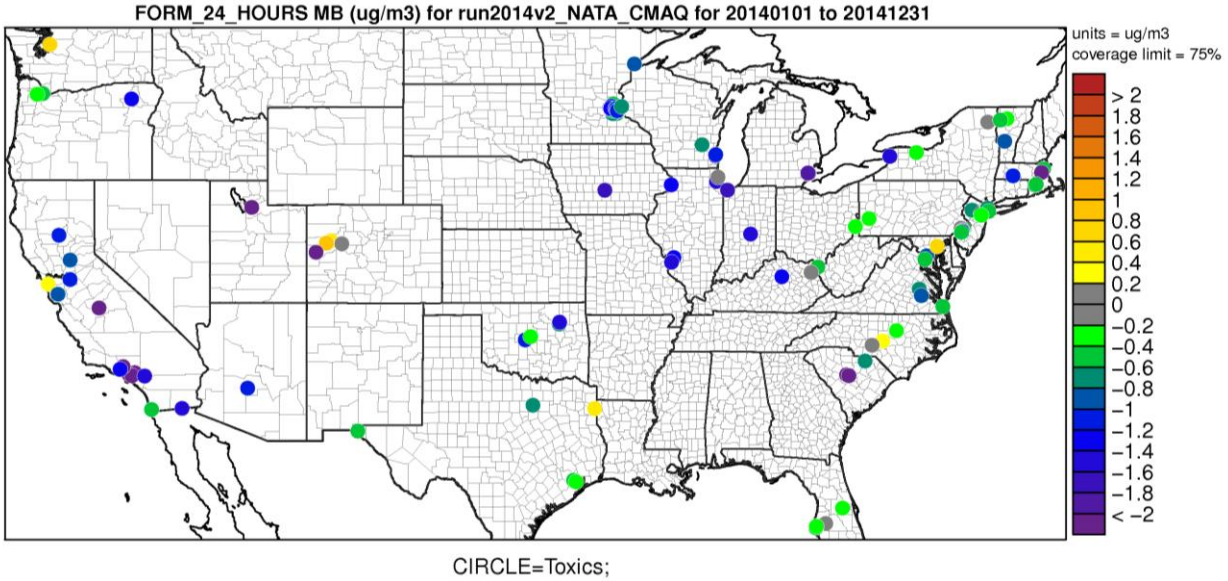

Figure 3-19. Mean bias (%) for formaldehyde at 2014 monitoring sites in the CMAQ modeling domain

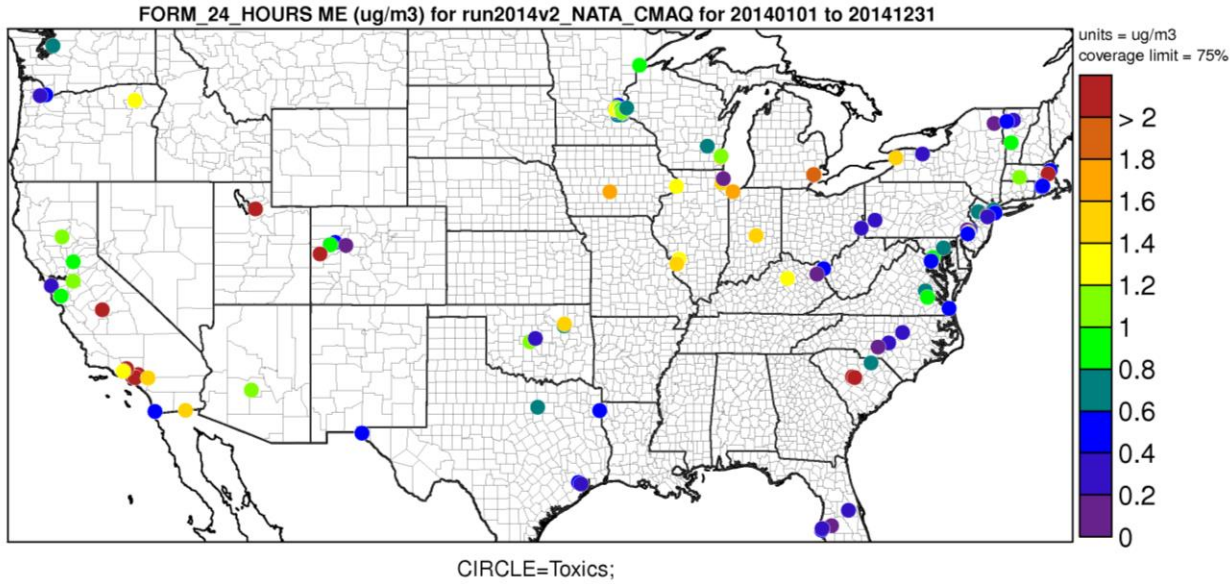

Figure 3-20. Mean error (%) for formaldehyde at 2014 monitoring sites in the CMAQ modeling domain

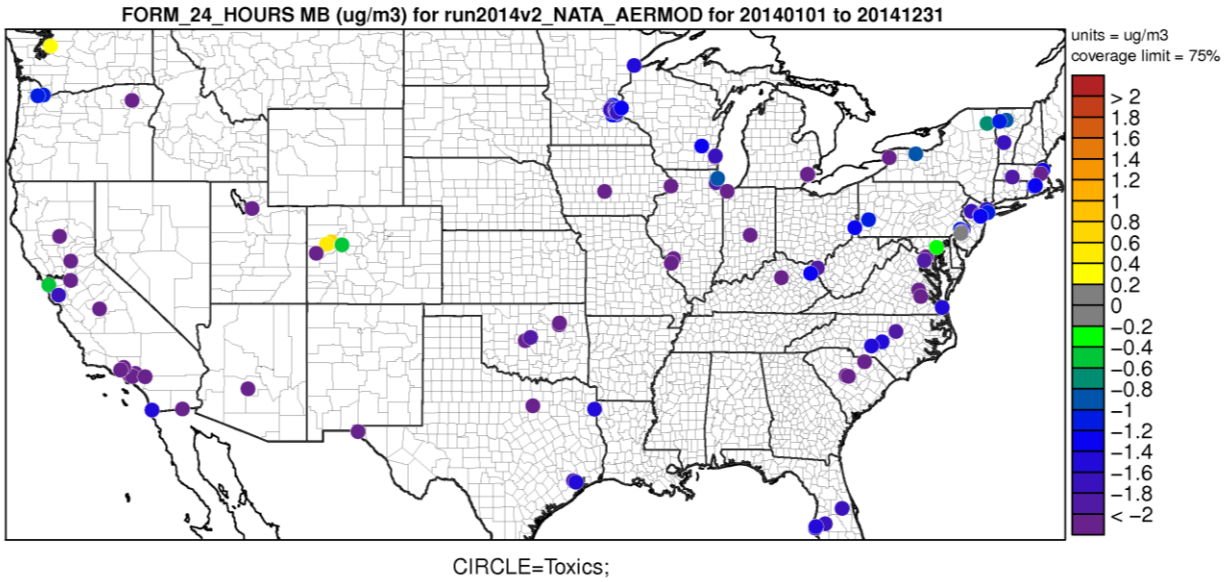

Figure 3-21. Mean bias (%) for formaldehyde at 2014 monitoring sites in the AERMOD modeling domain

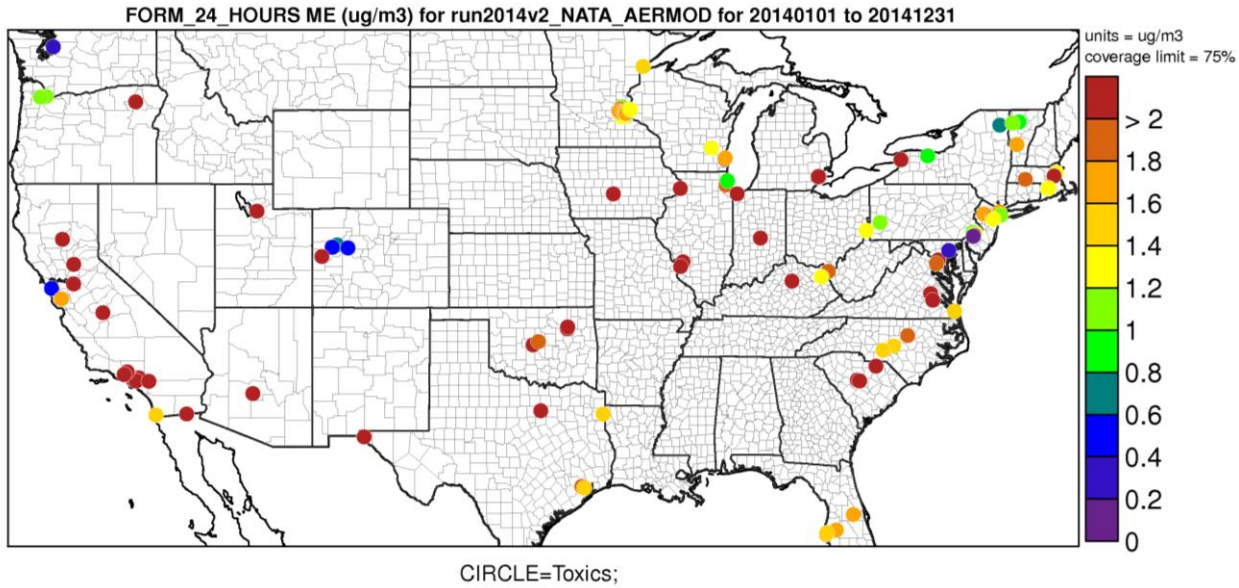

Figure 3-22. Mean error (%) for formaldehyde at 2014 monitoring sites in the AERMOD modeling domain

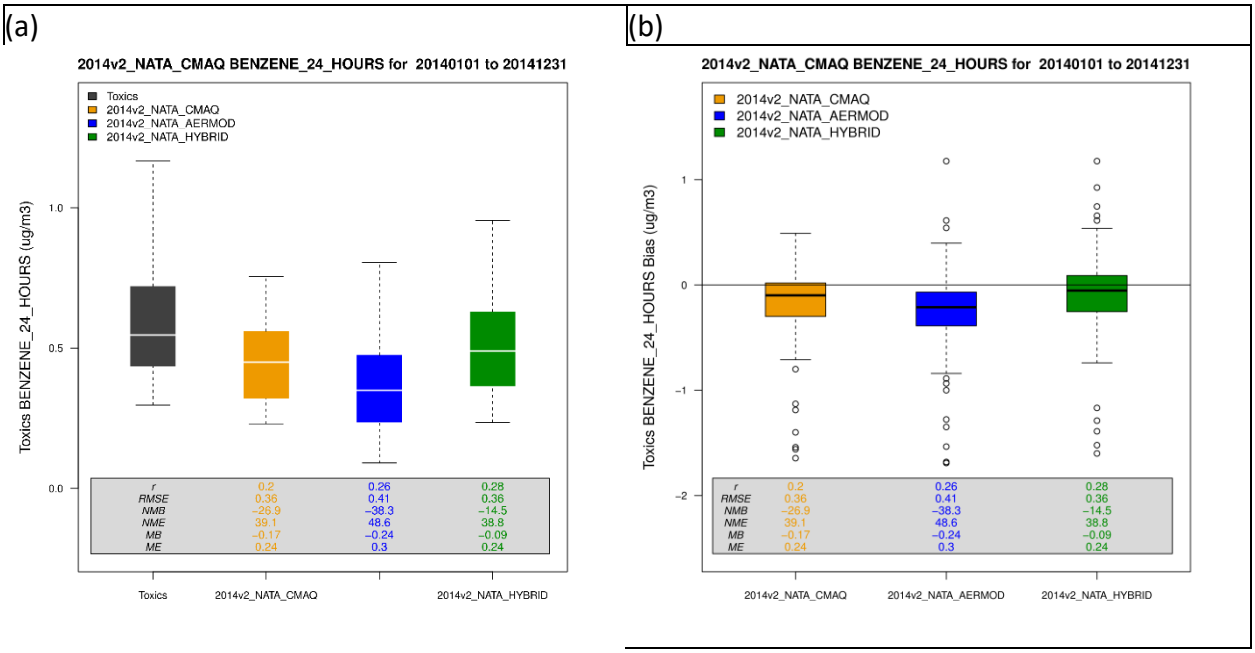

Figure 3-23. Benzene boxplots of (a) distribution (μg/m^3) and (b) bias difference (μg/m^3) for CMAQ, AERMOD and Hybrid models compared to ambient observations (BENZENE_24_HOURS)

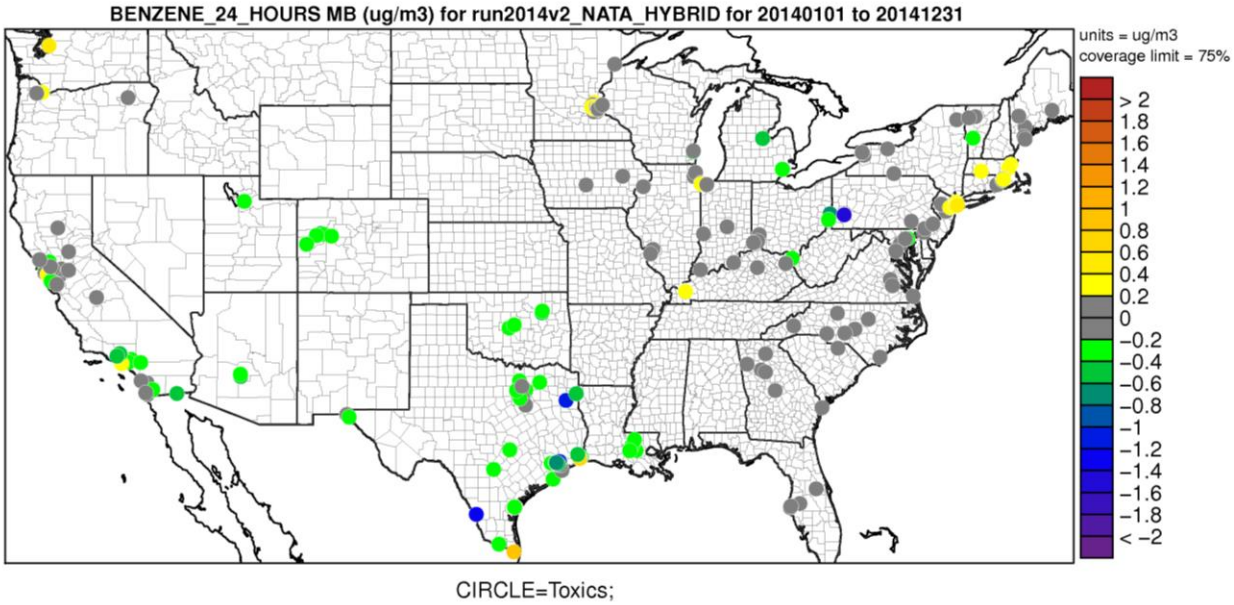

Figure 3-24. Mean bias (%) for benzene at 2014 monitoring sites (BENZENE_24_HOURS) in the Hybrid modeling domain

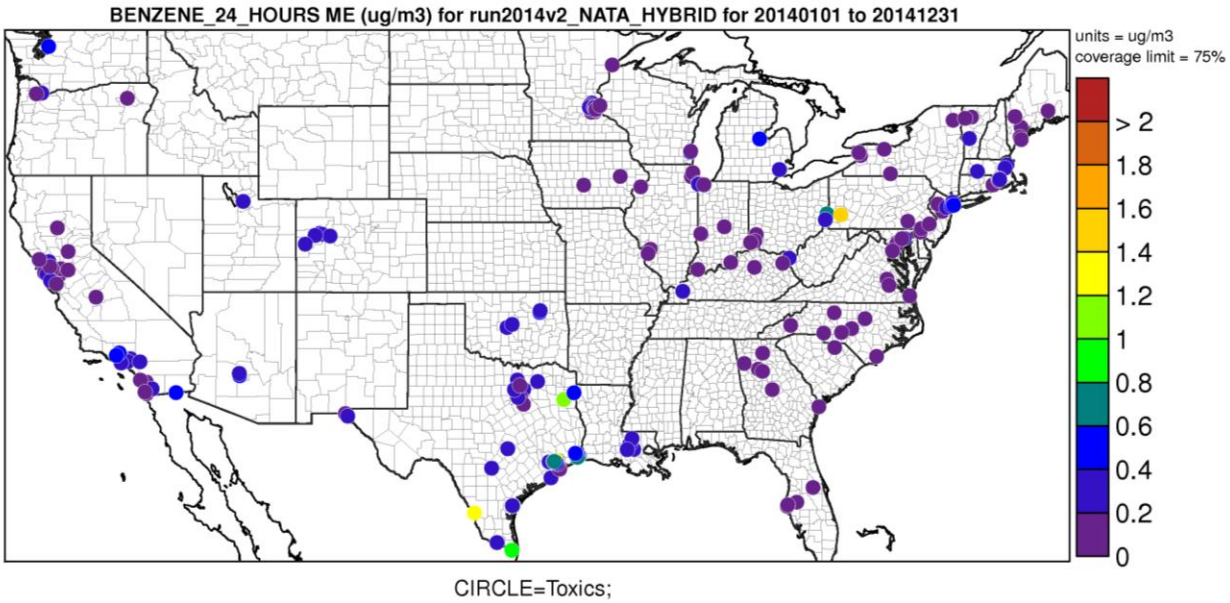

Figure 3-25. Mean error (%) for benzene at 2014 monitoring sites (BENZENE_24_HOURS) in the Hybrid modeling domain

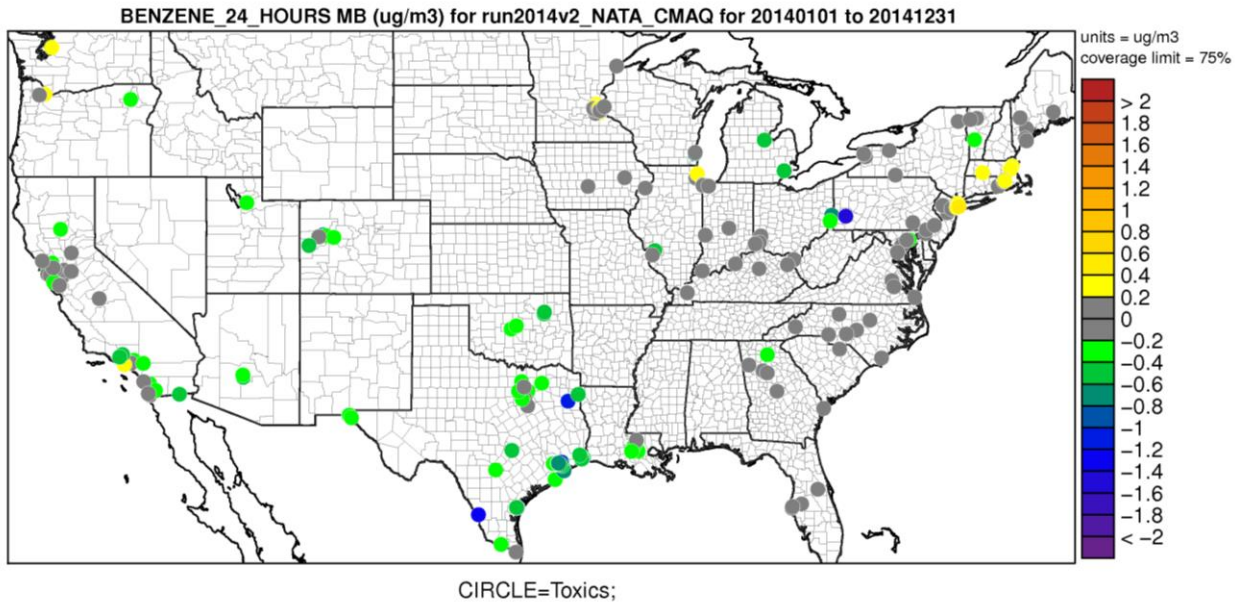

Figure 3-26. Mean bias (%) for benzene at 2014 monitoring sites (BENZENE_24_HOURS) in the CMAQ modeling domain

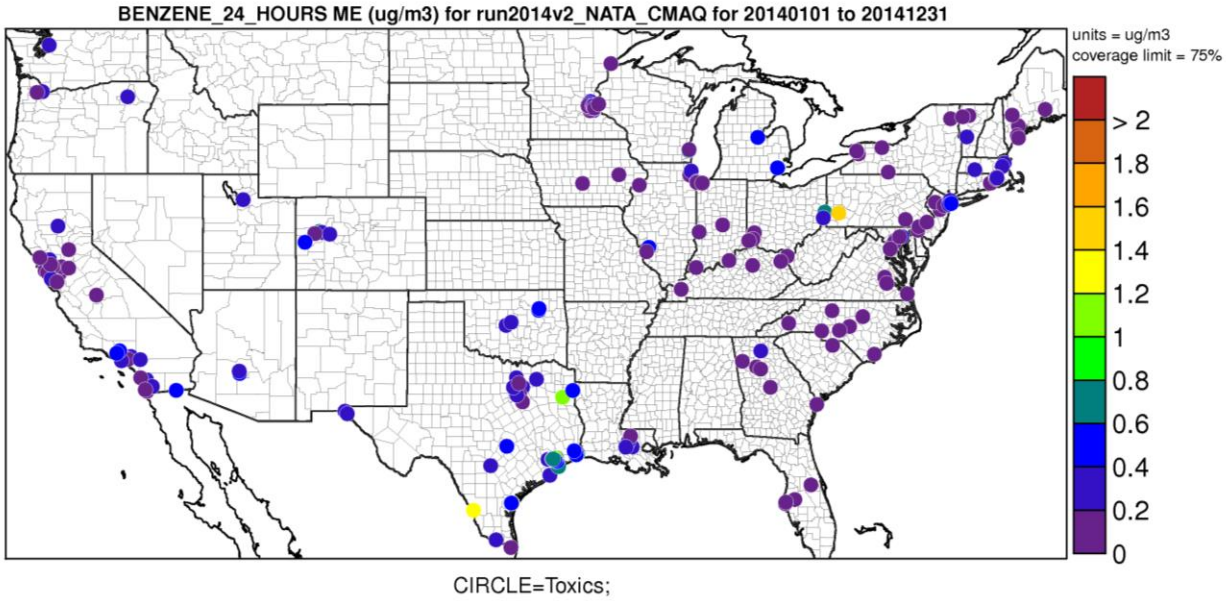

Figure 3-27. Mean error (%) for benzene at 2014 monitoring sites (BENZENE_24_HOURS) in the CMAQ modeling domain

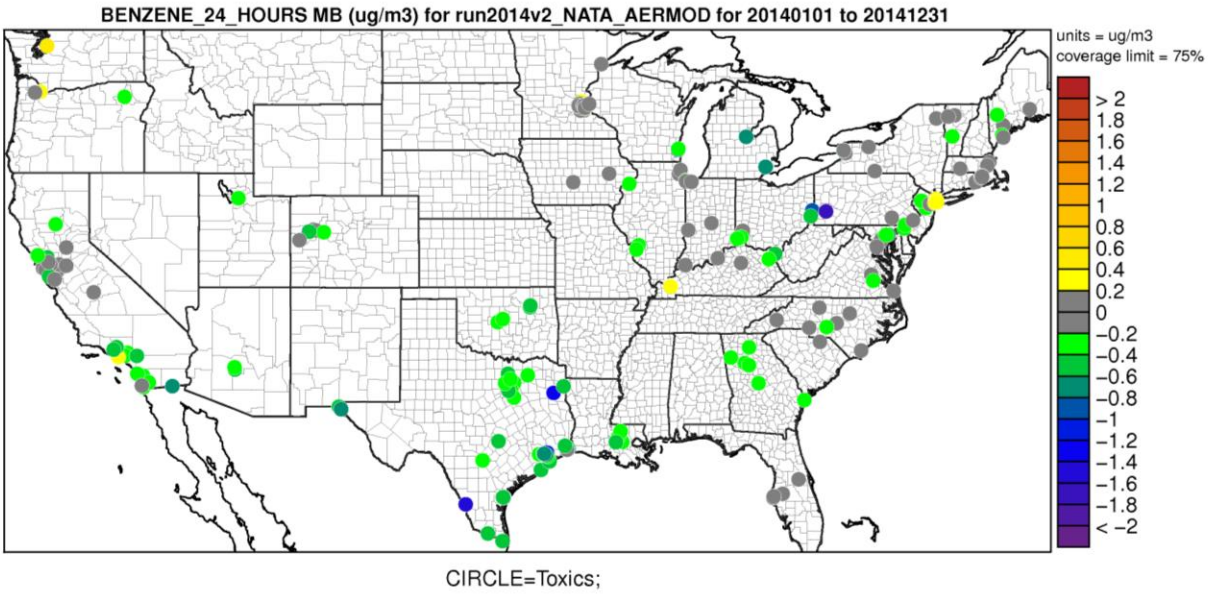

Figure 3-28. Mean bias (%) for benzene at 2014 monitoring sites (BENZENE_24_HOURS) in the AERMOD modeling domain

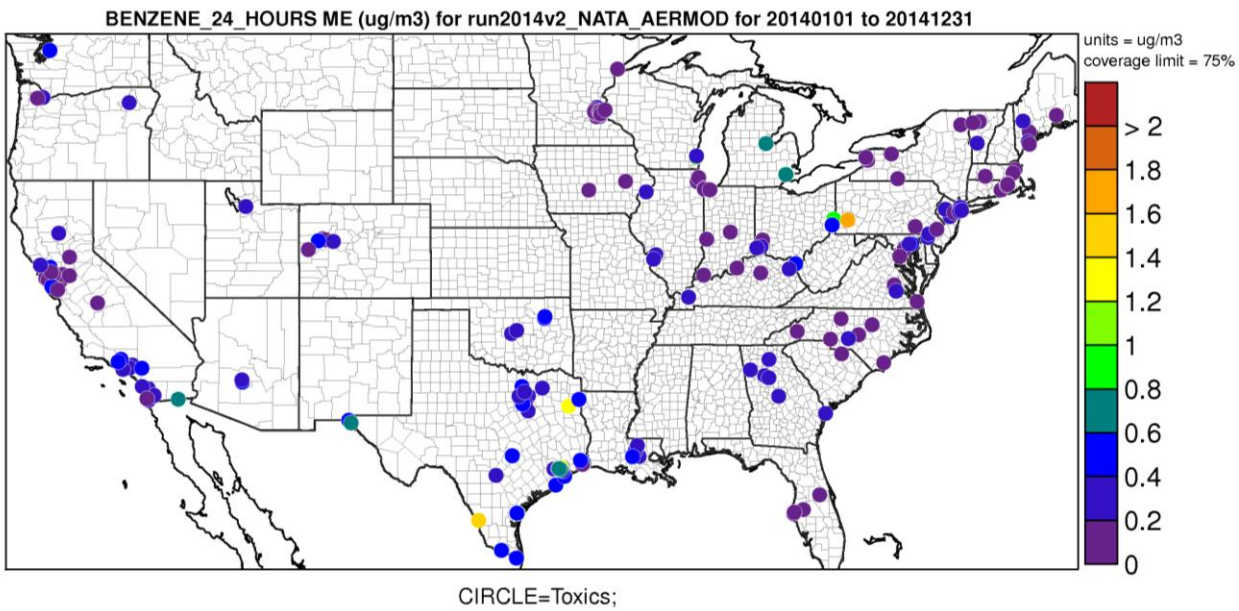

Figure 3-29. Mean error (%) for benzene at 2014 monitoring sites (BENZENE_24_HOURS) in the AERMOD modeling domain

3.7.4. Non-hybrid Evaluation

An annual operational model performance evaluation for HAPs used in the non-hybrid model calculation was conducted to estimate the ability of the AERMOD model to replicate the 2014 HAP observed ambient concentrations. Statistical assessments of modeled results versus observed pairs were paired in time and space and aggregated on an annual basis. Table 3-11 provides a list of HAPs evaluated in the

non-hybrid model performance evaluation and the number of pairs (based on completeness criteria of observations, Section 3.7.1) used in the annual median. Figure 3-30 shows the 2014 non-hybrid HAP monitoring locations. Results from the non-hybrid evaluation are presented in Appendix E.

Table 3-11. List of non-hybrid HAPs evaluated

Model Air Toxic	Measured Air Toxic	No. of Sites
Antimony	ANTIMONY_PM25_24_HOURS	156
	ANTIMONY_PM10_24_HOURS	24
	ANTIMONY_TSP_24_HOURS	33
Cobalt	COBALT_PM25_24_HOURS	169
	COBALT_PM10_24_HOURS	29
	COBALT_TSP_24_HOURS	33
Selenium	SELENIUM_PM25_24_HOURS	279
	SELENIUM_PM10_24_HOURS	26
	SELENIUM_TSP_24_HOURS	32
Methyl Bromide (Bromomethane)	METHYLBROM_5_MINUTES	12
	METHYLBROM_24_HOURS	110
Methyl Chloroform (1,1,1-Trichloroethane)	MTHYLCHLRF_5_MINUTES	12
	MTHYLCHLRF_24_HOURS	79
Carbon disulfide	CARBNDISULF_24_HOURS	72
Methyl Isobutyl Ketone (4-Methyl-2-pentanone)	MIBK_24_HOURS	50
Propanal (Propionaldehyde)	PROPIONAL_24_HOURS	79
Cumene (Isopropylbenzene)	CUMENE_24_HOURS	29
	CUMENE_1_HOUR	15
2,2,4-Trimethylpentane	TRMEPN224_24_HOURS	77
	TRMEPN224_1_HOUR	15
Bromoform (Tribromomethane)	BROMOFORM_24_HOURS	2
Chlorobenzene	CHLROBZNE_24_HOURS	35
1,2,4-Trichlorobenzene	TRICBZ124_24_HOURS	19
Benzyl Chloride (alpha-Chlorotoluene)	BENZYLCHLO_24_HOURS	13
Hexachloro-1,3-butadiene	HEXCHLRBT_24_HOURS	8
Methyl tert-butyl ether	MTBE_24_HOURS	19
p-Dioxane (1,4-Dioxane)	P_DIOXANE_24_HOURS	9
Vinyl Acetate	VINYLACET_24_HOURS	13
Ethyl Chloride (Chloroethane)	ETHYLCHLRD_24_HOURS	16
Ethylidene Dichloride (1,1-Dichloroethane)	ETHIDDICHLD_24_HOURS	16
Methyl Methacrylate	MMETACRYLAT_24_HOURS	4
Vinylidene Chloride (1,1-Dichloroethylene)	VINYLIDCLOR_24_HOURS	5
1,1,2-Trichloroethane	TRICLA112_24_HOURS	3

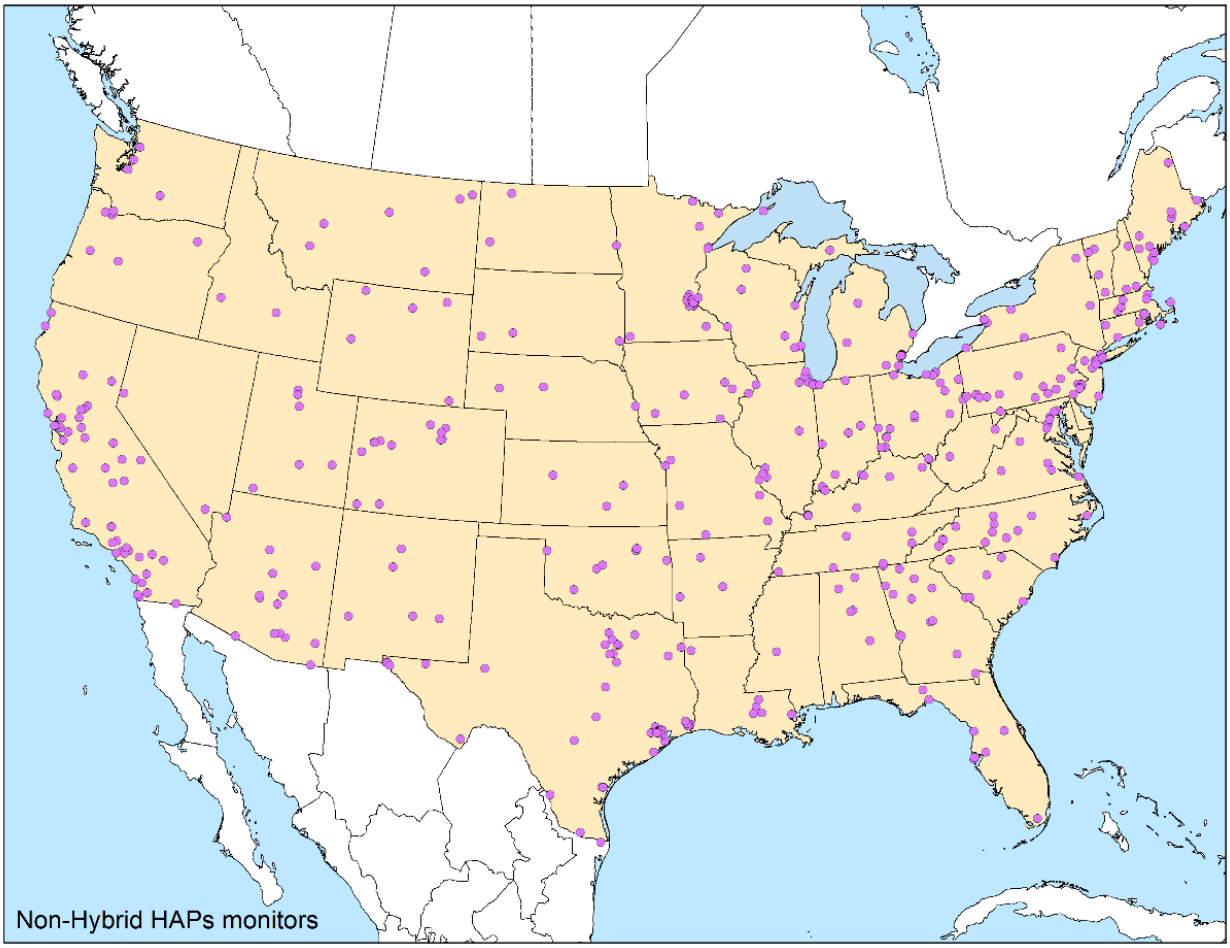

Figure 3-30. 2014 monitoring locations for the non-hybrid HAPs evaluation

4. Estimating Exposures for Populations

Estimating inhalation exposure concentrations (ECs) is a critical step in determining potential health risks. Ambient concentrations do not consider that people move through locations and microenvironments where pollutant concentrations can differ. Different people have different daily activities, spend different amounts of time engaged in those activities, and engage in those activities in different locations. Most activities occur indoors (e.g., in homes, workplaces, schools and vehicles) where pollutant concentrations can differ from those outdoors. Therefore, the average concentration of a pollutant that people breathe can differ significantly from the ambient concentration at a fixed outdoor location.

This section contains a discussion of how EPA estimated ECs for the 2014 NATA. It begins with an overview of the surrogate approach used that included new exposure modeling for some NATA pollutants and applications of exposure-to-ambient concentration ratios for the remaining pollutants. This is followed by a more detailed description of this approach, a summary of the user inputs and other data required, and an overview of the quality-assurance measures included in estimating exposures. Further details on the exposure calculations for the 2014 NATA can be found in Appendix F.

4.1. Estimating Exposure Concentrations

For the 2014 NATA, EPA used a combination of direct modeling and exposure factors to estimate inhalation ECs for NATA. This approach used census tract-level ambient concentrations estimated with air quality models, as described in Section 3, and yielded census tract-level exposure concentration estimates that we used to determine potential health risks for NATA.

EPA used version 7 of the EPA Hazardous Air Pollutant Exposure Model (HAPEM7) to conduct direct exposure modeling for the 2014 NATA. HAPEM, described in detail in Section 4.2, is a screening-level exposure model that estimates inhalation ECs corresponding to estimated ambient-pollutant concentrations. We used HAPEM7 for a selected group of surrogate pollutants and source categories. For each surrogate pollutant and NATA category (i.e., point, nonpoint, on-road mobile and nonroad mobile), EPA calculated the ratio of EC to ambient concentration (i.e., an exposure factor) for each census tract. Using each pollutant's chemical properties, we then mapped each pollutant/category combination to the surrogate pollutants and source categories. Per census tract, we multiplied the ambient concentration of the pollutant by the surrogate's exposure factor, resulting in estimated ECs. Section 4.4 further describes this exposure-factor approach.

4.2. About HAPEM

Nearly two decades ago, EPA developed HAPEM for Mobile Sources (HAPEM-MS) to assess inhalation exposure to air toxics from highway mobile sources. This version of HAPEM used carbon monoxide as a tracer for highway mobile-source air toxic emissions. Today, HAPEM7 predicts inhalation ECs for a wide range of air toxics using either modeled ambient concentrations or measured data (without regard to source category), and the model no longer uses carbon monoxide as a tracer.

Following other improvements, HAPEM version 4 and later (including HAPEM7) can estimate annual average human-exposure levels nationwide at a spatial resolution as fine as the census tract level (EPA 2002b, EPA 2005c, EPA 2007b, EPA 2015b). These changes make HAPEM7 suitable for regional and

national inhalation risk assessments such as NATA. The 1996 and 1999 NATAs estimated Inhalation ECs using HAPEM4 and HAPEM5 respectively; the 2011 and 2014 NATAs both used HAPEM7 (EPA did not use HAPEM6 for NATA). Table 4-1 outlines some key differences between these three HAPEM versions. A complete history of the model can be found in the User's Guide for HAPEM7 (EPA 2015b).

Table 4-1. Key differences between recent versions of HAPEM

Characteristic	HAPEM4	HAPEM5	HAPEM7
Data source for population demographics	1990 U.S. Census	2000 U.S. Census	2010 U.S. Census
Characterization of microenvironmental factors	Point estimates	Probability distributions	Same as HAPEM5
Method for creation of annual average activity patterns from daily activity-pattern data	Resampling of daily diaries for each of 365 days without accounting for autocorrelation	Sampling a limited number of daily diaries to represent an individual's range of activities, accounting for	Same as HAPEM5, except now includes commuter-status criterion
Interpretation of exposure-concentration range for a given cohort/tract combination	Uncertainty for the average annual EC for the cohort/tract combination	Variability of annual ECs across cohort/tract members	Same as HAPEM5, except now includes adjustments based on proximity to roadway

HAPEM uses a general approach of tracking representative individuals of specified demographic groups as they move among indoor and outdoor microenvironments and between locations. As described in the following section, personal-activity and commuting data, specific to a hypothetical person's demographic groups, are used to determine the census tracts containing residential and work locations and the microenvironments within each tract. Using stochastic sampling, the model estimates ECs by selecting empirically based factors reflecting the relationship between ECs within each microenvironment and the outdoor (ambient) air concentrations at that location.

To estimate long-term ECs for a hypothetical person, the pollutant concentrations in each microenvironment visited are first combined into a daily-average concentration. The daily averages are then combined with proper weighting for season and day type to calculate a long-term average. Finally, the long-term averages are stratified by demographic group and census tract to create a distribution of ECs for each stratum. The median of each distribution represents the best estimate of exposure for a "typical" person of that demographic group in that census tract. In this case, "typical" does not refer to a specific individual in the population or even the average over a group of individuals. Rather, this is a hypothetical person living at the centroid of a census tract who engages in the usual activities (both indoor and outdoor) for someone in that demographic group and census tract.

Additional technical information on HAPEM can be found in the User's Guide for HAPEM7 (EPA 2015b).

4.3. HAPEM Inputs and Application

HAPEM requires four main types of information to estimate ECs: (1) ambient concentrations of air toxics, (2) population data from the U.S. Census Bureau, (3) population-activity data and (4) microenvironmental data. The subsections below discuss these inputs, along with descriptions of the

data used for NATA and related information on how EPA configured the model and applied it to conduct direct exposure modeling.

4.3.1. Data on Ambient Air Concentrations

HAPEM typically uses annual average, diurnally distributed ambient air concentrations as input data. These concentrations can be monitoring data or concentrations estimated using a dispersion model or other air quality model.

For the 2014 NATA, EPA estimated annual average ambient concentrations for each census tract using a hybrid CMAQ-AERMOD approach discussed in Section 3.5. To ensure that exposure concentrations were completed in time for NATA's release, the ambient data used in the EC calculations came from a preliminary assessment based on NEI version 1 emissions data; this concession does not significantly affect the ECs calculated. EPA stratified the air quality outputs for a selected group of pollutants by one or more of the four principal NATA categories (i.e., point, nonpoint, on-road mobile and nonroad mobile), using those results as surrogates for the remaining pollutants not modeled in CMAQ-AERMOD. Thus, exposure-model results generated for NATA can be summarized for each principal NATA category or any combination of those categories.

4.3.2. Population Demographic Data

HAPEM divides the exposed population into cohorts such that each person in the population is assigned to one and only one cohort, and all the cohorts combined make up the entire population. A cohort is defined as a group of people whose exposure is expected to differ from exposures of other cohorts due to certain characteristics shared by the people within that cohort. For the 2014 NATA, we specified cohorts by residential census tract and age, with the population in each census tract divided into six age groups: 0–1, 2–4, 5–15, 16–17, 18–64 and ≥65 years of age. These groups were developed using demographic data derived from the 2010 U.S. Census. EPA aggregated the predicted inhalation ECs across cohorts to estimate ECs for the general population.

4.3.3. Data on Population Activity

HAPEM uses two types of data to define activities for the modeled population: activity-pattern data (specifying the frequency, location and duration of daily activities) and commuting-pattern data (specifying the work tracts for people living in each home tract). HAPEM uses these data together to place a hypothetical commuter in either the home or work tract and in a specific microenvironment at each 3-hour time step (the time step used for NATA). The microenvironment assignments and locations derived from these data are then used to calculate ECs (as explained in the next section).

Data on human activity patterns are used to determine the frequency and duration of exposure within various microenvironments (such as indoors at home, in-vehicle and outdoors). Activity-pattern data are taken from demographic surveys of individuals' daily activities that specify the sequence, duration and locations of those activities. The default source of activity-pattern data used by HAPEM and for NATA is EPA's Consolidated Human Activity Database (CHAD; EPA 2015a). To develop the version of CHAD used in NATA (version June 2014), data from 21 individual U.S. studies of human activities were combined into one complete data system containing over 45,000 person-days of activity-pattern records (NATAs before 2011 used previous versions of CHAD containing fewer studies and person-days of data). Because of design limitations in the studies from which it is derived, CHAD may not well represent all

demographic groups, particularly ethnic minorities and low-income populations. Also, the activity-pattern data in CHAD is mostly limited to one- or two-day periods. Extrapolation of these short-term records to the annual activity patterns needed for assessments of air toxics exposure introduces some uncertainty into the analysis.

To address this extrapolation uncertainty, HAPEM uses a stochastic process to create simulated long-term (multi-day) activity patterns from daily activity-pattern data that account for day-to-day autocorrelation. These algorithms create annual average activity patterns from daily activity-pattern data to better represent the variability among individuals within a cohort-tract combination. For each day type and demographic group, daily-activity diaries were divided into three groups based on similarity using a cluster analysis. To simulate the activities of an individual, one diary was selected from each group for each day type, resulting in nine diaries in total. Then, for each day type, the sequence of the selected diaries was determined according to the probability of transition from one cluster group to another, as determined by analyses of the CHAD data. The simulation was repeated 30 times, resulting in a set of 30 estimates of annual ECs for each demographic group in each census tract. Use of a limited number of diaries and the transition probabilities is a way to account for day-to-day autocorrelation of activities for an individual, so each exposure-concentration estimate represents an estimate for an individual rather than an average for the group. Therefore, with this approach, the range represents the variability of ECs across the group. These algorithms were used beginning with HAPEM5 (i.e., beginning with the 1999 NATA).

Commuting-pattern data, the second type of population activity data used in HAPEM, are derived for each cohort from a U.S. Census database containing information on tract-to-tract commuting patterns. These data specify the number of residents in each tract that work in that tract and every other census tract (i.e., the population associated with each home-tract/work-tract pair) and the distance between the centroids of the two tracts. An important limitation is that the commuting-pattern data included in HAPEM do not account for the movement of school-age children who travel (or commute) to a school located outside of their home tract.

4.3.4. Microenvironmental Data

A microenvironment is a three-dimensional space in which human contact with an environmental pollutant occurs. In HAPEM, this space is treated as a well-characterized, relatively homogenous location with respect to pollutant concentrations for a specified period. The inhalation exposure estimate is determined by the sequence of microenvironments visited by the individual. The concentration in each microenvironment is estimated by using the three microenvironmental factors listed below to adjust the ambient-concentration estimate for the census tract where it is located:

- a penetration factor that is an estimate of the ratio of the microenvironmental concentration to the concurrent outdoor concentration in the immediate vicinity of the microenvironment; penetration factors are pollutant-specific estimates that are derived from reported measurement studies;
- a proximity factor that is an estimate of the ratio of the outdoor concentration in the immediate vicinity of the microenvironment to the outdoor concentration represented by the ambient air concentration input to the model; and
- an additive factor that accounts for emission sources within or near a particular microenvironment, such as indoor emission sources. As noted below, the additive factor is not used for NATA.

The relationship between the estimated ECs, the input ambient concentrations and these three factors is demonstrated by the equation below.

$$C_{(i,k,t)} = CONC_{(i,t)} \times PEN_k \times PROX_k + ADD_k$$

Where:

$C_{(i,k,t)}$	=	EC predicted within census tract *i* and microenvironment *k* for time step *t*, in units of µg/m^3
$CONC_{(i,t)}$	=	ambient concentration for census tract *i* for time step *t*, in units of µg/m^3
PEN_k	=	penetration factor for microenvironment *k*
$PROX_k$	=	proximity factor for microenvironment *k*
ADD_k	=	additive factor accounting for sources within microenvironment *k*, in units of µg/m^3

Stochastic processes can be used to select work tracts, ambient air concentrations and microenvironmental factors. This important feature allows exposures to be characterized with probability distributions rather than point estimates, which more accurately reflect the variability of these components and simulate some of the variability found in measurement studies.

In HAPEM, the characteristics of each microenvironment are used to assign each microenvironment to one of three groups: indoors, outdoors and in-vehicle. The 2014 NATA used the 18 microenvironments shown in Table 4-2. The microenvironments in the indoor group were further classified as associated with either residence or other buildings, while those in the outdoor group were categorized as either near-road or away-from-road. Each group consists of microenvironments expected to have similar penetration factors, thus allowing microenvironmental factors developed for one microenvironment to be applied to other microenvironments in the same group. Within each census tract, HAPEM uses estimates of the number of people living within each of three distance-from-road bins to stochastically vary the proximity factor based on distance-from-road (i.e., proximity factors are higher for microenvironments near major roadways, lower for microenvironments relatively far from major roadways). The additive factor (ADD_k) in the expression for EC, above, was set to zero for NATA because indoor-source data are currently incomplete (recall that NATA covers only pollutants derived from outdoor sources).

An important consideration is that data to support quantitative microenvironmental factors are not well developed for many of the air toxic compounds and for most of the microenvironments, which introduces uncertainty into the analysis of exposures. Section 7 contains a discussion on uncertainty and variability regarding this and other issues for NATA.

Table 4-2. Microenvironments used in HAPEM modeling for the 2014 NATA

Indoors	Outdoors	In Vehicle
Residence Residential *Other Building* Air Travel Bar/Restaurant Hospital Office Public Access School Waiting Inside for Public Transit	*Near-road* Motorcycle/Bicycle Outdoors, Near Roadway Outdoors, Parking Garage Outdoors, Service Station Residential Garage Waiting Outdoors for Public Transit *Away-from-road* Ferryboat Outdoors Other	Car/Truck Public Transit

4.4. Exposure Factors

HAPEM exposure modeling for NATA requires substantial time and resources for data collection and processing, computing and model processing. Due to these requirements, EPA conducted HAPEM modeling for the 2014 NATA only for selected pollutants, which we present below along with how we used them to estimate ECs for the remaining NATA pollutants.

- **Coke oven emissions** (emitted by point sources and present in ambient air as either particulates or gases) and **diesel PM** (modeled as particulates from nonpoint and mobile sources) were special cases that EPA modeled as themselves in HAPEM and not used as surrogates for any other pollutants not modeled in HAPEM.

- **Benzene** and **1,3-butadiene** are gas-phase pollutants emitted by many processes (and all four principal NATA categories) in nearly all U.S. locations. EPA selected benzene as the surrogate for all other gas-phase pollutants not modeled in HAPEM (EPA considers benzene modeling in NATA to be more reliable than 1,3-butadiene modeling).

- Unspeciated, generic PAHs ("**PAH, total**"), which are pollutants that can be present in either gas phase or particulate phase in ambient air, are emitted by all four principal NATA categories and from a wide variety of processes. EPA selected "PAH, total" as the surrogate for all other mixed-phase pollutants not modeled by HAPEM.

- **Chromium (VI)** is a highly toxic particulate-phase pollutant emitted by all four principal NATA categories. EPA selected it as the surrogate for all other particulate pollutants not modeled in HAPEM and emitted by point or nonpoint sources.

- EPA selected **nickel**, a particulate-phase pollutant emitted by a variety of processes spread across the United States, as the surrogate for all other particulate pollutants not modeled in HAPEM and emitted by mobile sources.

Appendix F to this document contains further details on the application of HAPEM7 in the 2014 NATA analysis. The spreadsheet file "2014_NATA_Exposure_Factors.xlsx" within the Supplemental Data folder accompanying this TSD spreadsheet contains the tract-level exposure-to-ambient concentration ratios (i.e., exposure factors) for each surrogate pollutant. (Access the NATA website at https://www.epa.gov/national-air-toxics-assessment.)

Overall, the HAPEM exposure predictions are lower than the corresponding predicted air quality values. This reduction likely results from the inability of many pollutants to penetrate efficiently into an indoor environment. (Recall that indoor sources of air toxics have not been included in any versions of NATA completed to date).

4.5. Evaluating Exposure Modeling

A model-performance evaluation can provide valuable information regarding model uncertainty when using computer-simulation models of human exposures to pollutants. Also, a well-conducted evaluation can greatly increase confidence in model results for a given application or use. One type of performance evaluation uses measurements and environmental data as a benchmark to compare modeling estimates. EPA has worked with the Mickey Leland Center (NUATRC 2011) on past assessments to help identify new and independent sources of personal-monitoring data for use in comparison with the NATA results.

Extensive peer review involving independent scientific and technical advice from scientists, engineers and economists can be another valuable component of a model evaluation. In July 2000, HAPEM4 underwent external peer review by technical experts for both the microenvironmental factors used in the model and the overall application of the model for NATA. A discussion of several of the issues addressed by these reviews is included in Appendix A of the report for the 1996 NATA presented to EPA's Science Advisory Board for review (EPA 2001b). In 2001, EPA's Scientific Advisory Board reviewed the application of HAPEM4 as part of the 1996 NATA review (EPA 2001a). Although several limitations were identified in the current methodology, HAPEM4 was acknowledged as an appropriate tool to help better understand the relationship of human exposures to ambient-concentration levels. Since then, numerous studies have used and cited subsequent HAPEM versions, including HAPEM7.

4.6. Summary

- Estimating inhalation ECs is a critical step in determining potential health risks because ambient concentrations do not account for movements of individuals among locations and microenvironments where pollutant concentrations can differ.
- We estimated inhalation ECs for each pollutant/source group/census tract for the 2014 NATA using the HAPEM7 model.
- These ECs can be used to determine census tract-level potential health risks.

5. Characterizing Effects of Air Toxics

Exposure to air toxics is associated with increased incidence of cancer and a variety of adverse noncancer health effects. The type and severity of effects depends on several factors, including the identity and nature of the chemical to which an individual is exposed, the magnitude and duration of exposure, and the unique behaviors and sensitivities of exposed individuals.

EPA uses a toxicity assessment to identify and quantify the adverse health effects associated with exposure to a chemical, following EPA risk assessment methods. As indicated in Figure 1-3 of this document and described in more detail in Volume 1 of EPA's ATRA Reference Library (EPA 2004a), two processes constitute toxicity assessment: hazard identification (during which the specific adverse effects are identified that can be causally linked with exposure to a given chemical) and dose-response assessment (which characterizes the quantitative relationship between chemical dose or concentration and adverse effects, that is, the hazard(s) identified in the first step).

> The phrase "dose-response" is used generally throughout this document to refer to the relationship between a level of a chemical and a physical response. The values EPA uses for inhalation, however, are derived for exposure concentration, although with consideration of dose. Consideration of the relationship between exposure concentration, dose and dosimetry (how the body handles a chemical once it is inhaled) is inherent in the derivation of values. The term "toxicity values" is used here to refer to the RfCs and UREs used in inhalation risk assessment.

Ultimately, the results of the toxicity assessment, referred to in this document as "toxicity values," are used along with exposure estimates to characterize health risks for exposed populations (as described in Section 6). Although the toxicity assessment is integral to the overall air toxics risk assessment, it is usually done prior to the risk assessment. EPA has completed this toxicity assessment for many air toxics and has made available the resulting toxicity information and dose-response values, which have undergone extensive peer review.

This section explains how toxicity assessments are used in the NATA risk assessment process. Specifically, the sections that follow provide an overview of the cancer and noncancer toxicity values used in NATA and the primary sources of these values. They also describe several adjustments and assumptions to toxicity values specific to the NATA risk assessment process.

5.1. Toxicity Values and Their Use in NATA

The toxicity values used in NATA are quantitative expressions used to estimate the likelihood of adverse health effects given an estimated level and duration of exposure. These toxicity values are based on the results of dose-response assessments, which estimate the relationship between the dose and the frequency or prevalence of a response in a population or the probability of a response in any individual. Because NATA is focused on long-term exposures, the toxicity values used in NATA are based on the results of chronic dose-response studies when such data are available. Chronic dose-response assessments can be used to help evaluate the specific 70-year-average (i.e., "lifetime") ECs associated with cancer prevalence rates, or, for noncancer effects, the concentrations at which noncancer adverse health effects might occur given exposure over an extended time (possibly a lifetime, but the time frame also can be shorter).

The toxicity values that are combined with ECs to conduct the risk characterization in NATA are based on the results of quantitative dose-response assessments. The actual values used, however, are not strictly considered dose-response or concentration-response values. To estimate cancer risks in NATA, EPA converted the results of cancer dose-response assessments for a given chemical to a URE that incorporates certain exposure assumptions. This value can be multiplied by the 70-year-average EC to obtain a lifetime cancer risk estimate for each individual. To evaluate the potential for noncancer adverse health effects, we used chronic dose-response data to estimate a threshold that is the EC in air at which adverse health effects are assumed to be unlikely (i.e., the RfC). These two types of values are described in more detail in the following section.

The toxicity values used in NATA are consistent with those OAQPS has compiled for chronic inhalation exposures to air toxics. The full set of toxicity values used for the 2014 NATA (and their sources) can be accessed via the NATA Supplemental Data file; see Appendix B for details. Sources of chronic dose-response assessments used for the 2014 NATA were prioritized according to OAQPS risk assessment guidelines and level of peer review, as discussed below.

5.2. Types of Toxicity Values

Each toxicity value used in NATA is best described as an estimate within a range of possible values appropriate for screening-level risk assessments. Note that the uncertainty in the dose-response assessments and toxicity values that NATA relies on is to some extent one-sided, providing a conservative (health-protective) estimate of risk. The "true" cancer risk and potential for adverse noncancer impacts are believed to be lower than those estimated in this assessment, although the possibility remains that they could be greater. Uncertainty in the derivation of the dose-response values and in other aspects of the NATA process is discussed in Section 7.

5.2.1. Cancer URE

The **URE** is the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 microgram per cubic meter ($\mu g/m^3$) in air. UREs are considered upper-bound estimates, meaning they represent a plausible upper limit to the true value. The true risk is likely to be less, but could be greater.

A cancer dose-response curve is used to demonstrate the quantitative relationship between dose and the likelihood of contracting cancer. If the dose-response relationship is linear, the cancer response is assumed to increase proportionally with the dose (which might be expressed as an EC, an absorbed internal dose, a dose to a specific organ or tissue, or other measure). We have proposed that linear extrapolation of carcinogenic risk in the low-dose region of the curve is a reasonable approach for estimating risk at relatively low exposures, such as those typically experienced by the general population for air toxics (i.e., the true value of the risk is unknown, and could be as low as zero). An upper-bound lifetime cancer risk represents a plausible upper limit to the true probability that an individual will contract cancer due to exposure over a 70-year lifetime to a given hazard (e.g., exposure to an air toxic).

For an inhalation risk assessment (and for NATA), a URE can be used to calculate the estimated cancer risk from inhalation ECs. A URE is calculated by using dose-response information for a chemical and developing a factor in the appropriate units that can be combined directly with ECs in air to estimate individual cancer risks, given certain assumptions regarding the exposure conditions. Specifically, the

URE represents the upper-bound of the excess cancer risk estimated to result from continuous exposure to a concentration of 1 µg of a substance per m3 of air, over a 70-year lifetime and assuming a daily inhalation rate of about 20 m3/day. The risk value is derived from the slope of the dose-response curve as estimated using a linearized multistage statistical model in the low-dose portion of the curve. The interpretation of the URE is as follows: If the URE is 3 × 10-6 µg/m3, no more than three excess tumors would develop per 1 million people if they were exposed daily for a lifetime to a concentration of 1 µg/m3. To the extent that true dose-response relationships for some air toxics compounds are not strictly linear, this assumption could result in overestimates of cancer risk. The upper bound is not a true statistical confidence limit because the URE reflects unquantifiable assumptions about effects at low doses. Thus, although the actual carcinogenic risk is likely to be lower than what is reflected in the URE, it also might be higher.

The URE estimates the toxic potency of a chemical. EPA's weight-of-evidence (WOE) descriptors provide estimates of the level of certainty regarding a chemical's carcinogenic potential. We evaluate three broad categories of toxicological data to make a WOE determination: (1) human data (primarily epidemiological); (2) animal data (results of long-term experimental animal bioassays) and (3) supporting data, including a variety of short-term tests for genotoxicity and other relevant properties, pharmacokinetic and metabolic studies and structure-activity relationships. We evaluate these data in combination to characterize the extent to which they support the hypothesis that an agent or chemical causes cancer in humans. The approach outlined in EPA's Guidelines for Carcinogen Risk Assessment (EPA 2005a) considers available scientific information regarding carcinogenicity. It provides a narrative approach to characterizing carcinogenicity rather than assigning chemicals to specific categories (as was done previously by EPA according to the 1986 guidelines). To provide some measure of clarity and consistency in an otherwise free-form, narrative characterization, standard descriptors are used as part of the hazard narrative to express the conclusion regarding the WOE for carcinogenic-hazard potential. The five recommended standard hazard descriptors are described below.

EPA's Weight of Evidence (WOE) Descriptors
(EPA 2005a)

- Carcinogenic to humans
- Likely to be carcinogenic to humans
- Suggestive evidence of carcinogenic potential
- Inadequate information to assess carcinogenic potential
- Not likely to be carcinogenic to humans

Carcinogenic to Humans: This descriptor indicates strong evidence of human carcinogenicity. It is appropriate when the epidemiologic evidence of a causal association between human exposure and cancer is convincing. Alternatively, this descriptor might be equally appropriate with a lesser weight of epidemiologic evidence that is strengthened by other lines of evidence. It can be used when all the following conditions are met: (1) evidence of an association between human exposure and either cancer or the key precursor events of the agent's mode of action is strong but insufficient for a causal association; (2) evidence of carcinogenicity in animals is extensive; (3) the mode(s) of carcinogenic action and associated key precursor events have been identified in animals and (4) evidence is strong that the key precursor events that precede the cancer response in animals are anticipated to occur in humans and progress to tumors, based on available biological information.

Likely to Be Carcinogenic to Humans: This descriptor is appropriate when the WOE is adequate to demonstrate carcinogenic potential to humans but does not reach the WOE for the descriptor "Carcinogenic to Humans." Adequate evidence consistent with this descriptor covers a broad spectrum.

At one end of the spectrum is evidence for an association between human exposure to the agent and cancer and strong experimental evidence of carcinogenicity in animals. At the other end, with no human data, the weight of experimental evidence shows animal carcinogenicity by a mode or modes of action that are relevant or assumed to be relevant to humans. The use of the term "likely" as a WOE descriptor does not correspond to a quantifiable probability. Moreover, additional data, such as information on the mode of action, might change the choice of descriptor for the illustrated examples.

Suggestive Evidence of Carcinogenic Potential: This descriptor is appropriate when the WOE is suggestive of carcinogenicity; that is, a concern for potential carcinogenic effects in humans is raised, but the data are judged insufficient for a stronger conclusion. This descriptor covers a spectrum of evidence associated with varying levels of concern for carcinogenicity, ranging from a positive cancer result in the only study on an agent to a single positive cancer result in an extensive database that includes negative studies in other species. Depending on the extent of the database, additional studies may or may not provide further insights.

Inadequate Information to Assess Carcinogenic Potential: This descriptor is appropriate when available data are judged inadequate for applying one of the other descriptors. Additional studies generally would be expected to provide further insights.

Not Likely to Be Carcinogenic to Humans: This descriptor is appropriate when the available data are considered robust for deciding no basis for human hazard concern exists. In some instances, positive results in experimental animals can occur when the evidence is strong and consistent that each mode of action in experimental animals does not operate in humans. In other cases, there can be convincing evidence in both humans and animals that the agent is not carcinogenic. A descriptor of "not likely" applies only to the circumstances supported by the data. For example, an agent might be "Not Likely to Be Carcinogenic" by one route but not necessarily by another. In those cases that have one or more positive animal experiments but the results are judged to be not relevant to humans, the narrative discusses why the results are not relevant. As with the "likely" descriptor, the term "not likely" here does not correspond to a quantifiable probability.

Important to note is that these WOE categories express only a relative level of certainty that these substances might cause cancer in humans. The categories do not specifically connote relative levels of hazard or the degree of conservatism applied in developing a dose-response assessment. For example, a substance with suggestive evidence of carcinogenic potential might impart a greater cancer risk to more people than another substance that is carcinogenic to humans.

The process of developing UREs includes several important sources of uncertainty. Many of the air toxics in NATA are classified as "likely" carcinogens. The term likely, as used in this instance, means that data are insufficient to prove these substances definitively cause cancer in humans. That some are not human carcinogens at environmentally relevant ECs is possible, and the true cancer risk associated with these air toxics might be zero. UREs for most air toxics were developed from animal data using health-protective methods to extrapolate to humans. Actual human responses may differ from those predicted. For more information, see EPA's Guidelines for Carcinogen Risk Assessment (EPA 2005a).

5.2.2. Noncancer Chronic RfC

The RfC is an estimate of a continuous inhalation exposure that is thought to be without an appreciable risk of adverse health effects over a lifetime. The population considered when deriving RfCs includes sensitive subgroups (i.e., children, asthmatics and the elderly). The RfC is derived by reviewing a health-effects database for a chemical and identifying the most sensitive and relevant endpoint, along with the principal study or studies demonstrating that endpoint. The value is calculated by dividing the no-observed-adverse-effect level (or an analogous exposure level obtained with an alternate approach, e.g., a lowest-observed-adverse-effect level or a benchmark dose) by uncertainty factors reflecting the limitations of the data used.

> The **RfC** is an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

As with UREs for cancer risk assessment, the process of developing RfCs includes several important sources of uncertainty, which span perhaps an order of magnitude. Uncertainty factors are intended to account for (1) variation in sensitivity among the individuals in the population, (2) uncertainty in extrapolating laboratory animal data to humans, (3) uncertainty in extrapolating from data obtained in a study involving a less-than-lifetime exposure, (4) uncertainty in using lowest-observed-adverse-effect-level or other data rather than no-observed-adverse-effect-level data and (5) inability of any single study to address all possible adverse outcomes in humans adequately. Additionally, an adjustment factor is sometimes applied to account for scientific uncertainties in the data or study design not explicitly captured in the uncertainty factors (e.g., a statistically inadequate sample size or poor exposure characterization). For more information, refer to EPA's Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (EPA 1994).

Unlike linear dose-response assessments for cancer, noncancer risks generally are not expressed as a probability that an individual will experience an adverse effect. Instead, in an air toxics risk assessment, the potential for noncancer effects in humans is typically quantified by calculating the ratio of the inhalation EC to the RfC. This ratio is referred to as the hazard quotient (HQ). For a given air toxic, exposures at or below the RfC (i.e., HQs are 1 or less) are not likely to be associated with adverse health effects. As exposures increase above the RfC (i.e., HQs are greater than 1), the potential for adverse effects also increases. The HQ, however, should not be interpreted as a probability of adverse effects.

Additional information is provided in the description of risk characterization for NATA in Section 6 of this document.

5.3. Data Sources for Toxicity Values

Information on dose-response assessments for evaluating chronic exposures for NATA was obtained from multiple sources and prioritized according to OAQPS risk assessment guidelines and level of peer review. Our approach for selecting appropriate toxicity values generally places greater weight on the EPA-derived toxicity values than those from other agencies (listed below).

Additionally, the approach of favoring EPA values (when they exist) has been endorsed by EPA's Science Advisory Board. This ensures the use of values most consistent with well-established and scientifically based EPA science policy. A spreadsheet file "NATA_Pollutants.xlsx" within the Supplemental Data folder

accompanying this TSD contains the toxicity values for both cancer and noncancer chronic effects used in the 2014 NATA. Cancer effects are characterized according to the extent to which available data support the hypothesis that a pollutant causes cancer in humans.

5.3.1. U.S. EPA Integrated Risk Information System

We disseminate dose-response assessment information in several forms, depending on the level of internal review. The Integrated Risk Information System (**IRIS**) is an electronic database prepared and maintained by EPA that contains information on human-health effects that could result from exposure to various substances in the environment. These assessments have undergone external peer review and subsequent revision, compliant with requirements EPA instituted in 1996 for the IRIS review process.

Externally peer-reviewed assessments under development for IRIS were given first consideration for NATA. These assessments, which reflect the most recent available toxicity information and data analysis, were used in some cases to supersede existing values on IRIS. Current IRIS values were used for NATA when peer-reviewed IRIS values under development were not available.

5.3.2. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry

The Agency for Toxic Substances and Disease Registry (ATSDR) publishes minimal risk levels (MRLs) for many substances based on health effects other than cancer. The MRL is defined as an estimate of human exposure to a substance that is likely to be without an appreciable risk of adverse effects (other than cancer) over a specified duration of exposure. For noncancer values in the 2014 NATA, inhalation MRLs were used when IRIS RfC values were not available or when the ATSDR value was based on more recent, peer-reviewed data and analysis methods than the IRIS value (because the ATSDR concept, definition and derivation are analogous to IRIS). ATSDR does not develop assessments based on carcinogenicity. After internal and external review, MRLs are published in pollutant-specific toxicological-profile documents. ATSDR regularly updates these toxicological-profile documents; they are available at Toxic Substances Portal MRLs (ATSDR 2015).

5.3.3. California Environmental Protection Agency Office of Environmental Health Hazard Assessment

California's Office of Environmental Health Hazard Assessment (OEHHA) develops UREs based on carcinogenicity and reference exposure levels (RELs) based on health effects other than cancer. The REL is defined as a concentration level at or below which no adverse health effects are anticipated. For cancer and noncancer values in the 2014 NATA, OEHHA UREs and inhalation RELs were used when their derivation was determined to be consistent with the concepts and definitions of IRIS or ATSDR. OEHHA dose-response information is available at Air Toxicology and Epidemiology (OEHHA 2016). Technical support documents for assessing hot spots are available on the OEHHA website at Hot Spots Guidelines (OEHHA 2015).

5.3.4. U.S. EPA Health Effects Assessment Summary Tables

The Health Effects Assessment Summary Tables (EPA 1997) are a comprehensive listing consisting almost entirely of provisional UREs, RfCs and other risk assessment information of interest that various EPA offices have developed. The assessments, which have never been submitted for EPA consensus,

were last updated in 2001. NATA uses information from these tables only when no values from the sources discussed in Sections 5.3.1 through 5.3.3 are available.

5.3.5. World Health Organization International Agency for Research on Cancer

The International Agency for Research on Cancer of the World Health Organization (WHO) coordinates and conducts research on cancer and provides information on related cancer research and epidemiology. Although the agency does not develop quantitative dose-response values, it has published a series of monographs (WHO 2018) on the carcinogenicity of a wide range of substances. The following "degrees of evidence" published by the International Agency for Research on Cancer were used when EPA WOE determinations were not available for a substance or are out of date (see the NATA Glossary of Terms in Appendix A for definitions of each):

- Group 1: Carcinogenic to humans;
- Group 2A: Probably carcinogenic to humans;
- Group 2B: Possibly carcinogenic to humans;
- Group 3: Not classifiable as to human carcinogenicity; and
- Group 4: Probably not carcinogenic to humans.

5.4. Additional Toxicity Decisions for Some Chemicals

After the dose-response information was prioritized, we made additional changes to some of the chronic inhalation exposure values to address data gaps, increase accuracy and avoid underestimating risk for NATA.

5.4.1. Polycyclic Organic Matter

A substantial proportion of polycyclic organic matter (POM) reported in the 2014 NEI was not speciated into individual compounds. For example, some emissions of POM were reported in NEI as "7-PAH" or "16-PAH," representing subsets of certain POM, or simply as "total PAH" or "polycyclic organic matter." In other cases, individual POM compounds were reported for which no quantitative cancer dose-response value has been published in the sources used for NATA. As a result, we made simplifying assumptions that characterize emissions reported as POM. This allows us to quantitatively evaluate cancer risk for these species without substantially under- or overestimating risk (which can occur if all reported emissions of POM are assigned the same URE). To accomplish this, POM emissions as reported in NEI were grouped into categories. EPA assigns dose-response values based on the known or estimated toxicity for POM within each group and on information for the POM speciation of emission sources, such as wood fires and industrial processes involving combustion.

For the 2014 NATA, we divided unspeciated POM emissions into eight POM groups. The first two groups included unspeciated POM (including "total PAH") and individual POM species with no URE assigned. Both groups were assigned a URE equal to 5 percent of that for pure benzo[a]pyrene, accounting for toxicity and the estimated emission profile of POM compounds. Groups 3 through 7 comprised POM

compounds for which emissions were reported as individual compounds and for which UREs have been estimated. Compounds in these groups were categorized based on toxicity, and an appropriate URE was assigned to each category based on toxicity of the compounds included in the group. Category 8 was composed of unspeciated polynuclear aromatic hydrocarbons reported as 7-PAH and was assigned a URE equal to 18 percent of that for pure benzo[a]pyrene. We discuss the POM groups used for the 2014 NEI in Section 2.1.1.1.

We concluded that three PAHs – anthracene, phenanthrene and pyrene – are not carcinogenic, and therefore no URE was assigned to these for the 2014 NATA. Details of the analysis that led to this conclusion can be found in the document entitled Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures: In Support of Summary Information of the Integrated Risk Information System (IRIS) (EPA 2010a).

5.4.2. Glycol Ethers

Much of the emission-inventory information for the glycol ether category reported only the total mass for the entire group without distinguishing among individual glycol ether compounds. In other cases, emissions of individual glycol ether compounds that had not been assigned dose-response values were reported. Individual glycol ether compounds vary substantially in toxicity. To avoid underestimating the health hazard associated with glycol ethers, we protectively applied the RfC for **ethylene glycol methyl ether** (the most toxic glycol ether for which an assessment exists) to glycol ether emissions of unspecified composition.

5.4.3. Acrolein

EPA first derived an IRIS RfC for acrolein in 2003 (EPA 2003a). This value was based on a 1978 subchronic rodent study that identified a lowest-observed-adverse-effect level (LOAEL) for nasal lesions (Feron et al. 1978). In 2008, the OEHHA derived a chronic reference exposure level for acrolein that was based on a more recent subchronic rodent study. The newer study identified a no-observed-adverse-effect level (NOAEL) for nasal lesions (OEHHA 2008; Dorman et al. 2008). Because both studies identified nasal lesions as the critical effect and because the Dorman et al. (2008) study identified a NOAEL, we used the more recent OEHHA REL for acrolein in the 2014 NATA.

5.4.4. Metals

Several decisions made for the 2014 NATA regarding the toxicity values used for metal compounds are discussed in this section.

Chromium (VI) compounds. We used the IRIS RfC for particulate chromium (VI) instead of the RfC for chromic acid mists and dissolved aerosols to avoid underestimating the health hazard associated with these compounds. The RfC for particulate chromium (VI) is less than those RfCs for chromic acid mists and dissolved aerosols.

Lead. We consider the primary National Ambient Air Quality Standard (NAAQS) for lead, which incorporates an ample margin of safety, to be protective of all potential health effects for the most susceptible populations. The NAAQS, developed using the EPA Integrated Exposure, Uptake, Biokinetic Model, was preferred over the RfC for noncancer adverse effects because the NAAQS for lead was developed using more recent toxicity and dose-response information on the noncancer adverse impacts

of lead. The NAAQS for lead was set to protect the health of the most susceptible children and other potentially at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurobehavioral and neurocognitive effects (which are the effects to which children are most sensitive). The lead NAAQS, a rolling 3-month average level of lead in total suspended particles, was used as a long-term value in NATA.

Nickel compounds. The cancer inhalation URE for most of the emissions of nickel compounds included in NATA (including unspecified nickel emissions reported as "nickel compounds") was derived from the IRIS URE for insoluble nickel compounds in crystalline form. Soluble nickel species, and insoluble species in amorphous form, do not appear to produce genotoxic effects by the same toxic mode of action as insoluble crystalline nickel. Nickel speciation information for some of the largest nickel-emitting sources, including oil and coal combustion, suggests that at least 35 percent of total nickel emissions could be soluble compounds. The remaining insoluble nickel emissions, however, are not well characterized. Consistent with this limited information, we conservatively assumed for NATA that 65 percent of emitted nickel is insoluble and that all insoluble nickel is crystalline. Because the nickel URE listed in IRIS is based on nickel subsulfide and represents pure insoluble crystalline nickel, it was adjusted to reflect an assumption that 65 percent of the total mass of emitted nickel might be carcinogenic. In cases where a chemical-specific URE was identified for a reported nickel compound, it was used without adjustment. Furthermore, the MRL in Table 2 of the ATSDR is not adjusted because the noncancer effects of nickel are not thought to be limited to the insoluble crystalline form.

Manganese. We used the ATSDR MRL for manganese (Mn) as the chronic inhalation reference value in the 2014 NATA. There is an existing IRIS RfC for Mn (EPA 1993), and ATSDR published an assessment of Mn toxicity which includes a chronic inhalation reference value (i.e., an ATSDR Minimal Risk Level, MRL). (ATSDR 2012). Both the 1993 IRIS RfC and the 2012 ATSDR MRL were based on the same study (Roels et al. 1992); however, ATSDR used updated dose-response modeling methodology (benchmark dose approach) and considered recent pharmacokinetic findings to support their MRL derivation. Because of the updated methods, we determined that the ATSDR MRL is the appropriate noncancer health reference value for manganese in NATA.

5.4.5. Adjustment of Mutagen UREs to Account for Exposure During Childhood

For carcinogenic chemicals acting via a mutagenic mode of action (i.e., chemicals that cause cancer by damaging genes), we recommend that estimated risks reflect the increased carcinogenicity of such chemicals during childhood. This approach is explained in detail in the Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (EPA 2005b). Where available data do not support a chemical-specific evaluation of differences between adults and children, the Supplemental Guidance recommends adjusting for early-life exposures by increasing the carcinogenic potency by 10-fold for children up to 2 years old and by 3-fold for children 2 to 15 years old. These adjustments have the aggregate effects of increasing the estimated risk by about 60 percent (a 1.6-fold increase) for a lifetime of constant inhalation exposure. EPA recommends making these default adjustments only for carcinogens known to be mutagenic and for which data to evaluate adult and juvenile differences in toxicity are not available.

For NATA 2014, we adjusted the UREs for acrylamide, benzidine, chloroprene, coke oven emissions, ethyl carbamate, ethylene oxide, methylene chloride, nitrosodimethylamine and PAHs upward by a factor of 1.6 to account for the increased risk during childhood exposures. Although trichloroethylene is

carcinogenic by a mutagenic mode of action, the age-dependent adjustment factor for the URE only applies to the portion of the slope factor reflecting risk of kidney cancer. For full lifetime exposure to a constant level of trichloroethylene exposure, we adjusted the URE upward by a factor of 1.12 (rather than 1.6 as discussed above). For more information on applying age-dependent adjustment factors in cases where exposure varies over the lifetime, see Toxicological Review of Trichloroethylene (EPA 2014).

These nine air toxics were the only ones that met the adjustment criteria described above at the time of this assessment. The overall lifetime adjustment was applied because a single, lifetime-average EC was estimated for NATA rather than age-group-specific exposures. Note that the IRIS assessment contains vinyl chloride UREs for both exposure from birth and exposure during adulthood. However, the overall vinyl chloride URE already includes exposure from birth. Thus, we used that value with no additional factor applied.

5.4.6. Diesel Particulate Matter

Diesel PM (DPM) mass (expressed as μg DPM/m3) has historically been used as a surrogate measure of exposure for whole diesel exhaust. Although uncertainty exists as to whether DPM is the most appropriate parameter to correlate with human health effects, it is considered a reasonable choice until more definitive information about the mechanisms of toxicity or mode(s) of action of diesel exhaust becomes available.

In EPA's 2002 Diesel Health Assessment Document (Diesel HAD), exposure to diesel exhaust was classified as likely to be carcinogenic to humans by inhalation from environmental exposures, in accordance with the revised draft 1996/1999 EPA cancer guidelines. Several other agencies (National Institute for Occupational Safety and Health, the International Agency for Research on Cancer, the World Health Organization, California EPA and the U.S. Department of Health and Human Services) had made similar hazard classifications prior to 2002. EPA also concluded in the 2002 Diesel HAD that it was impossible to calculate a cancer unit risk for diesel exhaust due to limitations in the exposure data for the occupational groups or the absence of a dose-response relationship.

In the absence of a cancer unit risk, the Diesel HAD sought to provide additional insight into the significance of the diesel exhaust cancer hazard by estimating possible ranges of risk that might be present in the population. An exploratory analysis was used to characterize a possible risk range, and found that environmental risks from diesel exhaust exposure could plausibly range from a low of 10^{-5} to as high of 10^{-3} for long-term exposures. Because of uncertainties, the analysis acknowledged that the risks could be lower than 10^{-5}, and a zero risk from diesel exhaust exposure was not ruled out.

Noncancer health effects of acute and chronic exposure to diesel exhaust emissions are also of concern to EPA. The agency derived a diesel exhaust reference concentration (RfC) after considering four well-conducted chronic rat inhalation studies showing adverse pulmonary effects. The RfC is 5 $\mu g/m^3$ for diesel exhaust measured as diesel particulate matter. This RfC does not consider allergenic effects such as those associated with asthma, immunologic effects or the potential for cardiac effects. Emerging evidence in 2002, discussed in the Diesel HAD, suggested that exposure to diesel exhaust could exacerbate these effects, but the exposure-response data were lacking at that time to derive an RfC.

The Diesel HAD noted that the cancer and noncancer hazard conclusions applied to the general use of diesel engines then on the market, and as cleaner engines replace a substantial number of existing ones, the applicability of the conclusions would need to be reevaluated.

Several studies published since 2002 continue to report increased lung cancer with occupational exposure to older engine diesel exhaust. Of note since 2011 are three new epidemiology studies that examined lung cancer in occupational populations (for example, in truck drivers, underground nonmetal miners and other diesel motor related occupations). These studies (Garshick et al. 2012; Silverman et al. 2012; Olsson et al. 2011) reported increasing risks with exposure to diesel exhaust, and positive exposure-response relationships were also evident to varying degrees. These newer studies (along with others that have appeared in the scientific literature) add to the evidence EPA evaluated in the 2002 Health Assessment Document and further reinforce the lung cancer hazard concern. The findings from these newer studies do not necessarily apply to newer technology diesel engines since the newer engines have large reductions in the emission constituents.

In June 2012, the World Health Organization's International Agency for Research on Cancer (IARC) evaluated the full range of cancer-related health-effects data for diesel engine exhaust (IARC 2014). IARC concluded that diesel exhaust should be regarded as "carcinogenic to humans." This designation was an update from its 1988 evaluation that considered the evidence to be indicative of a "probable human carcinogen." IARC is a recognized international authority on the carcinogenic potential of chemicals and other agents.

Also in 2012, EPA and industry asked the Health Effects Institute to convene a panel to review recently published epidemiology studies of occupational exposures to diesel engine exhaust. The request was in part to determine whether new studies could be used in a quantitative risk assessment (QRA) to calculate a cancer URE. In a final report published at the end of 2015 (HEI 2015), the panel concluded that newer studies made considerable progress toward addressing a number of major limitations in previous epidemiologic studies of diesel engine exhaust. It further stated that, although uncertainties still remain, these newer studies provide a useful basis for potentially conducting a QRA of diesel engine exhaust exposures, but specifically to diesel engine exhaust from older diesel engines. Currently, there are no ongoing activities at EPA related to conducting a QRA for diesel engine exhaust.

5.5. Summary

- To evaluate the potential of a given air toxic to cause cancer and other adverse health effects, we identified potential adverse effects that the substance causes and evaluated the specific ECs at which these effects might occur.
- The URE represents the upper-bound excess cancer risk estimated to result from continuous exposure to a concentration of 1 µg of a substance per m^3 of air over a 70-year lifetime.
- The RfC is an estimate of a continuous inhalation EC over a 70-year lifetime that is thought to be without an appreciable risk of adverse effects. The population considered in the derivation of RfCs includes sensitive subgroups (i.e., children, asthmatics and the elderly).
- Dose-response-assessment information for chronic exposure was obtained from multiple sources and prioritized according to conceptual consistency with OAQPS risk assessment guidelines and level of peer review.
- After considering dose-response information, EPA adjusted some chronic-toxicity values to increase accuracy and to avoid underestimating risk.

6. Characterizing Risks and Hazards in NATA

Risk characterization, the final step in our risk assessment process for air toxics, combines the information from modeled exposure estimates with the dose-response assessment. The result is a quantitative estimate of potential cancer risk and noncancer hazard associated with real-world exposure to air toxics. The term "risk" implies a statistical probability of developing cancer over a lifetime. Noncancer "risks," however, are not expressed as a statistical probability of developing a disease. Rather, noncancer "hazards" are expressed as a ratio of an exposure concentration (EC) to a reference concentration (RfC) associated with observable adverse health effects (i.e., a hazard quotient).

This section contains information on the risk characterization conducted for NATA. After a brief overview of the risk-related questions that NATA is intended to address, the methods used to characterize cancer risk and noncancer hazards for NATA are described. A discussion of the quantitative results included in NATA follows this description.

6.1. The Risk-characterization Questions NATA Addresses

NATA risk characterization considers both cancer risk and the potential for noncancer effects from inhalation of air toxics nationwide, in both urban and rural areas. The purpose of NATA is to understand cancer risks and noncancer hazards to help EPA and others identify air toxics and source categories of greatest potential concern and to set priorities for collecting additional data. The assessment represents a "snapshot" in time for characterizing risks from exposure to air pollutants; it is not designed to characterize risks sufficiently for regulatory action. The risk characterization for NATA, which was limited to inhalation risk from outdoor sources, was designed to answer the following questions:

- Which air toxics pose the greatest potential risk of cancer or adverse noncancer effects across the entire United States?
- Which air toxics pose the greatest potential risk of cancer or adverse noncancer effects in specific areas of the United States?
- Which air toxics pose less, but still significant, potential risk of cancer or adverse noncancer effects across the entire United States?
- When risks from inhalation exposures to all outdoor air toxics are considered in combination, how many people could experience a lifetime cancer risk greater than levels of concern (such as 1-in-1 million or 100-in-1 million)?
- When potential adverse noncancer effects from long-term exposures to all outdoor air toxics are considered in combination for a given target organ or system, how many people could experience exposures that exceed the reference levels intended to protect against those effects (i.e., a hazard quotient greater than 1)?

6.2. How Cancer Risk Is Estimated

To estimate cancer risks in NATA, the results of cancer dose-response assessments for a given chemical were converted to a unit risk estimate (URE). That URE was then multiplied by the estimated inhalation

exposure concentration to obtain an estimate of individual lifetime cancer risk. The approach used in NATA for characterizing cancer risk is consistent with EPA's 2005 final Guidelines for Carcinogen Risk Assessment (EPA 2005a). When used with the cancer UREs described in Section 5, the approach is also consistent with EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (EPA 2005b).

6.2.1. Individual Pollutant Risk

In NATA, individual lifetime cancer risk associated with exposure to a single air pollutant was estimated by multiplying an average estimated long-term exposure concentration by the corresponding URE for that pollutant. Thus, the equation below estimates the probability of an individual developing cancer over a lifetime from the exposure being analyzed due to a given inhalation exposure, over and above that due to any other factors.

$$Risk = EC \times URE$$

Where:

Risk = estimated incremental lifetime cancer risk for an individual due to exposure to a specific air toxic, unitless (expressed as a probability)

EC = estimate of long-term inhalation exposure concentration for a specific air toxic, in units of $\mu g/m^3$

URE = the corresponding inhalation unit risk estimate for that air toxic, in units of $1/(\mu g/m^3)$

Note that UREs are typically upper-bound estimates, so actual risks may be lower than predicted. Also, the true value of the risk is unknown.

6.2.2. Multiple-pollutant Risks

EPA estimates individual lifetime cancer risks resulting from exposure to multiple air toxics by summing the chronic cancer risk for each air toxic that can be quantified. This estimate of risk focuses on the additional lifetime risk of cancer predicted from the exposure being analyzed, over and above that due to any other factors. The following equation estimates the predicted cumulative individual cancer risk from inhalation of multiple substances:

$$Risk_{tot} = Risk_1 + Risk2 + \ldots + Risk_i$$

Where:

$Risk_{tot}$ = total cumulative individual lifetime cancer risk, across *i* substances

$Risk_i$ = individual risk estimate for the *i*th substance

In NATA, the estimated ECs are not considered upper bounds. Rather, they represent central-tendency estimates of ECs at the census tract level. Because cancer slope factors are 95-percent upper-confidence

intervals (not "most probable estimates"), summing traditional risk levels can cause the resulting sum to overestimate a 95-percent upper-confidence-level risk for a mixture.

In NATA, we assume that exposures to multiple carcinogens can be added together to estimate risks. This approach has drawbacks: Effects from multiple chemicals may be greater or less than additive, and statistical limitations exist. But this straightforward calculation is widely used to estimate cumulative risks, especially in screening assessments like NATA.

Information on non-additive interactions is not readily available in a form that can be used for NATA. Without this specific information, cancer risk from various chemicals is conservatively assumed to be additive. Thus, the cancer risks from all air toxic compounds listed as carcinogenic or likely carcinogenic to humans were summed to determine cumulative cancer risks for NATA. More information on EPA's methods for conducting risk assessment of mixtures can be found in the Framework for Cumulative Risk Assessment (EPA 2003b).

6.3. How Noncancer Hazard is Estimated

To evaluate the potential for noncancer adverse health effects, EPA uses chronic dose-response data to estimate a reference concentration (RfC) – the EC at which adverse health effects are assumed to be unlikely. (See Section 5.2.2 5.2.2for more information on noncancer RfCs.) Due to the wide variety of endpoints, hazard-identification procedures for noncancer effects have not been described as completely in EPA guidance as those for carcinogens. But EPA has published guidelines for assessing several specific types of chronic noncancer effects (mutagenicity, developmental toxicity, neurotoxicity and reproductive toxicity). These can be found at Products and Publications Relating to Risk Assessment Produced by the Office of the Science Advisor (EPA 2016). EPA has also published a framework for using studies of these and other effects in inhalation risk assessment (EPA 1994).

EPA's Chronic Noncancer Guidelines

- Mutagenicity (EPA 1986)
- Developmental Toxicity (EPA 1991)
- Neurotoxicity (EPA 1998)
- Reproductive Toxicity (EPA 1996)

6.3.1. Individual Pollutant Hazard

EPA estimated chronic noncancer hazards for NATA by dividing a chemical's estimated long-term EC by the RfC for that chemical to yield a hazard quotient (HQ). The following equation estimates the noncancer hazard due to a given inhalation exposure:

$$HQ = \frac{EC}{RfC}$$

Where:

HQ	=	the hazard quotient for an individual air toxic, unitless
EC	=	estimate of long-term inhalation exposure concentration for a specific air toxic, in units of mg/m^3
RfC	=	the corresponding reference concentration for that air toxic, in units of mg/m^3

An HQ value less than or equal to 1 indicates that the exposure is not likely to result in adverse noncancer effects. An HQ value greater than 1, however, does not necessarily suggest a likelihood of adverse health effects and cannot be interpreted to mean that adverse health effects are statistically likely to occur. The statement is simply whether, and by how much, an EC exceeds the RfC, indicating that a potential exists for adverse health effects.

6.3.2. Multiple-pollutant Hazard

We estimated chronic noncancer hazards for multiple air toxics by summing chronic noncancer HQs for individual air toxics that cause similar adverse health effects. The result is a hazard index (HI). Aggregation in this way produces a target-organ-specific HI, defined as a sum of HQs for individual air toxics that affect the same organ or organ system. More information on chemical mixtures risk assessment methods can be found in the EPA supplementary guidance for risk assessment of mixtures (EPA 2000).

The following equation estimates the HI from inhalation of multiple substances:

$$HI = HQ_1 + HQ_2 + \ldots + HQ_i$$

Where:

HI	=	the hazard index for chronic exposure to air toxics 1 through *i*, unitless
HQ_i	=	the hazard quotient for the *i*th air toxic, where all *i* air toxics are assumed to affect the same target organ or organ system, unitless

As with the HQ, an HI value less than or equal to 1 indicates that the exposure is not likely to result in adverse noncancer effects. An HI value greater than 1, however, does not necessarily suggest a likelihood of adverse health effects and cannot be interpreted as a statistical probability of adverse effects occurring.

This equation assumes an additive effect from simultaneous exposures to several chemicals. Summing HQs is inappropriate when effects from multiple chemicals are synergistic (greater than additive) or antagonistic (less than additive). As is the case with cancer risk, quantitative information on non-additive interactions resulting in noncancer hazards is not readily available; consequently, the noncancer HQs are assumed to be additive for chemicals with the same target organ or organ system.

For NATA, we report HIs for 14 target organs or systems. Results indicate that respiratory hazards are the primary noncancer hazards for inhalation exposures to the modeled chemicals.

6.4. How Risk Estimates and Hazard Quotients Are Calculated for NATA at Tract, County and State Levels

The cancer risk and HQs for each modeled air toxic are estimated from ECs (not ambient concentrations) by combining them with UREs and inhalation RfCs (or their equivalents). As described previously, the modeling conducted for NATA resulted in ambient concentrations for each air toxic emitted by modeled sources, with the level of spatial resolution varying by source type and the corresponding modeling approach (see Section 3).

6.4.1. Model Results for Point Sources: Aggregation to Tract-level Results

The NATA modeling step generates ambient concentrations at the block level. For risk and exposure calculations, we aggregated these results from the block level to the tract level by taking a population-weighted average of all block-level concentrations within a given tract, as follows:

$$Conc_{tract_i} = \frac{\sum Conc_{block_j} \times Pop_{block_j}}{\sum Pop_{block_j}}$$

Where:

$Conc_{tract_i}$ = ambient concentration for census tract *i*

$Conc_{block_j}$ = ambient concentration for census block *j* (contained within tract *i*), estimated by AERMOD

Pop_{block_j} = population of blocks contained in tract *i*

6.4.2. Background Concentrations and Secondary Pollutants: Interpolation to Tract-level Results

Background concentrations, as well as estimated concentrations of secondary pollutants generated by the CMAQ model, were estimated for levels other than census tract and thus required interpolation "down" to the tract level. Background concentrations were estimated at the county level. To obtain tract-level concentrations, the county-level estimate was assigned to all census tracts within that county. For secondary pollutants, concentrations were estimated using CMAQ. The results for each grid were then applied evenly to all tracts located within the grid.

6.4.3. Aggregation of Tract-level Results to Larger Spatial Units

Tract-level ambient concentrations were aggregated up to the county, state and national levels using a method that weights concentration according to the population within a region. For a county, for example, a population-weighted ambient concentration was estimated by multiplying the tract-level concentrations by the population of each tract, summing these population-weighted concentrations, and dividing by the total county population encompassing all tracts to obtain a final population-weighted, county-level concentration. The process for aggregating from the tract to the county level can be expressed using the following equation:

$$Conc_{county_k} = \frac{\sum Conc_{tract_i} \times Pop_{tract_i}}{Pop_{county_k}}$$

Where:

$Conc_{county_k}$ = population-weighted concentration for county *k*

$Conc_{tract_i}$ = ambient concentration in tract *i* (contained within county *k*)

Pop_{tract_i} = population in tract *i* (contained within county *k*)

Pop_{county_k} = population in county *k*

This same method was applied when aggregating up to the state or national level, using the appropriate concentration and population values. NATA results include ambient concentrations, ECs, cancer risks, and noncancer HQs at the tract, county, state and national levels.

The ambient concentrations derived at the block level also were used to estimate ECs using either direct exposure modeling with HAPEM or with the exposure factors derived from HAPEM modeling (i.e., ratios of EC to estimated ambient concentration). (See Section 4 for a more thorough discussion of NATA exposure modeling and estimates.) Because the exposure factors were applied at the tract level, each census block was assigned the tract-level EC or exposure factor and then the census block-level ECs are estimated. As was done with the ambient-level concentrations, the block-level ECs were used to estimate cancer and noncancer effects and to aggregate these concentrations up to larger spatial scales. To aggregate tract-level concentrations up to the county-, state- or national-level concentrations, the tract-level concentrations were population-weighted.

6.5. The Risk Characterization Results That NATA Reports

NATA provides a snapshot of the outdoor air quality and the risks to human health that would result if air toxic emission levels remain unchanged. The assessment was based on an inventory of air toxics emissions from 2014. Individuals were assumed to spend their entire lifetimes exposed to these air toxics. Therefore, we did not account for the reductions in emissions that have occurred since the year of the assessment, or those that might happen in the future due to regulations for mobile and industrial sources.

Each NATA represents an update and enhancement to the previous NATA. Because improvements in methodology are made with each successive assessment, comparing assessment results from year to year is not meaningful. Any change in emissions, ambient concentrations or risks might be due to improvement of methodology, to real changes in emissions or source characterization, or both.

The evaluation of national-scale results and comparison of risks among chemicals make it possible to estimate which air toxics pose the greatest potential risk to human health in the United States. NATA reports a summary of these findings. Cancer risks are presented as lifetime risks, meaning the risk of developing cancer due to inhalation exposure to each air toxic compound over a normal lifetime of 70 years. Noncancer hazards are presented in terms of the ratio between the exposure and an RfC for inhalation exposures (i.e., the HQ). As described previously in this section, HQs are combined across chemicals where a common target organ or system is expected to estimate HI (i.e., for respiratory).

Using these quantitative results, NATA classifies certain pollutants as drivers or contributors at the national or regional scale based on certain criteria. Table 6-1 contains the criteria for classifying the air toxics included in NATA at the regional and national level. In general, drivers and contributors were defined as air toxics showing a particular level of risk or hazard for some number of people exposed.

For example, for a pollutant to be categorized in NATA as a cancer contributor at the national level, the individual lifetime cancer risk for that pollutant must have been shown by the assessment to be at least 1-in-1 million and the number of people exposed to that pollutant must have been shown to be at least 25 million. For a pollutant to be categorized in NATA as a regional driver of noncancer health effects, the chronic hazard index for that pollutant must have been shown to exceed 1 and the number of people exposed to that pollutant must have been shown to be at least 10,000.

The NATA results for 2014 indicated that most individuals' estimated risk was between 1-in-1 million and 100-in-1 million, although a small number of localized areas showed risks of higher than 100-in-1 million. Although individuals and communities may be concerned about these results, recall that NATA is not designed to assess specific risk values at local levels. The results are best used as a tool to prioritize pollutants, emissions sources and locations of interest for further investigation.

Table 6-1. Criteria establishing NATA drivers and contributors of health effects for risk characterization

Risk-characterization Category	Criterion (Criteria in both columns must be met)	
	Individual Health Risk or Hazard Index Exceeds…	**Minimum Number of People Exposed (in millions) is…**
Cancer Risk *(value in first column represents individual lifetime cancer risk, in 1 million)*[a]		
National cancer driver	10	25
Regional cancer driver (either set of criteria can be used)	10	1
	100	0.01
National cancer contributor	1	25
Regional cancer contributor	1	1
Hazard Index *(value in first column represents chronic hazard index for any organ/organ system)*[b]		
National noncancer driver	1	25
Regional noncancer driver	1	0.01

[a] Cancer risks are upper-bound lifetime cancer risks; that is, a plausible upper limit to the true probability that an individual will contract cancer over a 70-year lifetime as a result of a given hazard (such as exposure to a toxic chemical). This risk can be measured or estimated in numerical terms (e.g., one chance in a hundred).
[b] Hazard index is the sum of the HQs for substances that affect the same target organ or organ system. Because different pollutants can cause similar adverse health effects, combining HQs associated with different substances is often appropriate to understand the potential health risks associated with aggregate exposures to multiple pollutants.

Furthermore, the risks estimated by the assessment do not consider indoor sources of air toxics or ingestion exposure to any pollutants. Also, although NATA estimates cancer and noncancer risks for numerous pollutants, additional chemicals might exist that are not identified or for which toxicity information is unavailable. Therefore, these risk estimates represent only a subset of the total potential cancer and noncancer risk associated with air toxics.

Analytical results (including modeled ambient concentrations, exposure and risks) for each NATA are also provided at the census tract, county and state levels for those who wish to do their own technical analyses using the most refined output available. In performing such analyses, users must be extremely mindful of the purposes for which NATA was developed. NATA was developed as a screening tool to inform both national and more localized efforts to collect air toxics information and characterize emissions (e.g., prioritize pollutants or areas of interest for more refined data collection such as monitoring). The results are most meaningful when viewed at the state or national level. Nevertheless, reported spatial patterns within a county likely represent actual variations in *overall average* population risks. Less likely, however, is that the assessment pinpoints the exact locations where higher risks exist or that the assessment captures the highest risks in a county.

Using these results alone to draw conclusions about local concentrations and risk is inappropriate. This assessment does not attempt to identify areas or populations that have significantly higher risks than others. Rather, it focuses on characterizing geographic patterns and ranges of risk across the country. In general, however, spending time in larger urban areas tends to pose greater risks than spending time in

smaller urban and rural areas because the emissions of air toxics tend to be higher and more concentrated in areas with more people. This trend is not universal, however, and can vary from pollutant to pollutant according to its sources. The trend also can be affected by exposures and risk from non-inhalation and indoor sources of exposure.

Based on the NATA results, millions of people live in areas where air toxics pose potential health concerns. Although air quality continues to improve, more needs to be done to meet the CAA's requirements to reduce the potential exposure and risk from these chemicals. EPA will continue to develop air toxic regulations and cost-effective pollution prevention and other control options to address indoor and urban pollutant sources that significantly contribute to risk.

You can access all NATA results via the NATA website (https://www.epa.gov/national-air-toxics-assessment).

6.6. Summary

- The purpose of NATA is to understand cancer risk and noncancer health effects to help EPA and others identify pollutants and source categories of greatest potential concern and to set priorities for collecting additional information to improve future assessments.
- Cancer risk is expressed as a statistical probability that an individual will develop cancer. Cancer risks were assumed to be additive across chemicals for NATA.
- Noncancer hazard is expressed as an HQ, which is the ratio of the EC to an RfC associated with observable adverse effects. Noncancer hazards were assumed to be additive across chemicals that effect the same target organ or organ system.
- NATA estimates most individuals' cancer risk to be between 1-in-1 million and 100-in-1 million, although a small number of localized areas showed risk higher than 100-in-1 million.
- Air toxics data for NATA are presented at the national, state, county and census tract levels. The results are most meaningful when used to identify patterns of risk over larger areas. Using these results in the absence of additional information to draw conclusions about local concentrations and risk is inappropriate.

7. Variability and Uncertainty Associated with NATA

7.1. Introduction

This section discusses the variability and uncertainty associated with NATA. Clearly understanding these two concepts – found in all broad-scale assessments that rely on models and data – will help you understand which questions NATA can answer appropriately, and which it cannot.

Key Definitions for this Section

Variability represents the *diversity or heterogeneity in a population or parameter* (e.g., variation in heights of people). Variability cannot be reduced by taking more (or better) measurements; however, it can be accounted for by a more detailed modeling approach (e.g., modeling peoples' heights in terms of age will reduce the unexplained variability due to variation in heights).

Uncertainty refers to the *lack of knowledge* regarding the actual values of model input variables (parameter uncertainty) and of physical systems (model uncertainty). Uncertainty can be reduced through improved measurements and improved model formulation.

As stated in Section 1, NATA results should not be used for limited-scale or site-focused applications. NATA results are intended to characterize broad-scale risk to help identify those air toxics and source types associated with the highest exposures and posing the greatest potential health risks. The results are intended to identify geographic patterns and ranges of risks across the country. To avoid over-interpretation and misapplication of the results, users must first understand the concepts of variability and uncertainty and then must recognize the role that these elements play in NATA results.

Air toxic emissions, air concentrations and exposures are not the same throughout the United States, and the risks associated with air toxics are not the same for all people. Some areas have higher concentrations than others. At certain times, the concentration is higher at a given location than at other times. The risks for some individuals are below the national average, while for others the risks are above the national average. For these reasons, understanding how the ambient (outdoor) air concentration, exposure and risks from air toxics vary throughout the United States is essential for understanding NATA. This information comes from a process called variability analysis.

EPA seeks to protect health with reasonable confidence based on the best data available. Estimates of air concentrations, exposures and risks, however, must always involve assumptions. Assumptions are necessary to simplify the problem at hand. They make NATA possible given available information and resources. That said, assumptions introduce uncertainties into NATA results because we can never be fully confidence that the assumptions are entirely correct. Understanding the extent of these uncertainties, the level of confidence that can be placed in statements related to the assessment, and how this confidence affects the ability to make reasoned decisions is essential. This information comes from a process called uncertainty analysis.

7.2. How NATA Addresses Variability

The NATA process focuses on the variation in ambient air concentrations, exposures and risks across the United States, Puerto Rico and the U.S. Virgin Islands. Included, for example, are variations in source locations and the amounts of pollutants these sources emit, variations in meteorological conditions across the country, and variations in the daily activities of people. This section presents information on the key components that drive variability in risks associated with air toxics and the variability

components that NATA addresses. A brief explanation is also provided on how NATA results should be interpreted given variability.

7.2.1. Components of Variability

NATA results show how air concentrations, exposures and risks vary across broad areas of the country. They do not fully characterize how concentration, exposure and risk vary among individuals, except to the extent these individuals live in different geographic regions and are affected by the values typical of a census tract in that region. NATA results also do not fully characterize how ambient air concentrations might vary temporally and they do not show how concentrations vary spatially within a census tract. The following list explains some of the components of variability that determine differences in ambient air concentrations and individual risks.

Temporal. Sources do not emit pollutants at constant rates. Similarly, the meteorological conditions that affect dispersion in the atmosphere vary over time. Thus, the ambient air concentration at a given location can vary over time.

Geographic. The influence of pollutant emissions on a location's ambient concentration depends on the degree of atmospheric dispersion of the emissions as they travel from the source to the location. Dispersion depends on both meteorological conditions, which vary from place to place, and the travel distance from the source. As a result, the ambient air concentration can vary greatly among different locations. The NATA analysis accounts for some geographic variation by using available meteorology data representative of the location and by modeling ambient concentrations for census areas, but the spatial resolution of model predictions is limited.

Individual location. Two individuals might live at different locations within the same census tract. The ambient concentration estimated for the tract is only an approximation of conditions at all locations in the tract. Different locations within that tract may have different average ambient concentrations. Therefore, exposures and risks may also vary.

Individual activity patterns. Two people may live at the same location but engage in different activities (called an "activity pattern") during each day. Concentrations of substances indoors often differ from concentrations outdoors. If one person spends more time indoors than the other person, the average air concentration to which the two are exposed will differ, even though the ambient air concentration is the same. Similarly, one person may spend more time in a car and be exposed to an air concentration that is typical near roads. The net effect would be that the concentration of each pollutant in the air inhaled by these two people would differ. In other words, their exposure differs.

In addition, the amount of outdoor pollution that penetrates into buildings and vehicles varies due to differences in ventilation and structural integrity. Thus, two people who live in the same location and spend the same amount of time indoors or in vehicles can still be exposed to different pollutant concentrations.

Susceptibility. Two individuals may live at the same location and engage in the same activities, but one person may be more susceptible than another. Susceptibility refers to the extent to which an individual takes a pollutant into the body, transports it into an organ or tissue that might be adversely affected by it, or develops an adverse effect.

A more susceptible person may develop a higher concentration of a pollutant in his or her organs or tissues, or have a higher chance of developing an adverse health effect, than another individual, even when exposures for both individuals are the same. For example, people breathe at different rates; two people breathing the same air may bring different amounts of a pollutant into their bodies. The amount of a pollutant reaching an organ or tissue can also vary between individuals, even if both bring the same amount into their lungs. The amount of time the pollutant remains in the body may also differ. Finally, the innate sensitivity to the effect may vary, even at equal doses in the tissues. The net effect of these factors is that either the dose of the pollutant delivered to the organs or tissues of the body or the level of response (or both) can differ substantially between two people even if they are exposed to the same pollutant concentrations.

The extent to which each factor described above influences variation in individual risk can depend on the age, gender or ethnic group to which an individual belongs, as well as on that individual's lifestyle.

These groups comprise different receptor populations, or cohorts, and the exposures and risks can differ among them.

7.2.2. Quantifying Variability

EPA conducts NATA to understand how ambient air concentrations, exposures and risks vary geographically – not among specific individuals. EPA calculates the ambient air concentrations for each specific, discrete location (i.e., census-block centroid or census-tract centroid; see discussion below) based on the emission sources and meteorological conditions affecting those specific tracts. Some temporal variation is accounted for in NATA calculations. For example, meteorological data used for air quality modeling is temporally dynamic. The air quality modeling therefore captures important variations in ambient conditions on an hourly basis before the resulting modeled ambient air concentrations are time averaged. The ambient concentration inputs to HAPEM are stratified into eight 3-hour time blocks; HAPEM then calculates ECs for each 3-hour time block before calculating an overall, long-term average EC. Although this approach to air quality and exposure modeling considers some important temporal variations, these time-stratified model outputs are averaged prior to the risk characterization step and are not included in the NATA results reported by EPA.

The NATA concentrations and risks, however, do reflect a degree of geographic variation. The smallest geographic area for which NATA results are reported is the census tract. Although results are reported at the census tract level, average risk estimates are far more uncertain at this level of spatial resolution than at the county or state level. Census tracts are small, relatively permanent statistical subdivisions of a county, typically having between 1,200 and 8,000 residents, with most having close to 4,000. Census tracts do not cross county boundaries. Their areas vary widely depending on the density of settlement. Census tracts tend to be small in densely populated areas but can be very large in sparsely populated areas.

Within census tracts are census blocks, the smallest geographic areas that the Census Bureau uses. Blocks are bounded by visible or virtual features such as streets, streams, and city or town boundaries. Census blocks are typically small in area and population; for example, in an urban area, a census block might correspond to a block bounded by city streets. In remote areas, however, census blocks might be large and irregular, comprising many square miles. Blocks typically have approximately 50 residents.

Air concentrations are estimated in NATA at various levels of resolution depending upon the source type modeled. Secondary formation, fires and biogenics (modeled in the CONUS) are at 12-km grid cell resolution. Other sources use census block resolution, though the emissions for some sources are at the grid cell level – these grid cell-level emissions originate from even broader geographic scales (county and national level) and are less certain at these finer scales, as discussed below.

For a given source type and modeling approach, variation in ambient air concentrations within a grid cell or census block is not explicitly modeled. For estimates at the block level, a representative ambient air concentration is estimated for a single location near the center of the block (i.e., the centroid, which is typically, but not always, the geographic center of the block chosen by the U.S. Census Bureau as a reference point). EPA then averages ambient concentrations estimated at the block level for the encompassing census tract, with concentration and risk results reported at the tract level. Assessment results do not reflect variations in the susceptibility of people within a census tract because the focus is to compare typical exposures and risks in different tracts. As a result, individual exposures or risks might differ by as much as a factor of 10 in either direction. You should consider exposures or risks determined in NATA as representative of the geographic area where an individual lives, but not as that individual's personal risk.

Thus, the results of the NATA analysis do not allow for a comparison of ambient air concentrations, exposures or risks between two individuals. They do, however, enable you to understand the variation in typical values for these quantities among counties or states and to a lesser degree among census tracts. For an individual, however, the values may differ from the typical value for the county or state if that individual lives in a part of the area that has a higher or lower than typical value, has an activity pattern that causes a higher or lower exposure than is typical, or is more (or less) susceptible than a "typical" person used in this assessment.

For the purposes of estimating and reporting risk, EPA assumes that individuals within a census tract have the same exposure and risk. This assumption allows NATA users to examine variation in individual exposure among census tracts, but not the variation within a census tract. Activity patterns are included for each of six cohorts defined by age. Even within a receptor population, some variability in activity patterns among individuals is considered. Differences in susceptibility, however, are not included in NATA. EPA took this approach for NATA for two primary reasons:

- **An overall purpose of NATA is to examine broad differences driven by geography.** NATA considers only geographic differences in pollutant concentration, exposure and risk. The goal is to understand how these three factors differ among people living in different geographic areas. EPA assesses these differences, as mentioned above, by tracking differences in air concentration in different census tracts, producing differences in the typical pollutant concentrations, exposures and risks in different tracts. Differences in susceptibility, however, can produce differences in risk between two individuals in the same census tract, and reporting on these differences is not a purpose of NATA.

- **The variability in susceptibility is difficult to model at the national scale.** Very limited information is available on differences in susceptibility among individuals. Even if EPA were to choose to calculate and report differences among individuals in a census tract, scientifically reliable information necessary to produce these calculations is not available for many of the pollutants. Given current information, it may be possible to estimate variability in the rates at which people breathe, but this is only a small part of the overall variation in susceptibility. EPA therefore has chosen not to incorporate this source of variation between individuals.

Considering these limitations, EPA elected to incorporate differences in emissions and meteorology (resulting in differences in ambient air concentration) and differences in location of typical individuals (resulting in differences in exposure) among census tracts. Variation in activity patterns for different age groups is reflected in the assessments to the degree that the age of residents varies by location. Variability in susceptibility is not included for the reasons given above. We address temporal variation in inputs by developing time-weighted averages of emissions characteristics, meteorological conditions and ECs. Temporal variation in the estimated ambient air concentrations, however, is not reflected in the results (only time-weighted annual averages are presented).

7.2.3. How Variability Affects Interpretation of NATA Results

The NATA analysis illustrates how ambient air concentration, exposure and risk vary throughout the United States. The assessment does not focus on the variation in exposure and risk among individuals. It focuses on variation among well-defined geographic areas, such as counties or states, based on calculations of ambient air concentration, exposure and risk in various census tracts. To a lesser degree, variation among demographic groups is also addressed by NATA in that differences in activity patterns are considered in modeling ECs using HAPEM. Risk results, however, are not presented separately for individual demographic groups.

The information contained in the maps, charts and tables produced in NATA display predictions of cancer risk and noncancer hazard. Cancer risk results include statements such as:

> "X percent of the census tracts in a given area are characterized by a typical lifetime excess cancer risk of less than R."

For this statement, if X is 25 percent and R is 1-in-1 million, the result would be:

> "25 percent of the census tracts are characterized by a typical risk of less than 1-in-1 million."

This statement does not necessarily mean that 25 percent of individuals in the specified area have a cancer risk of less than 1-in-1 million. Some people in these census tracts would be expected to have a risk above 1-in-1 million. Although a person may live in a census tract where the typical or average risk is less than 1-in-1 million, that person may live nearer the source than the average person in the census tract, may have an activity pattern that leads to greater exposure, or may be more susceptible. All these factors could cause that individual to experience a risk above the typical value for that census tract. Conversely, the individual could have a lower risk by living farther from the source, having an activity pattern that produces lower exposures, or being less susceptible.

The important point to remember when interpreting the maps and charts of the NATA analysis is that they show variation among values of ambient air concentration, exposure or risk in census tracts or larger areas such as counties. This presentation allows the user to identify geographic regions (counties or states) where these values are higher or lower than the aggregated national average for all census tracts. It does not allow users to identify individuals who have higher or lower values of ambient air concentration, exposure or risk. Nevertheless, individuals with a high risk are more likely to be in geographic regions characterized by a high risk than in those geographic regions characterized by a low risk. The same can be said for exposure (i.e., individuals with a high exposure are more likely to be found in geographic regions characterized by high exposure than in those regions characterized by low exposure).

7.3. How NATA Addresses Uncertainty

No scientific statement (in risk assessment or other areas of science) can be made with complete confidence. Risk estimates are always uncertain to some degree due to issues such as those discussed below. To maintain transparency and openness in the presentation of risk results, the party conducting a risk assessment must explain these uncertainties and how these uncertainties increase or decrease confidence.

The NATA analysis produces statements about variability in ambient air concentrations, exposures and risks across geographic regions for typical individuals, as described in Section 7.2. In this section, the discussion of uncertainty is intended to address the confidence with which these statements regarding variability can be made. Note that uncertainty does not prevent EPA from making a statement of risk, nor does it prevent EPA from taking reasonable actions. Uncertainty does require, however, that the nature of the uncertainty, and the implications for decisions, be understood so the degree of support for the statement can be correctly and properly interpreted.

7.3.1. Components of Uncertainty

Uncertainty arises from a variety of sources. To understand the sources of uncertainty affecting a risk assessment, it is instructive to consider the process by which a study such as NATA is performed, as described in the following sections.

Problem formulation. We must first define the problem to be addressed. For example, a question that might help define the problem could include, "Is the occurrence of adverse human health effects correlated with emissions from industrial facilities?" What the study is intended to address and how the results will be used should be clear at the outset. This initial step in the analysis introduces problem-formulation uncertainty. The purpose of NATA is described in Section 1 of this document, where the question addressed in the assessment is defined as precisely as possible (e.g., that the study is limited to estimates of health effects in human populations) and the reader is informed of the limitations of the assessment. The issue of problem-formulation uncertainty is not considered further in this document.

Defining the analysis components. This step describes what can influence the answer to the problem. In NATA, the multiple influences include emissions from a variety of sources (e.g., mobile, stationary, biogenic); atmospheric dispersion and chemistry; activity patterns for different cohorts; UREs and RfCs and other considerations. Where the science is poorly developed, the factors that must be included might not be clear. Resources may be limited, making the inclusion of all factors in the study infeasible. This step in the analysis, which results in the conceptual model for the assessment, introduces conceptual uncertainty. This issue is also addressed in the discussion of the limitations of NATA in Section 1, where the aspects of the problem that are (and are not) included in the study are addressed (e.g., that the study addresses inhalation of air toxics only). The issue of conceptual uncertainty is not considered further here.

Selecting models. All risk assessments use models. The NATA analysis uses a series of mathematical models. EPA uses models in NATA to produce the emissions inventory, to calculate ambient air concentrations, to calculate exposures and to calculate risks (for cancer and noncancer effects). All scientific models involve uncertainties because a model reduces a (potentially very complex) set of chemical, biological, physical, social or other processes to manageable algorithms that can be used to

perform calculations and make forecasts. The simplifications inherent in the development of a model introduce uncertainties.

Typically, more than one model is available to apply to a problem, and those models can produce different results. Thus, uncertainty is introduced as to which model, and which model results, should be used. As a simple example, NATA uses a linear statistical model to relate EC and cancer risk: Cancer risk equals the exposure (air concentration) multiplied by a URE. Uncertainty analysis involves asking a series of questions: Are we certain this linear relationship is correct? Could the relationship be quadratic (i.e., risk equals exposure multiplied by the square of the dose)? Could the relationship have a threshold (i.e., no risk is apparent until the exposure becomes sufficiently large)? What are the implications for estimates of risk if these different models are used? What are the implications for decisions if a clear choice among the models cannot be made?

This step in the analysis introduces model uncertainty. Judging model uncertainty can be both quantitative and qualitative. Qualitative issues involve the scientific plausibility of the model. Does the model include all important processes? Does it explain the phenomenon (e.g., atmospheric dispersion) well? Is the model well accepted in the scientific community – has it passed critical tests and been subject to rigorous peer review?

Quantitative issues involve comparing model results against sets of data (although this also involves issues of parameter uncertainty discussed in the next bullet). Does the model generally predict these data accurately? Are the predictions accurate to within a factor of 2; a factor of 4? What is the effect of any approximation methods used in the model?

Applying models. The models used in the NATA analysis require parameter inputs such as emission rates, stack heights, fractions of time spent indoors and UREs. Although models describe general relationships among properties of the real world (e.g., the linear relationship between exposure and cancer risk), parameters quantify these properties for specific cases (e.g., the numerical value of the URE for benzene). Parameters provide the numbers needed in the models. Various databases are available from which we can estimate these parameters, and the methods used to collect the data and to compile the databases introduce uncertainties. These factors all introduce parameter uncertainty.

Although parameter uncertainty has both quantitative and qualitative aspects, common practice is to characterize this source of uncertainty quantitatively, with some qualitative caveats. For example, parameter uncertainty might be characterized by a confidence interval, which states that the true value of the parameter (such as the stack height for a facility) probably lies somewhere between 40 and 60 meters or that the stack height is “known to be within” a factor of 1.2, or that the stack height is “accurate to within” 20 percent. Attached to this quantitative characterization of uncertainty will be a qualitative caveat such as “the estimate of this uncertainty is based on measurements made in 1990 at facilities similar to the one considered in this study, but a change in the design of stacks might have been made since 1990.” This qualitative statement provides some idea of the confidence with which the quantitative assessment of uncertainty can be applied.

7.3.2. Components of Uncertainty Included in NATA

NATA Components that Include Uncertainty

- Ambient concentrations
- Exposure estimates
- Risk estimates

For this discussion, we have divided the uncertainties in NATA into three sources, based on the three steps leading from the estimate of emissions to the calculations of risk. Uncertainty in ambient air concentrations is due to uncertainty in the emissions estimates and in the air quality models. Uncertainty in exposure is due to uncertainty in activity patterns, locations of individuals within a census tract, and microenvironmental concentrations as reflected in the exposure model. Finally, uncertainty in risk is due to uncertainty in the shape of the relationship between exposure and effects, the URE and the RfC. These three sources of uncertainty are discussed below.

Ambient air concentrations. Considering first the predictions of ambient air concentrations, the specific sources of uncertainty derive from the parameters for the following: emissions, stack data, particle sizes and reactivity, chemical speciation, terrain, boundary conditions, background concentration, meteorology and model equations. These sources of uncertainty are discussed briefly in this section.

Emissions parameters, including emission rates and locations of sources, are taken from the NEI database. The NEI is a composite of estimates produced by state and local regulatory agencies, industry and EPA. Some of these data were further modified during the NATA review. We have not fully assessed the quality of specific emission rates and locations in the NEI and resultant NATA emissions (e.g., industrial emissions from a specific census tract), although we have conducted reviews. Some of the parameter values may be out of date, errors might have been introduced in transcribing raw data to a computer file, and other data-quality issues may be present. Emission estimates use a variety of methods such as emission factors, material balances, engineering judgment and source testing. Some release point locations use an average facility location instead of the location of each specific unit within the facility. Release point parameters may be defaulted for some situations. Fugitive release parameters are not required and are defaulted where missing. In addition, TRI data does not provide release-point parameters other than identifying sources as “stack” or “fugitive”; the release parameters used historical defaults from previous inventories or new defaults.

Uncertainty also is inherent in the emission models used to develop inventory estimates. For example, we estimate county-level air toxic emissions from nonroad equipment by applying fractions of toxic total hydrocarbons to estimates of county-level hydrocarbons for gaseous air toxics and gas-phase PAHs and fractions of toxic particulate matter to estimates of county-level particulate matter for particle-phase PAHs. We use emission factors based on milligrams per mile for metals. The toxic fractions are derived from speciation data, based on limited testing of a few equipment types. The estimates of county-level total organic gases and particulates are derived from the EPA MOVES model. In MOVES, uncertainties are associated with emission factors, activity and spatial-allocation surrogates. National-level emissions for nonroad equipment in MOVES are allocated to the county level using surrogates, such as construction costs adjusted for geographic construction material cost (to allocate emissions of construction equipment) and employees in manufacturing (to allocate industrial equipment). Availability of more specific local data on equipment populations and usage will result in more accurate inventory estimates. For onroad sources, activity data either come from states or are allocated from states to counties using surrogates. Different surrogates are used for different emission types and geographic locations. These surrogates vary in quality from location to location.

For mobile and nonpoint sources, we typically allocate emissions rates from the county level to grid cells through a surrogate such as traffic data, land cover or other land use types (such as truck stops for heavy duty diesel idling emissions). This allocation introduces additional uncertainty because the data on the surrogates also have uncertainty, and the correlations between the surrogates and the emissions are imperfect.

The health effects of a pollutant depend on its chemical form when inhaled. For many sources, the emissions reported to the NEI or NEI database itself do not include information on chemical speciation of the pollutants of interest, but instead contains the total rate of pollutant emitted in all its forms. For example, chromium obtained from TRI or from some states is reported as chromium and are speciated into hexavalent and trivalent forms in an NEI augmentation step. We make assumptions about chemical speciation based on values estimated to be representative at such sources, considering information on source type, typical feedstock materials, knowledge of the process involved, or other relevant factors. Any one source, however, may have different values than the ones assumed.

The dispersion, or movement, of pollutants in the atmosphere is influenced by the topography of the area surrounding a source, which is characterized by terrain parameters. Although CMAQ model estimates consider topography, the AERMOD model estimates as implemented for NATA do not in all cases. AERMOD estimates for point sources consider topography, but the estimates for the emissions sources modeled as census-tract area sources do not because considering topography in the model requires a single source elevation, which is not always possible for large grid cell sources. Not accounting for terrain introduces uncertainty into predictions of ambient air concentrations, particularly in areas with hills or mountains.

Other sources of uncertainty in the modeling of ambient air concentrations are the values used for the boundary conditions in CMAQ and the background concentration estimates added to AERMOD concentrations for the non-CMAQ HAPs. These sources may include, for example, contributions from long-range transport of compounds from other counties and states. For more details on background concentrations, refer to the discussion in Section 3.

The model equations used in the air quality models represent another source of uncertainty. The AERMOD dispersion model uses steady-state Gaussian equations, which make several assumptions that simplify plume dispersion. The CMAQ model is more complex in its treatment of pollutant dispersion and atmospheric dynamics than AERMOD; nevertheless, many assumptions underlie its Eulerian approach to dispersion, which are outlined further in the science documentation for the CMAQ model.

While the hybrid approach of combining the CMAQ and AERMOD model output improves NATA's treatment of chemistry and transport, there are uncertainties in the implementation. The approach requires emissions and meteorological inputs to be consistent between the models. While we treated emissions as consistently as possible, some simplifications were necessary. The main difference was in the temporal treatment of the emissions. The temporal allocation used in AERMOD was not exactly the same as in CMAQ for the county-level sources, though average profiles based on the CMAQ temporal approach were developed for use in AERMOD. There were also differences in the spatial treatment of CMVs, though for the large vessels, AERMOD source characterization parameters were developed based on summaries of the CMAQ vertical distribution of emissions. In addition to inconsistencies in model inputs, the hybrid approach uses an AERMOD grid cell average to normalize the individual AERMOD concentrations within a grid cell. The AERMOD values are less representative of the true AERMOD

average in grid cells where there are fewer gridded receptors (i.e., nine gridded receptors were used in less-populated areas).

To help characterize the aggregate uncertainty of the predictions of the air quality models, EPA compared modeled concentrations to available monitoring data on ambient air quality. For each monitor-pollutant combination, we compared the predicted annual average concentrations at the monitor location to the sampled annual average concentrations. We present these comparisons in Section 3.7 of this document.

Measured concentrations were taken from EPA's Ambient Monitoring Archive, which includes National Air Toxics Trends Stations and state and local monitors reported to the Air Quality System. For the 2014 NATA, the exact locations of the monitors were used for the model-to-monitor comparison, an approach that increases accuracy over previous assessments. For more details about the model-to-monitor analyses for previous assessments, see Comparison of 1996 ASPEN Modeling System Results to Monitored Concentrations (EPA 2002c), Comparison of 1999 Model-Predicted Concentrations to Monitored Data (EPA 2006b), Comparison of 2002 Model-Predicted Concentrations to Monitored Data (EPA 2009) and Comparison of 2005 Model-Predicted Concentrations to Monitored Data (EPA 2010b).

Discrepancies between model predictions and concentration measurements can be attributed to five sources of uncertainty:

- emission characterization (e.g., specification of source location, emission rates and release characterization);
- meteorological characterization (e.g., representativeness);
- model formulation and methodology (e.g., characterization of dispersion, plume rise, deposition, chemical reactivity);
- monitoring; and
- boundary conditions/background concentrations.

Underestimates for some pollutants could be a result of the following:

- The NEI may be missing specific emission sources.
- Emission rates may be underestimated or overestimated due to emission-estimation techniques and/or spatial allocation of national estimates to county, and county estimates to grid cells.
- The accuracy of the monitor averages is uncertain; the monitors, in turn, have their own sources of uncertainty. Sampling and analytical uncertainty, measurement bias and temporal variation all can cause the ambient concentrations to be inaccurate or imprecise representations of the true atmospheric averages.

Exposure. Sources of uncertainty in the relationship between ambient air concentrations and ECs include those associated with microenvironmental factors and activity patterns. HAPEM calculates the EC in various microenvironments (e.g., indoors at home, in a car) based on inputs of predicted ambient air concentrations and microenvironmental factors. The factors are characterized as probability

distributions to reflect the variability found in air toxics measurements more fully. For many air toxics, the measurement studies needed to estimate microenvironmental factors are not available, so the values used are based on measurement studies of similar compounds in similar situations. This practice introduces uncertainty into the estimation of ECs for such compounds. In addition, even for air toxics with measurement studies, the estimated microenvironmental factors have some uncertainty because the number of such studies is limited. Furthermore, the uniform application of the microenvironmental factors to all census tracts introduces uncertainty by not accounting for possible geographic differences among tracts (e.g., different window-opening behavior, different levels of building integrity).

The activity-pattern sequences for individuals used in HAPEM are based on the Consolidated Human Activity Database (CHAD). As explained in Section4.3.3 HAPEM algorithms consider the variability in activity patterns among individuals within a cohort-tract combination. They do this largely by addressing correlation between subsequent activity patterns assumed to occur for each cohort-tract combination. The representativeness of the daily diaries in CHAD is uncertain because they are a compilation of many studies, including some older studies and some for which the data are based on non-random sampling. It is also uncertain how well the model algorithms represent actual daily autocorrelation between types of activity. This latter issue, however, pertains only to the variability of the ECs across the demographic group and not the median EC, which is the concentration reported by NATA.

The commuting data used in HAPEM are based on an EPA analysis of information from a special study by the U.S. Census Bureau (2010). HAPEM uses this information, reflecting 2010 data, in coordination with the activity-pattern data to place an individual in either the home tract or work tract at each time step. These data introduce some uncertainty because they simplify commuting patterns to a pair of home and work census tracts and may not reflect certain details of some commutes (e.g., the additional census tracts encountered by commuters who travel to non-adjacent tracts or more complex commuting patterns that are not point to point). An additional important consideration is that the commuting-pattern data included in HAPEM do not account for the movement of school-age children who travel (or commute) to a school located outside the tracts in which they reside.

Risk. Concerning the predictions of risk, the specific sources of uncertainty in dose-response relationships (in addition to those considered for ambient air concentration and exposure) are hazard identification, dose-response models for carcinogens, UREs and RfCs.

One component of predicting risk is hazard identification. NATA's cancer-risk estimates assume that a compound either is a carcinogen or produces a noncancer effect. We base this on the results of a hazard-identification stage that assesses the evidence that an air toxic produces either cancer or a noncancer effect. Because the evidence for either judgment is never unequivocal, a compound labeled as a carcinogen or one deemed to produce noncancer effects may produce neither effect in humans. This possibility introduces uncertainty into the calculation of risk – the risk could be zero. As the evidence for the original conclusion (i.e., that the compound produces the effect) increases, this uncertainty decreases.

NATA's cancer-risk estimates assume that the relationship between exposure and probability of cancer is linear. In other words, the probability of developing cancer is assumed proportional to the exposure (equal to the exposure multiplied by a URE). This type of dose-response model is used routinely in regulatory risk assessment because it is believed to be conservative; that is, if the model is incorrect, it is more likely to lead to an overestimate of risks than to an underestimate. Other scientifically valid, biologically based models are available. These produce estimates of cancer risk that differ from those

obtained from the linear model. Uncertainty in risk estimates is therefore introduced by the inability to justify completely the use of one model or the other (because each model has some scientific support). An essential consideration is that this uncertainty is, to some extent, one-sided. In other words, conservatism when uncertainty exists allows more confidence in the conclusion that true risks are less than predicted than in the conclusion that risks are greater than predicted.

URE parameters have associated uncertainty. In some cases, the UREs are based on maximum-likelihood estimates of the slope of the dose-response relationship derived from reliable data. In other cases, the UREs are based on "upper-bound" estimates (i.e., the slope is not the best estimate, but is a conservative value that is likely to lead to overestimates of risk) derived from less reliable data. For some compounds, the UREs are derived from human-exposure studies, but for others they are from animal exposures. These considerations introduce uncertainty into the URE values, and the amount of uncertainty varies among pollutants.

Another source of uncertainty in estimating risk derives from the values chosen for the RfC parameters used to calculate an HQ for noncancer health risk. The RfC, which (like the URE) is based on limited information, is uncertain; as a result, the value of HQ is uncertain. As is the case for UREs, the uncertainty in the RfC is generally one-sided, and the risk is unlikely to be greater than predicted.

7.4. Summary of Limitations in NATA

EPA developed this assessment to inform both national and more localized efforts to collect information and characterize or reduce air-toxics emissions (e.g., to prioritize pollutants or areas of interest for monitoring and community assessments). As described above, uncertainty and variability characterize many of the elements in the assessment process for NATA, as in other assessments that derive results from environmental data and modeling of environmental data. Because of this, EPA suggests exercising caution when using the results of these assessments, as the overall quality and uncertainty of each assessment vary from location to location and from pollutant to pollutant. More localized assessments, using local-scale monitoring and modeling, are often needed to better characterize local-level risks.

Recognizing the specific limitations in NATA results is critical to interpreting and using them properly, including that the results:

- apply to geographic areas, not specific locations;
- do not include comprehensive impacts from sources in Canada or Mexico;
- are restricted to the year to which the assessment pertains (because the assessment uses emissions data only from that year);
- do not reflect exposures and risk from all compounds;
- do not reflect all pathways of exposure;
- reflect only compounds released into the outdoor air;
- do not fully capture variations in background ambient air concentrations;

- may underestimate or overestimate ambient air concentrations for some compounds due to spatial uncertainties;
- are based on default, or simplifying, assumptions where data are missing or of poor quality; and
- may not accurately capture sources with episodic emissions or other uncertainties.

The results apply to geographic areas, not specific locations. The assessment focuses on variations in air toxics concentrations, exposures and risks among areas such as census tracts, counties and states. All questions asked, therefore, must focus on the variations among different areas. They cannot be used to identify "hot spots" where concentrations, exposures or risks may be significantly higher than other locations. Furthermore, this type of modeling assessment cannot address the kinds of questions an epidemiology study might, such as the relationship between cancer risks and proximity of residences to point sources, roadways and other sources of pollutant emissions.

The results do not include comprehensive impacts from sources in Canada or Mexico. The NATA results for states that border these countries do not thoroughly reflect these potentially significant sources of transported emissions.

The results apply to groups, not to specific individuals. Within a census tract, all individuals are assigned the same ambient concentration, chosen to represent a typical concentration.

Similarly, the exposure assessment uses activity patterns that do not fully reflect variations among individuals. As a result, the exposures and risks in a census tract should be interpreted as typical values rather than as means, medians or some other statistical average. The values are likely to be in the midrange of values for all individuals in the census tract.

The results for the 2014 NATA are restricted to 2014 because the assessment used emissions data from that year. Also, the assumption regarding emissions in the assessment is that the levels remain constant throughout one's lifetime (the emissions are not today's levels nor are they projected levels). Emissions continue to decrease, however, as (1) mobile-source regulations are phased in over time, (2) EPA-issued air-toxics regulations for major industrial sources reach compliance due dates, (3) state and industry initiatives to reduce air pollutants continue and (4) some facilities are closed or have made process changes or other changes that have significantly reduced their emissions since 2014.

The results do not reflect exposures and risk from all compounds. Only 138 of the 181 air toxics (180 CAA HAPs plus diesel PM) modeled in NATA have dose-response values. The remaining air toxics are not considered in the aggregate cancer risk or target-organ-specific hazard indexes. Of significance is that the assessment does not quantify cancer risk from diesel PM, although EPA has classified diesel PM as likely to be carcinogenic to humans by inhalation from environmental exposures. Currently, a URE for diesel PM has not yet been derived; therefore, a quantitative estimate of the cancer risks was included in the 2014 NATA. An IRIS RfC for diesel PM allows NATA to include a quantitative estimate of its noncancer effects.

The results do not reflect all pathways of exposure. The assessment includes only risks from direct inhalation of the emitted pollutants. It does not consider pollutants that might then deposit onto soil and into water and food, and therefore enter the body through ingestion or skin contact. Consideration of these routes of exposure could increase estimates of exposure and risk.

The assessment results reflect only compounds released into the outdoor air. The assessment does not include exposure to pollutants produced indoors, such as from stoves or out-gassing from building materials, or evaporative benzene emissions from cars in attached garages. For some compounds such as formaldehyde, these indoor sources can contribute significantly to the total exposure for an individual, even if only inhalation exposures are considered. In addition, the assessment does not consider pollutants released directly to water and soil. It does include secondary formation, the transformation of one pollutant into another in the atmosphere.

The assessment does not utilize CMAQ in all areas (i.e., not in Alaska, Hawaii, Puerto Rico and the U.S. Virgin Islands) and therefore does not estimate fires, biogenics and secondary formation based on location-specific data in these areas. It also does not use CMAQ for all pollutants and hence may not appropriately estimate long-range transport for these non-CMAQ pollutants. For pollutants not estimated in CMAQ, the assessment uses background ambient air concentrations based on remote concentration estimates, but these would not account for variations due to regional transport of these pollutants.

NATA may underestimate or overestimate ambient air concentrations for some compounds in some locations due to spatial uncertainty in mobile and nonpoint emissions, which are more uncertain at finer geographic scales.

The assessment uses default, or simplifying, assumptions where data are missing or of poor quality. Data for some variables used in the modeling for emissions and dispersion of pollutants (such as stack height and facility location) may be unavailable or flawed. In such instances, these values are replaced by default assumptions. For example, a stack height for a facility might be set equal to stack heights at comparable facilities or the location of the release points within a facility might be placed at the center of the facility. These substitutions introduce uncertainty into the final predictions of ambient concentrations, exposures and risks.

NATA may not accurately capture sources with episodic emissions except for those with continuous emissions monitoring (CEMS) data, which use hourly emissions. NATA also does not include any short-term (a few days or weeks) deviations from a facility's typical emissions pattern, such as during startups, shutdowns, malfunctions and upsets. NATA modeling uses temporal profiles for sources without CEMS that would not capture non-routine emissions spikes.

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Appendix A. Glossary

"N"-in-1 million cancer risk:
A risk level of "N"-in-1 million implies that up to "N" people out of one million equally exposed people would contract cancer if exposed continuously (24 hours per day) to the specific concentration over 70 years (an assumed lifetime). This would be in addition to cancer cases that would normally occur in one million unexposed people. Note that NATA looks at *lifetime* cancer risks. This shouldn't be confused with or compared to *annual* cancer risk estimates. To compare an annual cancer risk estimate with NATA results, multiply the annual estimate by 70 (or divide the lifetime risk by 70).

Activity-pattern data:
Data that depict actual human physical activity, the location of the activity and the time of day it takes place. The Hazardous Air Pollution Model (HAPEM) uses activity-pattern data from EPA's Comprehensive Human Activity Database (CHAD).

Adverse health effect:
A change in body chemistry, body function or cell structure that could lead to disease or health problems.

AMS/EPA Regulatory Model (AERMOD):
EPA's preferred model to simulate near-field (i.e., within 50 km) dispersion of emissions. AERMOD models near-surface (boundary-layer) air turbulence in simple and complex terrain. This allows AERMOD to simulate how pollutants move and disperse in the air. It calculates pollutant concentrations from surface and elevated point, area, line and volume sources at many discrete points (receptors).

Air toxics:
Pollutants known to cause or suspected of causing cancer or other serious health effects. Air toxics are also known as toxic air pollutants or hazardous air pollutants.* Health concerns are linked to both short- and long-term exposures to these pollutants. Many air toxics cause respiratory, neurological, immune or reproductive effects, particularly for more susceptible or sensitive groups such as children. Five important air pollutants are not included in the list of air toxics because the Clean Air Act addresses them separately as "criteria pollutants." These are particulate matter (PM), nitrogen oxides (NO_x), sulfur oxides (SO_x), ozone and carbon monoxide. Lead is both a criteria pollutant and an air toxic. Criteria pollutants are not addressed in NATA.

*Diesel particulate matter is not a hazardous air pollutant but is included in the NATA air toxics.

Ambient:
Surrounding, as in the surrounding environment. In NATA, ambient air refers to the outdoor air surrounding a person through which pollutants can be carried. Therefore, the ambient concentrations estimated by NATA are concentrations estimated in the outdoor environment. NATA also estimates exposure concentrations that result when a person moves through various microenvironments, including the indoor environment.

Ambient air monitoring:
Process of collecting outdoor air samples to determine how much of an air pollutant is present at a location. Monitoring is used to:

- assess the extent of pollution;
- provide air pollution data to the public in a timely manner;
- help implement air quality goals or standards;
- evaluate whether emissions control strategies are effective;
- provide data on air quality trends;
- help evaluate air quality models or modeling results; and
- support research (for example, long-term studies of the health effects of air pollution).

State, local and tribal agencies often monitor near places where screening tools (such as NATA) suggest the chance of high concentrations or risks.

Area and other sources:
Sources of air pollution that, by themselves, generally have lower emissions than “major sources” of air pollution (like factories). Area sources are often too small or too widespread to be inventoried as individual sources. They include facilities with air toxics emissions below the major source threshold as defined in the Clean Air Act (less than 10 tons of a single toxic air pollutant or less than 25 tons of multiple toxic air pollutants emitted in any one year). Area sources include smaller facilities, such as dry cleaners.

As a separate definition, area sources in air quality modeling refer to those modeled in two dimensions (with length and width), as compared to point sources modeled at a single location.

Assessment System for Population Exposure Nationwide (ASPEN):
A computer model used to estimate toxic air pollutant concentrations. The ASPEN model includes:

- rate of pollutant release;
- location of and height from which the pollutants are released;
- wind speeds and directions from the meteorological stations nearest to release;
- breakdown of the pollutants in the atmosphere after release (i.e., reactive decay);
- settling of pollutants out of the atmosphere (i.e., deposition);
- transformation of one pollutant into another (i.e., secondary formation or decay).

Atmospheric transformation (secondary formation):
The process by which chemicals are transformed into other chemicals in the air (atmosphere). When a chemical is transformed, the original pollutant no longer exists; it is replaced by one or more new chemicals. Compared to the original chemical, the transformed chemical can have more, less or the same toxicity. Transformations and removal processes affect both the fate of the chemical and how long it stays in the air, called its persistence. Persistence is important because human exposure to a chemical depends on the length of time the chemical remains in the air. In NATA, we use both “atmospheric transformation” and “secondary formation”; they mean the same thing.

Background concentrations:
The amount of a pollutant that exists in the air that does not come from a specific source. These pollutants may come from a natural source or from distance sources. Background concentrations can explain pollutant concentrations found even without recent human-caused emissions. In NATA, we add background concentrations to AERMOD concentrations but not to CMAQ concentrations, which include background already. Most risk from NATA background concentrations is from carbon tetrachloride, a common pollutant that has few emission sources but is persistent due to its long half-life.

Biogenic emissions:
Biogenic emissions are emissions from natural sources, such as plants and trees. These sources emit formaldehyde, acetaldehyde and methanol; formaldehyde and acetaldehyde are key risk drivers in NATA. Biogenic sources also emit large amounts of other nonhazardous VOCs. We estimate biogenic emissions with a model that uses vegetation and land use data with temperature and solar radiation data. In addition to being a primary source of air toxics, compounds emitted by biogenic sources sometimes react with human-caused pollutants to form secondary pollutants. The NATA biogenics source group includes only the primary emissions.

Cancer Risk:
The probability of contracting cancer over the course of a lifetime, assuming continuous exposure (assumed in NATA to be 70 years).

Carcinogen:
A chemical, physical or biological agent that can cause cancer.

Carcinogenicity:
Ability to produce cancer cells from normal cells.

Chemical Abstracts Service (CAS) number:
A unique number assigned to a chemical by the Chemical Abstracts Service, a service of the American Chemical Society. The purpose is to make database searches easier, as chemicals often have many names.

Census tracts:
Land areas defined by the U.S. Census Bureau. Tracts usually contain from 1,200 to 8,000 people, with most having close to 4,000 people. Census tracts are usually smaller than 2 square miles in cities, but are much larger in rural areas.

Cohort:
A group of people assumed to have identical exposures during a certain period. Using cohorts makes modeling exposures of a large population easier to manage. In NATA, we divide the entire population into a set of cohorts. Each person is assigned to one and only one cohort, and all the cohorts combined equal the entire population.

Community Multiscale Air Quality (CMAQ) modeling system:
An air quality model used in NATA. CMAQ estimates how pollutants move and disperse in the air. It includes the effect of atmospheric chemistry – how pollutants react in the air – a unique feature of the model. CMAQ's structure allows it to calculate concentrations over a very large area, including many emission sources.

Concentration:
A way to describe how much of a pollutant is in the air. Concentration is usually shown as an amount, or mass, of pollutant per certain volume of air. In NATA, most concentrations are in micrograms (µg) of air pollutant per cubic meter (m^3) of air (a "box" of air one meter on each side).

Consolidated Human Activity Database (CHAD):
An in-depth EPA database of human activity. CHAD includes data from over 20 activity studies dating to 1982. It also includes data from other assessments of human exposure, intake dose and risk.

Diesel particulate matter:
A mixture of particles that is part of diesel exhaust. EPA lists diesel exhaust as a mobile-source air toxic due to the cancer and noncancer health effects linked to exposure to whole diesel exhaust. Diesel PM (expressed as grams diesel PM/m^3) has been used as a surrogate exposure measure for whole diesel exhaust.

Dispersion model:
A computerized set of equations that uses emissions and meteorological data to simulate how air pollutants behave and move in the air. A dispersion model estimates outdoor concentrations of individual air pollutants at chosen locations (called receptors).

Emission Inventory System (EIS):
An EPA information system for collecting emission inventory data and generating emission inventories.

Emissions:
Pollutants released into the air.

Emission inventory:
A listing, by source, of the location and amount of air pollutants released into the air during some period (in NATA, a single year).

Exposure assessment:
An exposure assessment is part of an air toxics risk assessment such as NATA. The assessment determines (or estimates):

- how a person may be exposed to chemicals (for example, by breathing);
- how much of a chemical to which a person is likely to be exposed;
- how long and/or how often they will be exposed; and
- how many people are likely to be exposed.

HAP:
Hazardous air pollutant; another name for air toxics.

Hazard index (HI):
The sum of hazard quotients for toxics that affect the same target organ or organ system. Because different air toxics can cause similar adverse health effects, combining hazard quotients from different toxics is often appropriate. As with the hazard quotient, exposures below an HI of 1.0 likely will not result in adverse noncancer health effects over a lifetime of exposure. An HI equal to or greater than 1.0, however, doesn't necessarily suggest a likelihood of adverse effects.

Hazard quotient (HQ):
The ratio of the potential exposure to a substance and the level at which no adverse effects are expected (calculated as the exposure divided by the appropriate chronic or acute value). A hazard quotient less than or equal to 1.0 indicates that adverse noncancer effects are not likely to occur, and thus can be considered to have negligible hazard. For HQs greater than 1.0, the potential for adverse effects increases, but we do not know by how much.

Hazardous Air Pollutant Exposure Model (HAPEM):
A computer model designed to estimate inhalation exposure for specified population groups and air toxics. The model uses census data, human-activity patterns, ambient air quality levels, and indoor/outdoor concentration relationships to estimate an expected range of inhalation exposure concentrations for groups of people.

Human Exposure Model (HEM):
A computer model used primarily for conducting inhalation risk assessments for sources emitting air toxics to ambient air.

Inhalation exposure:
Introducing air toxics (or other pollutants) into the body via breathing. Once inhaled, air toxics can be deposited in the lungs, taken into the blood, or both.

Integrated Risk Information System (IRIS):
An EPA program that identifies and characterizes the health hazards of chemicals found in the environment. IRIS is EPA's preferred source of toxicity information.

Lifetime cancer risk:
The probability of contracting cancer over the course of a lifetime (assumed to be 70 years for the purposes of NATA).

Major sources:
Defined by the Clean Air Act as those stationary facilities that emit or have the potential to emit 10 tons of any one toxic air pollutant or 25 tons of more than one toxic air pollutant per year.

Median:
The middle value of a set of ordered values (i.e., half the numbers are less than or equal to the median value). A median is the 50th percentile of the data.

Metropolitan statistical area (MSA):
A region with a relatively high population density at its core and close economic ties throughout the area. As defined by the U.S. Census Bureau, an MSA must have at least one urban area of 50,000 or more inhabitants.

Microenvironment:
A small space in which human contact with a pollutant takes place. NATA models cohort activities in indoor, outdoor and in-vehicle microenvironments:

1. Indoor locations:
    - Residence
    - Office
    - Store

- School
- Restaurant
- Church
- Manufacturing facility
- Auditorium
- Healthcare facility
- Service station
- Other public building
- Garage

2. Outdoor locations:
   - Parking lot/garage
   - Near road
   - Motorcycle
   - Service station
   - Construction site
   - Residential grounds
   - School
   - Sports arena
   - Park/golf course

3. In-vehicle locations:
   - Car
   - Bus
   - Truck
   - Train/subway
   - Airplane
   - Other

Microgram:
One-millionth of a gram. One gram is about one twenty-eighth of an ounce, or about the weight of a raisin or paper clip.

Mobile source:
Air pollution sources that can move from place to place, like cars or trucks. Mobile sources are divided into two categories: on-road and nonroad vehicles/engines.

Monitoring:
See Ambient air monitoring.

Motor Vehicle Emission Simulator (MOVES):
An emissions modeling system that estimates emissions for mobile sources at the national, county, and project level for criteria air pollutants, air toxics and greenhouse gases.

National Air Toxics Assessments (NATA):
EPA's ongoing thorough review of air toxics in the United States. NATA results help scientists focus on pollutants, emission sources and places that may need further study to better understand risks. NATA also spurs improvements in what we know about U.S. air toxics. This includes expanding air toxics monitoring, improving and updating emission inventories, improving air quality modeling, driving research on health effects and exposures to both ambient and indoor air, and improving assessment tools.

National Emissions Inventory (NEI):
A national database of air emissions data. EPA prepares NEI with input from many state and local air agencies, from tribes and from industry. This database contains information on stationary and mobile sources that emit criteria air pollutants and their precursors, as well as hazardous air pollutants. NEI includes estimates of annual emissions, by

source, of air pollutants in each area of the country. NEI includes emission estimates for all 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands.

National Mobile Inventory Model (NMIM):
Computer tool containing EPA's NONROAD model for estimating county-level inventories of nonroad mobile emissions.

Noncancer risks:
Risks associated with health effects other than cancer.

Nonroad mobile sources:
Mobile sources not used on roads and highways for transportation of passengers or freight. Nonroad sources include:

- aircraft;
- heavy equipment;
- locomotives;
- marine vessels;
- recreation vehicles (snowmobiles, all-terrain vehicles, etc.); and
- small engines and tools (lawnmowers, etc.).

On-road mobile sources:
Mobile sources used on roads and highways for transportation of passengers or freight. On-road sources include:

- passenger cars and trucks
- commercial trucks and buses; and
- motorcycles.

Percentile:
Any one of the points dividing a set of values into parts that each contain 1/100 of the values. For example, the 75th percentile is a value such that 75 percent of the values are less than or equal to it.

Polycyclic organic matter (POM):
A broad class of compounds that includes polycyclic aromatic hydrocarbons. Polycyclic organic matter (POM) compounds form mainly from combustion and are present in the air as particles. Sources of POM emissions include:

- vehicle exhaust;
- forest fires and wildfires;
- asphalt roads;
- coal;
- coal tar;
- coke ovens;
- agricultural burning;
- residential wood burning; and
- hazardous waste sites.

Not all POM reported to EPA's National Emission Inventory is broken down by pollutant. So, we make some simplifying assumptions to model and assess the risk from the different pollutants that make up polycyclic organic matter.

Reference concentration (RfC):
An estimate of a continuous inhalation exposure unlikely to cause adverse health effects during a lifetime. This estimate includes sensitive groups such as children, asthmatics and the elderly.

Risk:
The probability that adverse effects to human health or the environment will occur due to a given hazard (such as exposure to a toxic chemical or mixture of toxic chemicals). We can measure or estimate some risks in numerical terms (for example, one chance in a hundred).

Rural:
A county is considered “rural” if it does not contain a metropolitan statistical area with a population greater than 250,000 and the U.S. Census Bureau designates 50 percent or less of the population as “urban.” Note that this definition does not necessarily apply for any regulatory or implementation purpose. It is consistent with the definition EPA used in the analyses to support the Integrated Urban Air Toxics Strategy.

Science Advisory Board (SAB):
A panel of scientists, engineers and economists who provide EPA with independent scientific and technical advice.

Secondary formation:
See "Atmospheric transformation (Secondary Formation)"

Secondary sources:
See "Atmospheric transformation (Secondary Formation)"

Sparse Matrix Operator Kernel Emissions (SMOKE):
A modeling system that processes emissions data for use in air quality models. It uses the Biogenic Emission Inventory System (BEIS) to model biogenic emissions. It also has a feature to use MOVES emission factors, activity data and meteorological data to compute hourly gridded on-road mobile emissions.

Stationary sources:
Sources of air emissions that do not move. Stationary sources include large industrial sources such as power plants and refineries, smaller industrial and commercial sources such as dry cleaners, and residential sources such as residential wood combustion and consumer products usage. Stationary sources may be “major” or “area” sources based on definitions in the Clean Air Act. In NATA, we present sources as “point” and “nonpoint” rather than “major” and “area” sources. “Point” and “nonpoint” reflect how we modeled each emission source. Some smaller sources that are area sources in the inventory (based on the amount of their emissions) are modeled as point sources because their location was identified with latitude and longitude coordinates.

Susceptibility:
The increased likelihood of an adverse effect. Susceptibility is often discussed in terms of relationship to a factor describing a human population (for example, life stage, demographic feature or genetic trait).

Toxicity weighting:
A way to prioritize pollutant emissions based on risk. To calculate toxicity-weighted emissions, we multiply emissions from a facility or source being assessed by a toxicity factor for each pollutant. Pollutants that are more harmful (for the same emission rate) have a higher toxicity factor. By weighting the amount of a pollutant released to its toxicity, we can compare relative risk from different pollutants in emission inventories. Toxicity weighting is very useful if the number of pollutants is large, helping risk assessors focus on pollutants that contribute the most to risk.

Typical:
Describes a hypothetical person living at a census-tract centroid (a reference point usually but not always located at the geographic center of a census tract) and doing the types of things (indoors and outdoors) that most people living in that tract would do. To describe that person’s risk, NATA divides the population into cohorts (groups assumed to have the same exposures each day) based on where they live, how old they are and their daily activity patterns. Fora census tract, we select age-appropriate activity patterns to model the range of exposure conditions for residents of the tract. We can then calculate a population-weighted typical exposure estimate for each cohort. We use this value to estimate risks for a “typical” individual residing in that tract.

Unit risk estimate (URE):
The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an air toxic at a concentration of 1 microgram per cubic meter ($\mu g/m^3$) in air. You can interpret the URE as follows: If the URE = 3×10^{-6} per $\mu g/m^3$, as many as three more people might be expected to develop cancer per one million people exposed daily for a lifetime to 1 microgram (µg) of the chemical in 1 cubic meter (m^3) of air. UREs are considered upper-bound estimates designed to keep us from underestimating risks. The true risk may be lower and is considered unlikely to

be higher. In NATA, we multiply the model-output concentrations for an air toxic by that pollutant's URE to calculate exposure risks from that air toxic.

Upper-bound:
A likely upper limit to the true value of a quantity. This is usually not a true statistical confidence limit.

Upper-bound lifetime cancer risk:
A likely upper limit to the true probability that a person will contract cancer over a 70-year lifetime due to a given hazard (such as exposure to a toxic chemical). This risk can be measured or estimated in numerical terms (for example, one chance in a hundred).

Urban:
A county is considered "urban" if it either includes a metropolitan statistical area with a population greater than 250,000 or the U.S. Census Bureau designates more than 50 percent of the population as "urban." Note that this definition does not necessarily apply for any regulatory or implementation purpose. It is consistent with the definition EPA used in the analyses to support the Integrated Urban Air Toxics Strategy.

Volatile organic compounds (VOCs):
Chemicals emitted as gases from certain solids or liquids. VOCs are known for being common indoor air pollutants. EPA regulates VOCs in the ambient air because some cause adverse health effects and because they can react with other pollutants to form ozone and secondary air toxics. Cars and trucks, some industries, and even plants and trees emit VOCs.

Weight-of-evidence for carcinogenicity (WOE):
A system used by the EPA for characterizing the extent to which available data support the hypothesis that an agent causes cancer in humans. The approach, outlined in EPA's *Guidelines for Carcinogen Risk Assessment* (2005), considers all scientific information in determining the WOE. Five standard descriptors are used as part of the WOE narrative:

1. Carcinogenic to humans.
2. Likely to be carcinogenic to humans.
3. Suggestive evidence of carcinogenic potential.
4. Inadequate information to assess carcinogenic potential.
5. Not likely to be carcinogenic to humans.

Each of these descriptors is explained in its own glossary entry. You can read more details about WOE narratives in the NATA Technical Support Document.

Carcinogenic to humans:
This descriptor indicates strong evidence of human carcinogenicity. It covers different combinations of evidence. This descriptor is appropriate when there is convincing epidemiologic evidence of a link between human exposure and cancer. It might also be appropriate when a lesser weight of epidemiologic evidence is strengthened by other lines of evidence.

This descriptor can be used when *all* of the following conditions are met:

- there is strong evidence of an association between human exposure and either cancer or the key precursor events of the agent's mode of action, but not enough for a causal association;
- there is extensive evidence of carcinogenicity in animals;
- the mode(s) of carcinogenic action and associated key precursor events have been identified in animals; and
- there is strong evidence that the key precursor events that precede the cancer response in animals are anticipated to occur in humans and progress to tumors, based on available biological information.

Likely to be carcinogenic to humans:
This descriptor is appropriate when the weight of evidence is enough to show the potential to cause cancer in humans but does not meet all conditions necessary to be called "carcinogenic to humans." Adequate evidence consistent with this descriptor covers a broad spectrum. At one end of the spectrum is a plausible association

between human exposure to the agent and cancer and strong experimental evidence of carcinogenicity in animals. At the other, with no human data, the weight of experimental evidence shows animal carcinogenicity by a mode or modes of action that are relevant or assumed to be relevant to humans. The use of the term “likely” as a WOE descriptor does not correspond to a quantifiable probability. Moreover, additional information, for example, on mode of action, might change the choice of descriptor for the illustrated examples.

Suggestive evidence of carcinogenic potential:
This descriptor is appropriate when the weight of evidence suggests carcinogenicity, raising concern for potential carcinogenic effects in human, but the data are judged insufficient for a stronger conclusion. This descriptor covers a spectrum of evidence ranging from a positive cancer result in the only study on an agent to a single positive cancer result in an extensive database that includes negative studies in other species. Depending on the extent of the database, additional studies might or might not provide further insights.

Inadequate information to assess carcinogenic potential:
This descriptor is appropriate when available data are judged inadequate for applying one of the other descriptors. Additional studies generally would be expected to provide further insights.

Not likely to be carcinogenic to humans:
This descriptor is appropriate when the available data are considered strong enough for deciding that there is no basis for cancer concerns for humans. In some cases, there can be positive results in experimental animals, but the evidence is strong and consistent that each mode of action does not operate in humans. In other cases, the evidence can be convincing that the agent is not carcinogenic in humans or animals. “Not likely” applies only to the circumstances supported by the data. For example, an agent might be “not likely to be carcinogenic” by one route but not necessarily by another. In cases having positive animal experiment(s), but the results are judged not to be relevant to humans, the narrative discusses why the results are not relevant.

Weather Research and Forecasting (WRF) model:
A mesoscale numerical weather-prediction system for atmospheric research and weather forecasting. It can generate atmospheric conditions using real input data or idealized conditions.

Appendix B. Air Toxics Modeled in the 2014 NATA

A master pollutant list for NATA in spreadsheet format, "NATA_Pollutants.xlsx," is provided in the Supplemental Data folder on the NATA website (https://www.epa.gov/national-air-toxics-assessment). This file includes all air toxics modeled in NATA and indicates the inventory types(s) reporting them. The file also includes the toxicity values used in NATA. The names shown in this spreadsheet match the terminology used in the 1990 Clean Air Act (CAA) Amendments; for example, the file lists "chromium compounds" but does not indicate which individual compounds containing chromium were modeled, and it lists four forms of xylenes (o-, m-, p- and mixed isomers), but these were grouped and modeled as a single entity. The file also contains indications about whether cancer risks and chronic noncancer hazard quotients were estimated for each air toxic.

The spreadsheet also contains an air toxic names crosswalk and metal speciation factors used to conduct the modeling of emissions. This crosswalk contains a link between lists of air toxic names in two data bases used for NATA:

- the names used in the National Emissions Inventory (NEI); and
- the names used for NATA.

In addition, the file contains the speciation of metal chemicals based on their metal mass fractions. The metal speciation factor was used to adjust modeled mass emissions prior to modeling and conducting risk calculations because metal toxicity is usually evaluated relative to the amount of metal ion present rather than the total mass of the metal compound. Most metal and cyanide compounds are reported in the 2014 NEI as just the metal or cyanide parts; consequently, most fractions are 1, including the two cyanide compounds. If the NEI data reporters did not adjust the emissions downward to account for just the metal part, a more health-protective (higher risk) result would be obtained.

Table B-I contains the air toxics that were *not* modeled for the 2014 NATA and why. Note that although diesel PM was modeled for NATA and is included in the list of air toxics modeled, it is not categorized as a HAP in the CAA. Diesel PM emissions were computed based on PM_{10} emissions from on-road and nonroad mobile sources burning diesel or residual fuels (see Appendix C).

Note that NEI = National Emissions Inventory.

Table B-I. Pollutants excluded from NATA

Pollutant	NEI Pollutant Code (CAS Number) a	Reason for Exclusion	In Previous NATAs?
Chromium III		– In building the NEI, chromium VI is emphasized, and chromium III may be missing data.	n[b]
2,3,7,8-Tetrachlorodibenzo-p-dioxin	1746016	Dioxins and furans are not in the 2011 NEI due to uncertainty in the completeness or accuracy of the S/L/T agency data for this group of pollutants. In addition, the most significant exposure route for dioxin is ingestion, not inhalation, so dioxin's relative contribution to NATA's inhalation risk estimates likely would not be large.	n[b]
Other dioxins/furans	multiple		n[b]
Radionuclides		Radionuclides are not in the 2011 NEI due to uncertainty in the completeness or accuracy of the S/L/T agency data for this group of pollutants. In addition, the NEI currently is not compatible with emissions reported in units other than mass, and therefore suitable emissions data have not been compiled for these substances on a national scale.	n[b]
DDE	72559 incorrectly referred to in the Section 112(b) list as 3547-04-4	This pollutant was not reported to the 2014 NEI.	n[b]
Fine mineral fibers (including rockwool, slagwool and fine mineral fibers)	Fine mineral fibers: 383 Rockwool: 617 Slagwool: 616	Rockwool and slagwool have zero emissions and fine mineral fibers are excluded from previous assessments.	n[b]
Asbestos	1332214	Air concentrations of asbestos are often measured in terms of numbers of fibers per unit volume, but the NEI provides tons, which cannot be converted.	n[b]
Diazomethane	334883	This pollutant has 0 emissions in the 2014NEI.	n[b]
Beta-propiolactone	57578	This pollutant has 0 emissions in the 2014NEI.	y

[a]In most cases, the NEI pollutant code is the same as the CAS number. In a few cases (e.g., coke oven emissions) a CAS number has not been assigned, and NEI uses a unique pollutant code.
[b]Also excluded from the 2011 NATA

Appendix C. Source Classification Codes that Define Diesel Particulate Matter

This appendix lists the source classification codes (SCC) for which the PM_{10} emissions were considered to be diesel particulate matter (PM). Diesel PM emissions were computed based on PM_{10} emissions from on-road and nonroad mobile sources burning diesel or residual fuels.

Note that NEI = National Emissions Inventory.

Table C-I. Source classification codes for which PM_{10} emissions were assigned to diesel particulate matter

NEI Category	SCC	Description
Point	28500201	Internal Combustion Engines;Railroad Equipment;Diesel;Yard Locomotives
	2270008005	*M;Off-highway Vehicle Diesel;Airport Ground Support Equipment;Airport Ground Support Equipment
Nonpoint	2280002100	*M;Marine Vessels, Commercial;Diesel;Port emissions
	2280002200	*M;Marine Vessels, Commercial;Diesel;Underway emissions
	2285002006	*M;Railroad Equipment;Diesel;Line Haul Locomotives: Class I Operations
	2285002007	*M;Railroad Equipment;Diesel;Line Haul Locomotives: Class II / III Operations
	2285002008	*M;Railroad Equipment;Diesel;Line Haul Locomotives: Passenger Trains (Amtrak)
	2285002009	*M;Railroad Equipment;Diesel;Line Haul Locomotives: Commuter Lines
	2285002010	*M;Railroad Equipment;Diesel;Yard Locomotives
	2280003100	*M;Marine Vessels, Commercial;Residual;Port emissions
	2280003200	*M;Marine Vessels, Commercial;Residual;Underway emissions
	2270001060	*M;Off-highway Vehicle Diesel;Recreational Equipment;Specialty Vehicles/Carts
	2270002003	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Pavers
	2270002006	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Tampers/Rammers
	2270002009	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Plate Compactors
	2270002015	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Rollers
	2270002018	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Scrapers
	2270002021	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Paving Equipment
	2270002024	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Surfacing Equipment
	2270002027	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Signal Boards/Light Plants
	2270002030	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Trenchers
	2270002033	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Bore/Drill Rigs
	2270002036	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Excavators
	2270002039	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Concrete/Industrial Saws
	2270002042	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Cement and Mortar Mixers
	2270002045	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Cranes
	2270002048	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Graders
	2270002051	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Off-highway Trucks
	2270002054	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Crushing/Processing Equipment
	2270002057	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Rough Terrain Forklifts

NEI Category	SCC	Description
	2270002060	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Rubber Tire Loaders
	2270002066	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Tractors/Loaders/Backhoes
	2270002069	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Crawler Tractor/Dozers
	2270002072	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Skid Steer Loaders
	2270002075	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Off-highway Tractors
	2270002078	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Dumpers/Tenders
	2270002081	*M;Off-highway Vehicle Diesel;Construction and Mining Equipment;Other Construction Equipment
	2270003010	*M;Off-highway Vehicle Diesel;Industrial Equipment;Aerial Lifts
	2270003020	*M;Off-highway Vehicle Diesel;Industrial Equipment;Forklifts
	2270003030	*M;Off-highway Vehicle Diesel;Industrial Equipment;Sweepers/Scrubbers
	2270003040	*M;Off-highway Vehicle Diesel;Industrial Equipment;Other General Industrial Equipment
	2270003050	*M;Off-highway Vehicle Diesel;Industrial Equipment;Other Material Handling Equipment
	2270003060	*M;Off-highway Vehicle Diesel;Industrial Equipment;ACRefrigeration
	2270003070	*M;Off-highway Vehicle Diesel;Industrial Equipment;Terminal Tractors
	2270004031	*M;Off-highway Vehicle Diesel;Lawn and Garden Equipment;Leafblowers/Vacuums (Commercial)
	2270004036	*M;Off-highway Vehicle Diesel;Lawn and Garden Equipment;Snowblowers (Commercial)
	2270004046	*M;Off-highway Vehicle Diesel;Lawn and Garden Equipment;Front Mowers (Commercial)
	2270004056	*M;Off-highway Vehicle Diesel;Lawn and Garden Equipment;Lawn and Garden Tractors (Commercial)
	2270004066	*M;Off-highway Vehicle Diesel;Lawn and Garden Equipment;Chippers/Stump Grinders (Commercial)
	2270004071	*M;Off-highway Vehicle Diesel;Lawn and Garden Equipment;Turf Equipment (Commercial)
	2270004076	*M;Off-highway Vehicle Diesel;Lawn and Garden Equipment;Other Lawn and Garden Equipment (Commercial)
	2270005010	*M;Off-highway Vehicle Diesel;Agricultural Equipment;2-Wheel Tractors
	2270005015	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Agricultural Tractors
	2270005020	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Combines
	2270005025	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Balers
	2270005030	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Agricultural Mowers
	2270005035	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Sprayers
	2270005040	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Tillers >6 HP
	2270005045	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Swathers
	2270005055	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Other Agricultural Equipment
	2270005060	*M;Off-highway Vehicle Diesel;Agricultural Equipment;Irrigation Sets
	2270006005	*M;Off-highway Vehicle Diesel;Commercial Equipment;Generator Sets

NEI Category	SCC	Description
	2270006010	*M;Off-highway Vehicle Diesel;Commercial Equipment;Pumps
	2270006015	*M;Off-highway Vehicle Diesel;Commercial Equipment;Air Compressors
	2270006020	*M;Off-highway Vehicle Diesel;Commercial Equipment;Gas Compressors
	2270006025	*M;Off-highway Vehicle Diesel;Commercial Equipment;Welders
	2270006030	*M;Off-highway Vehicle Diesel;Commercial Equipment;Pressure Washers
	2270006035	*M;Off-highway Vehicle Diesel;Commercial Equipment;Hydro-power Units! new SCC in 2002v2
	2270007010	*M;Off-highway Vehicle Diesel;Logging Equipment;Shredders >6 HP
	2270007015	*M;Off-highway Vehicle Diesel;Logging Equipment;Forest Eqp - Feller/Bunch/Skidder
	2270009010	*M;Off-highway Vehicle Diesel;Underground Mining Equipment;Other Underground Mining Equipment
	2270010010	*M;Off-highway Vehicle Diesel;Industrial Equipment;Other Oil Field Equipment
	2282020005	*M;Pleasure Craft;Diesel;Inboard/Sterndrive
	2282020010	*M;Pleasure Craft;Diesel;Outboard
	2285002015	*M;Railroad Equipment;Diesel;Railway Maintenance
On-road	2202210181	*D;Passenger Cars;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202210281	*D;Passenger Cars;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202210381	*D;Passenger Cars;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202210481	*D;Passenger Cars;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202210581	*D;Passenger Cars;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202310181	*D;Passenger Trucks;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202310281	*D;Passenger Trucks;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202310381	*D;Passenger Trucks;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202310481	*D;Passenger Trucks;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202310581	*D;Passenger Trucks;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202320181	*D;Light Commercial Trucks;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202320281	*D;Light Commercial Trucks;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202320381	*D;Light Commercial Trucks;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202320481	*D;Light Commercial Trucks;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202320581	*D;Light Commercial Trucks;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202410181	*D;Intercity Buses;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202410281	*D;Intercity Buses;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202410381	*D;Intercity Buses;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202410481	*D;Intercity Buses;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling

NEI Category	SCC	Description
	2202410581	*D;Intercity Buses;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202420181	*D;Transit Buses;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202420281	*D;Transit Buses;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202420381	*D;Transit Buses;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202420481	*D;Transit Buses;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202420581	*D;Transit Buses;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202430181	*D;School Buses;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202430281	*D;School Buses;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202430381	*D;School Buses;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202430481	*D;School Buses;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202430581	*D;School Buses;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202510181	*D;Refuse Trucks;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202510281	*D;Refuse Trucks;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202510381	*D;Refuse Trucks;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202510481	*D;Refuse Trucks;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202510581	*D;Refuse Trucks;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202520181	*D;Single Unit Short-haul Trucks;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202520281	*D;Single Unit Short-haul Trucks;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202520381	*D;Single Unit Short-haul Trucks;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202520481	*D;Single Unit Short-haul Trucks;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202520581	*D;Single Unit Short-haul Trucks;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202530181	*D;Single Unit Long-haul Trucks;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202530281	*D;Single Unit Long-haul Trucks;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202530381	*D;Single Unit Long-haul Trucks;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202530481	*D;Single Unit Long-haul Trucks;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202530581	*D;Single Unit Long-haul Trucks;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202540181	*D;Motor Homes;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202540281	*D;Motor Homes;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202540381	*D;Motor Homes;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202540481	*D;Motor Homes;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202540581	*D;Motor Homes;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202610181	*D;Combination Short-haul Trucks;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling

NEI Category	SCC	Description
	2202610281	*D;Combination Short-haul Trucks;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202610381	*D;Combination Short-haul Trucks;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202610481	*D;Combination Short-haul Trucks;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202610581	*D;Combination Short-haul Trucks;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202620153	*D;Combination Long-haul Trucks;Off-network: Extended Idle Exhaust
	2202620181	*D;Combination Long-haul Trucks;Off-network: All Exhaust, Evaporative, Brake, and Tire Except Refueling and Hoteling
	2202620191	*D;Combination Long-haul Trucks;Off-network: Auxiliary Power Exhaust
	2202620281	*D;Combination Long-haul Trucks;Rural Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling and
	2202620381	*D;Combination Long-haul Trucks;Rural Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202620481	*D;Combination Long-haul Trucks;Urban Restricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling
	2202620581	*D;Combination Long-haul Trucks;Urban Unrestricted Access: All Exhaust, Evaporative, Brake, and Tire Except Refueling

*M= Mobile Sources. *D=Highway Vehicles–Diesel

Appendix D. Estimating Background Concentrations for the 2014 NATA

The memo in this appendix contains the methods we used to estimate background concentrations for NATA 2014.

Sonoma Technology, Inc.
Environmental Science and Innovative Solutions

Technical Memorandum

August 17, 2016 STI-915217-6569-TM

To: Madeleine Strum, U.S. Environmental Protection Agency

From: Michael McCarthy

Re: NATA Remote Background Estimates Updated for 2014

Background

EPA contracted with STI to update the National Air Toxics Assessment (NATA) remote background estimates developed for the 2011–2014 values. In previous work, STI developed methods for estimating background concentrations for 2011 (McCarthy et al., 2015).

For the 2011 NATA, we investigated multiple types of "background" concentration estimates; for this project, we updated only the Remote Northern Hemisphere background estimates with 2014 values.

Remote Northern Hemisphere (NH) background is the annual mean concentration at remote receptor areas not impacted by local-scale (50 km) or regional-scale emissions of the pollutant. Examples of remote locations include the summit of Mauna Loa, the Aleutian Islands in Alaska, portions of the Pacific Coast between Oregon and California, and some parts of the Mountain West. These estimates represent the lowest concentrations that would be observed in the United States.

Methods

STI used concentrations from networks with monitoring sites in remote locations, where little influence from regional emissions is expected, to estimate background concentrations for some of the most important (from a risk perspective) air toxics. Remote National Oceanic and Atmospheric Administration (NOAA) Global Monitoring Division (GMD) sites[1] and the Trinidad Head Advanced Global Atmospheric Gases Experiment (AGAGE) site[2] primarily measure gases, and remote IMPROVE sites[3] measure metals.

[1] www.esrl.noaa.gov/gmd/
[2] http://agage.mit.edu/
[3] http://vista.cira.colostate.edu/improve/

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Annual mean concentrations for 2014 were generated at five NOAA GMD sites: Cape Kumukahi, HI (KUM); Mauna Loa, HI (MLO); Niwot Ridge, CO (NWR); Barrow, AK (BRW); and Alert, Canada (ALT). Other remote sites are available but were not selected, to be consistent with previous NATA background estimates. The annual mean concentrations were cosine-weighted by latitude to generate annual mean background estimates for carbon tetrachloride, benzene, dichloromethane, tetrachloroethene, and bromomethane. Measurement methods from this network have been reported in peer-reviewed articles such as Montzka et al. (2011; 1999). Cosine-weighted latitude averaging accounts for differences in the amount of NH air (i.e., there is more air at the equator then at the poles).

Annual mean concentrations of chloroform for 2014 were measured at AGAGE network sites. While multiple AGAGE sites are available in remote locations such as Mace Head, Ireland, and Cape Grim, Tasmania, the only measurements representative of the eastern Pacific Ocean are made at Trinidad Head, California; data from this site were used to generate remote concentration estimates. AGAGE data can be accessed at http://cdiac.ornl.gov/ndps/alegage.html (DOI: 10.3334/CDIAC/atg.db1001) and the original reference for the network is available from Prinn et al. (2000).

Metals are measured at the IMPROVE sites across the United States. Some of these sites are representative of clean air coming off the Pacific Ocean and were used to generate remote background concentration estimates for lead, manganese, and nickel. Annual mean concentrations from 2014 were generated for data from the Denali, Alaska (DENA); Kalmiopsis, Oregon (KALM); Point Reyes, California (PORE); Redwoods, California (REDW); Trapper Creek, Alaska (TRCR); Tuxedni, Alaska (TUXE); and Haleakala, Hawaii (HACR) sites. These were cosine-latitude averaged to generate mean concentrations for the toxics measurements made at those sites. The IMPROVE network data were used as available from the air toxics monitoring archive. Recent work on IMPROVE detection limits was described by Hyslop and White (2011).

Results

Estimates of NH concentrations from the remote network are presented in Table 1. In contrast to the 2011 table, we now present concentrations for the gas-phase species in units of pptv, $\mu g/m^3$ at standard temperature and pressure, and $\mu g/m^3$ at local conditions. Average concentrations of metals measured at IMPROVE sites were almost all below method detection limits (MDL) when using MDL/2 substitution for non-detect values. Thus, the remote concentration estimates should be considered upper-limit thresholds for concentrations.

For chromium VI, the total chromium estimate was multiplied by the average ratio of chromium VI:chromium TSP (0.0125) seen in air toxics archive measurements for previous years. This is still an upper-limit threshold, as measurements at IMPROVE sites were below the average MDL at those sites in 2014.

Input files and R code used to generate these estimates are provided as separate electronic file attachments in the delivery email.

Table 1. Remote concentration estimates (RCE) for 2014.

Pollutant	RCE STP[a] (µg/m^3) 2014	RCE LC[b] (µg/m^3) 2014	RCE (pptv) 2014	Remote Network	Location(s)
Chloroform	0.070	0.072	14.3	AGAGE	Trinidad Head
Methyl chloride (chloromethane)	1.16	0.99	563	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Benzene	0.109	0.096	34.0	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Carbon tetrachloride	0.530	0.453	84.4	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Methyl bromide (bromomethane)	0.028	0.024	7.2	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Methyl chloroform (1,1,1-trichloroethane)	0.020	0.017	3.7	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Dichloromethane (methylene chloride)	0.20	0.17	58.3	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Tetrachloroethene (perchloroethylene, tetrachloroethylene)	0.013	0.011	1.9	NOAA GMD	KUM, MLO, NWR, BRW, ALT
Chromium VI	<1.4E-06			IMPROVE Cr and NATTS Cr VI:Cr ratio	DENA, KALM, PORE, REDW, TRCR, TUXE, HACR
Arsenic	<2.1E-4			IMPROVE	DENA, KALM, PORE, REDW, TRCR, TUXE, HACR
Chromium	<1.1E-4			IMPROVE	DENA, KALM, PORE, REDW, TRCR, TUXE, HACR
Lead	<6.9E-04			IMPROVE	DENA, KALM, PORE, REDW, TRCR, TUXE, HACR
Manganese	3.8E-04			IMPROVE	DENA, KALM, PORE, REDW, TRCR, TUXE, HACR
Nickel	<1.0E-4			IMPROVE	DENA, KALM, PORE, REDW, TRCR, TUXE, HACR

[a] Standard temperature and pressure, 298 K and 101.325 kPa
[b] Local conditions – pressure was calculated using elevation and temperature based on average annual temperature measured at the site.

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Appendix E. Model Evaluation Summaries

In addition to the evaluations show in Section 3.7, EPA performed model evaluations for other NATA pollutants. These evaluations, including graphics, can be found in the Supplemental Data folder on the NATA website.

Appendix F. Exposure Factors for the 2014 NATA

The memorandum contained within this Appendix (below) describes in detail how EPA developed exposure factors for each chemical assessed in NATA. These calculated exposure factors can be found in the Supplemental Data folder accompanying this TSD.

MEMORANDUM

To: Ted Palma, U.S. EPA Office of Air Quality Planning and Standards

From: John Hader and Chris Holder, ICF

Date: June 25, 2018

Re: HAPEM7 Modeling for the 2014 National Air Toxics Assessment (NATA)

The National Air Toxics Assessment (NATA) is a nationwide EPA modeling assessment of the air concentrations, exposure concentrations,[1] and potential human health cancer and noncancer risks and hazards associated with inhalation exposure to Hazardous Air Pollutants (HAPs) emitted by manmade and natural sources of outdoor origin. As part of NATA, the Hazardous Air Pollutant Exposure Model (HAPEM), which is a U.S. Environmental Protection Agency (EPA) model, is used to perform screening-level assessments of long-term inhalation exposures to HAPs.

For the 2014 NATA, ICF ("we") used **Version 7 of HAPEM (HAPEM7),** with modeled air-concentration data provided by EPA, to **model exposure concentrations for seven selected HAPs, stratified by census tract and emission source type**. These HAPs also are used as surrogates for the many other HAPs included in NATA, as described in detail below. We used the annual-average exposure concentrations by age group, provided by the HAPEM modeling, to estimate lifetime-average exposure concentrations. **We then divided the lifetime exposure concentrations by the corresponding annual-average air concentrations creating "exposure factors". EPA can then estimate exposure to each NATA HAP in each census tract by multiplying the air concentration for the HAP by the exposure factor derived for the chemical's surrogate HAP.**

In this memorandum, we discuss HAPEM7, how we assigned the gas or particulate phase of the NATA HAPs, how EPA selected the seven HAPs modeled in HAPEM, how we set up the HAPEM runs, and how we developed the exposure factors.

[1] Exposure concentrations are time-averaged air concentrations to which a simulated individual is exposed. The time averaging considers the air concentrations in each place where the individual is simulated to spend time, and how long he or she spends there.

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1. Introduction to HAPEM and its Use in NATA

HAPEM is a model used by EPA to perform screening-level assessments of long-term inhalation exposures to HAPs. We updated HAPEM and its default, ancillary files in 2015, as discussed in the 2011 NATA documentation.[2] This latest version of HAPEM (HAPEM7)[3] estimates exposure concentrations using

- demographic and behavior data from the 2010 U.S. Census (covering all 50 U.S states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands),[4]
- compiled activity data from a recent version of EPA's Consolidated Human Activity Database (CHAD),[5] and
- updated data on population proximities to major roadways.

HAPEM7 stratifies exposure concentrations by

- location (U.S. Census tract),
- time of day,
- age group, and
- the individual emission source types and HAPs being modeled.

HAPEM is a probabilistic model that selects some model inputs from distributions of data to characterize exposure. These elements include commuting patterns, activity patterns, employment work location, microenvironmental factors, and (if desired) air concentrations. Including more simulated individuals (termed "replicates" in HAPEM) can increase the range of values selected for these probabilistic elements, across the simulated population.

[2] Appendix G of the Technical Support Document of EPA's 2011 National Air Toxics Assessment. December 2015. EPA Office of Air Quality Planning and Standards. Available at https://www.epa.gov/sites/production/files/2015-12/documents/2011-nata-tsd.pdf.

[3] As of October 23, 2017, HAPEM7 is available for download from https://www.epa.gov/fera/human-exposure-modeling-hazardous-air-pollutant-exposure-model-hapem. The HAPEM7 User's Guide also is available from that link, and it contains detailed discussions of the model's functionality and input files.

[4] For additional information on the census data parameterized in HAPEM, see Appendix B of The HAPEM User's Guide, Version 7 (July, 2015), available at https://www.epa.gov/sites/production/files/2015-12/documents/hapem7usersguide.pdf.

[5] For additional information on CHAD and how its data were parameterized in HAPEM, see https://www.epa.gov/healthresearch/consolidated-human-activity-database-chad-use-human-exposure-and-health-studies-and and Appendix B of The HAPEM User's Guide, Version 7 (July, 2015), available at https://www.epa.gov/sites/production/files/2015-12/documents/hapem7usersguide.pdf.

2. Air Quality Inputs to HAPEM7

2.1. HAPs Assessed for the 2014 NATA

For the 2014 NATA, EPA compiled an inventory of the annual mass of HAPs emitted from four NATA source types, namely

- point,
- non-point,
- on-road mobile, and
- non-road mobile.

These emissions were nationwide, typically at spatial resolutions of 12-km grids down to specific points. The assessed HAPs are shown in the far left column of Table 1 (under the "Chem" heading). In some cases, emissions of several chemicals were aggregated and modeled as a group, as indicated on the right side of Table 1 (under the "NATA" heading; the columns under the "NATA" heading provide the chemicals and chemical groups as they were modeled for NATA). Using these estimated emissions, temporal emission profiles based on source type, and hourly meteorology data selected by proximity, EPA used AERMOD[6] and CMAQ[7] to estimate ambient air concentrations. **The EPA air-modeling results provided for HAPEM exposure modeling were annual-average air concentrations at the level of census tracts, stratified by HAP, source type, and at three-hour increments across the day.**

2.2. Specifying Chemical Phases for HAPEM Modeling

For all source types, **HAPEM7 models concentrations for three chemical phases**. These phases are

- gaseous ("G"),
- particulate ("P"), and
- variable for typical atmospheric conditions ("G/P").

HAPEM estimates concentrations for user-specified microenvironments (ME). An ME is a generic location, such as indoors at home or outdoors near roadway, where a person spends time and breathes air, leading to chemical exposure. In HAPEM, MEs are treated as having well-mixed air concentrations at a given time, and the model estimates those ME concentrations relative to the outdoor air concentrations provided as input to the model. HAPEM7 is parameterized for 18 MEs, including eight indoor MEs (including residential, school, office,

[6] AERMOD: the atmospheric dispersion model developed by the American Meteorological Society and the EPA Regulatory Model Improvement Committee. See https://www.epa.gov/scram/air-quality-dispersion-modeling-preferred-and-recommended-models#aermod

[7] CMAQ: EPA's Community Multiscale Air Quality model. See https://www.epa.gov/cmaq

bar/restaurant, and similar), two in-vehicle MEs (personal vehicle and public transit), six outdoor MEs near roadways, and two outdoor MEs not near roadways.

Starting with outdoor ambient chemical concentrations, the model uses phase-specific penetration and proximity factors to estimate the ME chemical concentrations. A penetration factor describes how much of the chemical in the outdoor air penetrates the indoor or in-vehicle air. The penetration factor is a ratio in the form of [chemical air concentration in an indoor/in-vehicle ME] to [chemical air concentration directly outdoors of the ME]. A proximity factor parameterizes the heterogeneity of air concentrations across a Census tract. It describes how much higher or lower we expect the outdoor air concentration to be in the immediate vicinity of the ME relative to the Census tract outdoor concentration supplied in the input file, and it is a ratio in the form of [outdoor chemical air concentration in the immediate vicinity of the ME] to [tract-level outdoor chemical air concentration input to the model]. HAPEM7 has one set of penetration and proximity factors for mobile on-road sources, and a second set for all other source types. For mobile on-road sources, there are four categories of factors: three are for specific HAPs (benzene, 1,3-butadiene, and diesel particulate matter [DPM][8]) and a fourth category representing all other HAPs.

To prepare for NATA exposure modeling, **we categorized each of the NATA HAPs as G, P, or G/P based on available boiling-point data**, as defined in Table 2. We provide each HAP's boiling point and assigned HAPEM7 phase in Table 1 (left side under the "Chem" heading). If chemicals were modeled as a group, we assigned the group a G, P or G/P designation, as indicated in Table 1 (right side under the "NATA" heading) and as discussed later in this section.

We obtained the vast majority of boiling-point values from

- the Centers for Disease Control (CDC),[9]
- the National Institutes of Health (NIH),[10] or
- the Royal Society of Chemistry using their ChemSpider web site.[11]

These were judged to be the most reputable, comprehensive, user-friendly, and readily available sources of chemical boiling-point data. Each source allows the user to search by chemical name or Chemical Abstract Service (CAS) Registry Number. For HAPs whose boiling points we could not identify using these three sources, we searched a variety of additional data sources. We provide the source of each chemical's boiling-point value in the "Source" column of Table 1.

We could not identify empirical boiling-point data for some of the HAPs. For 25 HAPs (9 percent of all evaluated HAPs), we used predictive boiling points in order to categorize their chemical phases. These values came from ChemSpider, which generates estimated boiling points using three software modules: EPA's EPIsuite, the ACD/Labs Percepta Platform - PhysChem Module, and ChemAxon's predictive software platform. We typically selected the ACD/Labs values when available because these values were presented with confidence intervals and the conditions

[8] DPM is not a HAP as defined under Section 112(b) of the Clean Air Act; however, for ease of discussion we refer to it as a HAP in this memorandum.
[9] CDC: http://www.cdc.gov/niosh/npg.
[10] NIH: http://pubchem.ncbi.nlm.nih.gov/.
[11] CS: http://www.chemspider.com.

under which the boiling-point values were predicted (typically standard temperature and pressure); the other two platforms did not provide such information. If an ACD prediction was not available, we used the EPA EPIsuite value. Those boiling points that are predictive rather than empirical are flagged with a "P" in Table 1.

Note that the boiling-point ranges in Table 2 have imprecise endpoints (e.g., the high end of boiling points for G HAPs covers a range of 240 to 260°C). Forty of NATA HAPs have boiling points within these imprecise endpoints, meaning there was some uncertainty associated with assigning the phases for these HAPs. In order to make appropriate phase designations, we conducted a literature review for each of these HAPs to identify relevant information regarding its typical physical state. For example, 1-nitropyrene has a boiling point of 445°C, within the overlap of G/P and P boiling points. A review of the literature yielded several studies and reports identifying 1-nitropyrene as a particulate at typical atmospheric conditions, leading us to assign a designation of "P" to this HAP with a high degree of confidence. Where literature searches were uninformative, we assigned HAP phase based on the categorizations used for HAPEM5 to support the 1999 NATA. The combination of the additional literature review and consultation of the HAPEM5 designations allowed us to make phase designations for these HAPs. Seventeen HAPs have boiling points within the 240–260°C range; based on the literature review and HAPEM5 designations, we categorized 16 as G and 1 as G/P. Twenty HAPs have boiling points within the 400–480°C range; we categorized 16 as P and 4 as G/P. Three HAPs have wide-ranging boiling-point values; we categorized the two with higher ranges of boiling points (extending into the 400–480°C range) as G/P, and we categorized the one with a lower range of boiling points (extending only into the 240–260°C range) as G.

In addition to the above 40 HAPs, boiling-point values were specified by the CDC or EPA as "variable" for three HAPs (see the "V" designations in the boiling-point-value column in Table 1). We categorized two of these HAPs (coke oven emissions and cyanide) as G/P. We categorized coke oven emissions based on an EPA characterization of this pollutant as consisting of a mixture of particulates, volatiles, and semi-volatiles.[12] We characterized cyanide based on the fact that cyanide is not typically found in isolation in nature, but rather in a variety of compounds, some of which are typically solid (e.g., calcium cyanide, sodium cyanide) and some of which are typically gaseous (e.g., hydrogen cyanide).[13] The third HAP with "variable" boiling points was DPM and we assumed that it is typically a particulate.

For five HAPs, boiling-point data were either unavailable or were ill-defined (see the "NA", "D", and "S" designations in the boiling-point-value column in Table 1); one was Fine Mineral Fibers, which we categorized as P, and we left the remaining four (Extractable Organic Matter (EOM), propoxur, quinone, and toxaphene) uncategorized. For these four HAPs, EPA was health protective and set exposure concentrations equal to ambient outdoor concentrations per census tract, as indicated by "EF=1" designations in the "Matching Chemical Modeled in HAPEM" columns in Table 1. A setting of EF=1 is health-protective because it assumes that people always breathe outdoor ambient air, receiving no protection that may otherwise be afforded by the barriers and filtration systems of a building or vehicle (that is, a penetration factor of 1 rather than below 1). Without indoor sources of emissions (which are not included in NATA), outdoor air concentrations necessarily are the same or higher than those of indoor or in-vehicle MEs.

[12] https://www.epa.gov/sites/production/files/2016-01/documents/coke_rra.pdf
[13] http://www.atsdr.cdc.gov/

Where EPA modeled several HAPs as one group, we assigned the group's chemical phase based on the phase most frequently assigned to the group's component chemicals. Two NATA chemical groups did not easily accommodate this criterion, as discussed in the bullets below.

- For NATA chemical group CHROMHEX, its two components are Chromium (VI) and Chromium Trioxide, which are P and G/P phases, respectively. We assumed that Chromium (VI) was the primary chemical in the group (the one emitted in higher amounts) and assigned the group to P accordingly.

- For NATA chemical group CYANIDE, its two components are cyanide and hydrogen cyanide (HCN). Cyanide has a variable boiling point, while HCN's boiling point is 26ºC (making it a G chemical). Because HCN has the higher level of emissions, we assigned the group to G accordingly.

2.3. HAPs Modeled in HAPEM7 for the 2014 NATA

As noted previously, except for air-concentration data, HAPEM7 does not use any settings or inputs that are specific to each individual NATA HAP. Penetration and proximity factors vary only by the phase of the HAP, not by each HAP individually (except for mobile on-road sources, where benzene, 1,3-butadiene, and DPM have specific penetration and proximity factors). Therefore, except for those three HAPs for mobile on-road sources, the model inputs for HAPs of a given phase vary only by air concentration, and so their exposure concentrations output by HAPEM (i.e., the time-averaged air concentrations across the MEs where individuals are simulated to spend time) vary only by their air concentrations. This means that we can estimate the exposure concentration of one HAP of a given phase in HAPEM, and then in post-processing we can calculate the relationship between its air and exposure concentrations and apply this relationship to other HAPs of the same phase, significantly reducing the level of effort needed to conduct the exposure modeling.

EPA identified a small subset of NATA HAPs for which to conduct HAPEM exposure modeling. NATA uses the modeling results of this subset as-is, and uses the results as surrogate values for the remaining NATA HAPs not modeled in HAPEM. EPA used the following decision criteria in identifying this subset of HAPs to model.

1. The subset must include at least one HAP per phase (at least one G HAP, one P HAP, and one G/P HAP).

2. Each emission source type must be represented for each phase (for example, G HAPs must collectively cover the point, non-point, on-road mobile, and non-road mobile source types, and so on for P and G/P HAPs).

3. It is preferred that the selected HAPs have the potential to pose higher risks to human health nationwide, relative to other HAPs.

4. It is preferred that the selected HAPs be emitted in many spatially-diverse locations across the United States.

Using these criteria, **EPA selected seven HAPs for exposure modeling**. We list these HAPs below and in Table 3. The right four columns of Table 1 indicate how these modeled HAPs were mapped to the other NATA HAPs not modeled in HAPEM.

- **Benzene** and **1,3-butadiene** are emitted by many processes (and all four modeled source types) in nearly all U.S. locations. They each also have specific penetration and proximity factors for emissions from mobile on-road sources. **Benzene was selected to be the surrogate for all other G HAPs**.

- Unspeciated, generic PAHs ("**PAH, total**") are emitted by all four source types and from a wide variety of processes, so it was **selected to be the surrogate for all G/P HAPs except coke oven emissions,** which is a special case that was modeled by itself for point sources but not used as a surrogate for any other HAPs.

- **Chromium (VI)** is a highly toxic HAP that was **selected as the surrogate for all P HAPs emitted by point and non-point sources, except for DPM,** which was modeled as itself for non-point and mobile sources. DPM has specific penetration and proximity factors for emissions from mobile on-road sources. Note that the NATA air-concentration modeling included chromium (VI) emissions from all four source types, but its use as an exposure surrogate included only point and non-point sources because those are its major emitters.

- **Nickel was selected as the surrogate for P HAPs emitted by mobile sources**, except for DPM, which was modeled as itself for non-point and mobile sources. Nickel is emitted by a variety of processes across the United States. Note that NATA air-concentration modeling included nickel emissions from all four source types, but its use as an exposure surrogate included only mobile sources because chromium (VI) was designated as the more appropriate surrogate for point and non-point sources.

We used the air-concentration modeling outputs provided by EPA for these seven HAPs, stratified by source type, three-hour increment of the day, and census tract, as the air-quality inputs for **seven HAPEM7 runs**.

3. HAPEM7 Runs

3.1. Design

For each of the seven HAPEM7 runs (one run for each modeled chemical), we used the HAPEM7 **default census- and CHAD-based files**. Each run assessed the **18 HAPEM7 MEs** and **all populated census tracts in the United States, Puerto Rico, and the U.S. Virgin Islands**. The air-quality inputs were in three-hour periods for each HAP, tract, and source type (that is, for each day, average air concentrations for the first three hours of the day, the second three hours, etc., totaling eight values per day for each HAP, tract, and source type). We used the **six default HAPEM7 age groups** (discussed below in Section 3.3) and **three day-types** (summer weekdays, non-summer weekdays, and weekends). We linked each HAP to its appropriate HAPEM7 penetration- and proximity-factors files, and we used **30 replicates (simulated individuals) per age group** evaluated per tract. ICF has previously shown that the tract-mean exposure concentrations of an age group are reasonably stable when using 30 replicates, striking a good balance between model runtime and the stability of model outputs (that is, at a 95-percent probability level, 30 replicates are needed to estimate the tract-mean exposures to within 20 percent).[14]

[14] Source: "Benzene Case Study for PO3-NTA006-ICF", a technical memorandum from Arlene Rosenbaum, Michael Huang, and Jonathan Cohen (ICF) to Ted Palma (U.S. EPA), September 30, 2002.

3.2. Quality Assurance and Quality Control

We reviewed the HAPEM7 control files ("parameters" files) for accuracy, and then we reviewed the log, "counter," and "mistract" HAPEM7 output files to identify any potential errors in the modeling. One tract identifier was modified by the U.S. Census after 2010 (after the HAPEM7 population files were developed using the 2010 census)—the 2014 NATA's air-concentration data used the tract's latest identifier of 51019050100, which we renamed to its old identifier (51515050100) for HAPEM7 modeling (its geography did not change). We switched it back to the current identifier in the results delivered to EPA. We detected no other errors in the inputs or outputs. We present below additional information gleaned from the QA/QC activities.

- EPA modeled all U.S. census tracts to develop air concentration estimates. However, 584 tracts (less than 1 percent of U.S. tracts) were not modeled in HAPEM because the 2010 Census indicated zero population.
- A total of 73,450 tracts were modeled for exposure concentrations for the 2014 NATA.

3.3. Post-processing for Exposure Factors

We utilized the HAPEM7 outputs for the seven modeled HAPs to estimate exposure factors that EPA then applies to all HAPs assessed in NATA, based on HAP phase and source type. For each tract and source type in a HAP-specific HAPEM7 run, we calculated the estimated **70-year lifetime-average exposure concentration for each modeled replicate**. We calculated these average concentrations as the time-weighted average of exposures for the six HAPEM7 age groups, as shown below.

```
Lifetime average exposure conc. =
  [ages 00-01 exposure conc. × (2/70)]
+ [ages 02-04 exposure conc. × (3/70)]
+ [ages 05-15 exposure conc. × (11/70)]
+ [ages 16-17 exposure conc. × (2/70)]
+ [ages 18-64 exposure conc. × (47/70)]
+ [ages 65+   exposure conc. × (5/70)]
```

We then calculated the **population-median lifetime-average exposure concentration in each tract** (median calculated from the 30 replicates in a tract), stratified by HAP and source type. For a given HAP and tract, summing these median concentrations across source types yields an estimated "typical" lifetime-average HAP exposure concentration from all contributing sources.

For each assessed HAP in a tract, **we calculated exposure factors by dividing these median lifetime-exposure concentrations by the corresponding annual-average outdoor air concentrations** (stratified by source type as well as the all-source total). **EPA can then multiply these exposure factors by the air concentrations of any HAP of the same phase-type, resulting in estimated lifetime-exposure concentrations for that HAP**. For example, for a given tract, to estimate the exposure concentrations of fluorene (a G/P HAP) emitted by non-point sources, EPA will multiply its non-point air concentrations by the non-point exposure factors for "PAH, total" (the surrogate for G/P HAPs). The exposure factors typically were between roughly 0.4 and 1.0 (larger factors generally for on-road mobile sources and gases; smaller factors typically for the other source types and particulates).

The primary limitation of this exposure-factor method is related to commuting. HAPEM7 simulates the movement of replicates to and from work. Some replicates will work in the same tract where they live, so that the outdoor air concentrations of their "home tract" equal those of their "work tract". For these replicates, the exposure-factor method is accurate, because the exposure factors account only for home-tract exposure to the modeled HAP, and the air-concentration denominator in the factor calculation also corresponds only to home-tract air concentrations of the unmodeled HAP. For replicates who commute outside their home tract, they work in a tract with different air concentrations than in their home tract, affecting their exposure during work hours (usually less than half the day). When the work air tract concentrations are similar to the home tract air concentrations, then the exposure factor method provides a good approximation of exposure for unmodeled HAPs. However, when work tract and home tract air concentrations are highly dissimilar, the exposure factors method estimates are less accurate because the exposure factors account for some home-tract exposures and some very different work-tract exposures to the modeled HAP, while the air-concentration denominator in the factor calculation corresponds only to home-tract air concentrations of the unmodeled HAP.

Instances of highly dissimilar work tract and home tract concentrations are most easily detected when exposure factors are above 1, indicating the work-tract air concentrations are higher than those of the home tract. For a relatively small number of tracts, exposure factors were larger than 10 and, for seven tracts, exposure factors were larger than 100. In an effort to improve the representativeness of the modeled exposure factors and their application to unmodeled HAPs, **we limited exposure factors to be no larger than the values shown in** Table 4 (exposure factors that were above these values were set to the maximum values). To define these upper limits on the exposure factors, we calculated the median exposure factor and standard deviation of exposure factors across all tracts for each combination of HAP and source type; the upper limit was then defined as *median+standard deviation*. The calculations for medians and standard deviations did not include exposure factors of 100 or larger, which we considered to be outliers. They also did not consider instances where air concentrations or exposure concentrations were zero, which occurred at 584 tracts as discussed in Section 3.2. In these instances, we set the exposure factors equal to 1.0, indicating that the exposure concentration equals the air concentration. All applications of the exposure factors for the 2014 NATA use these truncated values, including exposure factors initially set equal to 1.0 and including the HAPs explicitly modeled in HAPEM7.

4. Outputs

We performed quality assurance checks of the post-processing by thoroughly reviewing and testing the post-processing R code in order to ensure calculations were being performed correctly, and we also performed other broad checks to ensure all records were properly read in and that flagged records were properly processed.

Table 1. HAPs Assessed in the 2014 NATA, with their HAPEM7 HAP Phases and Surrogate Chemical Assignments

Chem.				NATA					
	Boiling Point					Matching Chemical Modeled in HAPEM[d]			
Name	Value (°C)[a]	Source[b]	Phase[c]	Name	Phase[c]	P	NP	M-OR	M-NR
Acetaldehyde	20	CDC	G	ACETALD	G	Benz	Benz	Benz	Benz
Acetamide	165	CDC	G	ACETAMIDE	G	Benz	Benz	Benz	Benz
Acetonitrile	82	CDC	G	ACETONIT	G	Benz	Benz	Benz	Benz
Acetophenone	202	NIH	G	ACETOPHEN	G	Benz	Benz	Benz	Benz
Acrolein	53	CDC	G	ACROLEI	G	Benz	Benz	Benz	Benz
Acrylic acid	141	CDC	G	ACRYLCACID	G	Benz	Benz	Benz	Benz
Acrylamide	175	CDC	G	ACRYLMID	G	Benz	Benz	Benz	Benz
Acrylonitrile	77	CDC	G	ACRYLONITRL	G	Benz	Benz	Benz	Benz
2-Acetylaminofluorene	400 P	CS	G/P	ACTYALFLUR2	G/P	PAH	PAH	PAH	PAH
Allyl chloride	45	CDC	G	ALLYLCHLORD	G	Benz	Benz	Benz	Benz
4-Aminobiphenyl	302	CDC	G/P	AMNOBIPNYL4	G/P	PAH	PAH	PAH	PAH
Aniline	184	CDC	G	ANILINE	G	Benz	Benz	Benz	Benz
Antimony	1,587	CDC	P	ANTIMONY	P	Cr6	Cr6	Ni	Ni
Arsenic	612	CDC	P	ARSENIC	P	Cr6	Cr6	Ni	Ni
Benzene	80	CDC	G	BENZENE	G	Benz	Benz	Benz	Benz
Benzidine	400	CDC	G/P	BENZIDINE	G/P	PAH	PAH	PAH	PAH
Benzotrichloride	221	NIH	G	BENZOTRICHL	G	Benz	Benz	Benz	Benz
Benzyl chloride	179	NIH	G	BENZYLCHLO	G	Benz	Benz	Benz	Benz
BERYLLIUM	2,500	NIH	P	BERYLLIUM	P	Cr6	Cr6	Ni	Ni
Biphenyl	256	NIH	G	BIPHENYL	G	Benz	Benz	Benz	Benz
Bis(chloromethyl)ether	106	CDC	G	BISCHLROME	G	Benz	Benz	Benz	Benz
Bromoform	149	CDC	G	BROMOFORM	G	Benz	Benz	Benz	Benz
Bis(2-ethylhexyl)phthalate	386	CDC	G/P	BS2TYLHXYLP	G/P	PAH	PAH	PAH	PAH
beta-Propiolactone	162	http://www.cdc.gov/niosh/docs/81-123/pdfs/0528.pdf	G	BT-PRPLACTN	G	Benz	Benz	Benz	Benz
1,3-Butadiene	138	NIH	G	BUTADIE	G	Buta	Buta	Buta	Buta
Cadmium	765	CDC	P	CADMIUM	P	Cr6	Cr6	Ni	Ni
Calcium cyanamide	>2,444	CDC	P	CALCIUMCYA	P	Cr6	Cr6	Ni	Ni
Captan	314	CS	G/P	CAPTAN	G/P	PAH	PAH	PAH	PAH
Carbaryl	315	CS	G/P	CARBARYL	G/P	PAH	PAH	PAH	PAH
Carbon disulfide	47	CDC	G	CARBNDISULF	G	Benz	Benz	Benz	Benz
Carbonyl sulfide	-50	NIH	G	CARBNYLSUL	G	Benz	Benz	Benz	Benz
Carbon tetrachloride	77	CDC	G	CARBONTET	G	Benz	Benz	Benz	Benz
Catechol	245	CDC	G	CATECHOL	G	Benz	Benz	Benz	Benz
Chloroform	62	CDC	G	CHCL3	G	Benz	Benz	Benz	Benz
Chloroacetic acid	106	CDC	G	CHLACETACD	G	Benz	Benz	Benz	Benz
2-Chloroacetophenone	244	CDC	G	CHLACETPH2	G	Benz	Benz	Benz	Benz
Chloramben	312	CS	G/P	CHLORAMBEN	G/P	PAH	PAH	PAH	PAH
Chlordane	175	NIH	G	CHLORDANE	G	Benz	Benz	Benz	Benz
Chlorine	-33	CDC	G	CHLORINE	G	Benz	Benz	Benz	Benz
Chloroprene	59	CDC	G	CHLOROPRENE	G	Benz	Benz	Benz	Benz
Chlorobenzilate	146	NIH	G	CHLROBZLAT	G	Benz	Benz	Benz	Benz
Chlorobenzene	132	CDC	G	CHLROBZNE	G	Benz	Benz	Benz	Benz
Chloromethyl methyl ether	59	CDC	G	CHLROMME	G	Benz	Benz	Benz	Benz
Chromium (VI)	2,642	CDC	P	CHROMHEX	P	Cr6	Cr6	Ni	Ni
Chromium Trioxide	250	CDC	G/P						

Chem.				NATA					
	Boiling Point					Matching Chemical Modeled in HAPEM[d]			
Name	Value (°C)[a]	Source[b]	Phase[c]	Name	Phase[c]	P	NP	M-OR	M-NR
Chromium III	2,672	http://books.google.com/books?id=SFD30BvPBhoC&pg=PA123&lpg=PA123&dq=chromium+III+melting+point&source=bl&ots=upHljDrKMy&sig=dlSMKFL5z0sVI0z8Z4NhlsFHqgE&hl=en&sa=X&ei=4nkIVPLvJ4LS8AGbiYD4DA&ved=0CFkQ6AEwCQ#v=onepage&q=chromium%20III%20melting%20point&f=false	P	CHROMTRI	P	Cr6	Cr6	Ni	Ni
Ethylene dichloride	83	CDC	G	CL2_C2_12	G	Benz	Benz	Benz	Benz
Trichloroethylene	87	CDC	G	CL3_ETHE	G	Benz	Benz	Benz	Benz
Cobalt	3,100	CDC	P	COBALT	P	Cr6	Cr6	Ni	Ni
Coke oven emissions	V	CDC	G/P	COKEOVEN	G/P	Coke	Coke	Coke	Coke
Cresol/Cresylic Acid (Mixed Isomers)	202	CDC	G	CRESOLS	G	Benz	Benz	Benz	Benz
m-Cresol	202	CDC	G						
o-Cresol	191	CDC	G						
p-Cresol	202	CDC	G						
Cumene	152	CDC	G	CUMENE	G	Benz	Benz	Benz	Benz
Cyanide	V	CDC	G/P	CYANIDE	G	Benz	Benz	Benz	Benz
Hydrogen cyanide	26	CDC	G						
2,4-Dichlorophenoxy Acetic Acid	345 P	CS	G/P	D24SALTS	G/P	PAH	PAH	PAH	PAH
Diethyl sulfate	210	NIH	G	DETHLSULFAT	G	Benz	Benz	Benz	Benz
Diazomethane	-23	CDC	G	DIAZOMETHAN	G	Benz	Benz	Benz	Benz
Dibenzofuran	287	NIH	G/P	DIBENZOFUR	G/P	PAH	PAH	PAH	PAH
1,2-Dibromo-3-chloropropane	196	CDC	G	DIBRM3CHLPR	G	Benz	Benz	Benz	Benz
Dibutyl Phthalate	340	CDC	G/P	DIBUTYLPHTH	G/P	PAH	PAH	PAH	PAH
3,3'-Dichlorobenzidine	400	NIH	G/P	DICHLBZD33P	G/P	PAH	PAH	PAH	PAH
Dichlorvos	140 at 40 mmHG	NIH	G	DICHLORVOS	G	Benz	Benz	Benz	Benz
1,4-Dichlorobenzene	173	CDC	G	DICHLRBNZN	G	Benz	Benz	Benz	Benz
Dichloroethyl ether	177	CDC	G	DICHLROETET	G	Benz	Benz	Benz	Benz
1,3-Dichloropropene	108	NIH	G	DICLPRO13	G	Benz	Benz	Benz	Benz
Diesel PM	V	http://www.epa.gov/region1/eco/airtox/diesel.html	P	DIESEL_PM10	P	DPM	DPM	DPM	DPM
Diethanolamine	268	NIH	G/P	DIETHNLAMIN	G/P	PAH	PAH	PAH	PAH
Dimethylcarbamoyl chloride	167	NIH	G	DIMTHYCARB	G	Benz	Benz	Benz	Benz
N,N-Dimethylformamide	153	CDC	G	DIMTHYFORM	G	Benz	Benz	Benz	Benz
4-Dimethylaminoazobenzene	371	CS	G/P	DIMTHYLAMAZ	G/P	PAH	PAH	PAH	PAH
Dimethyl phthalate	284	NIH	G/P	DIMTHYLPHTH	G/P	PAH	PAH	PAH	PAH
Dimethyl sulfate	188	NIH	G	DIMTHYLSULF	G	Benz	Benz	Benz	Benz
3,3'-Dimethylbenzidine	300	CDC	G/P	DIMTYLBZ33P	G/P	PAH	PAH	PAH	PAH
1,1-Dimethyl Hydrazine	64	CDC	G	DIMTYLHYD11	G	Benz	Benz	Benz	Benz
3,3'-Dimethoxybenzidine	391	CS	G/P	DIMTYOXB33P	G/P	PAH	PAH	PAH	PAH
2,4-Dinitrotoluene	300	NIH	G/P	DINITOTOL24	G/P	PAH	PAH	PAH	PAH
4,6-Dinitro-o-cresol	312	CDC	G/P	DINITROCRES	G/P	PAH	PAH	PAH	PAH
2,4-Dinitrophenol	312	CS	G/P	DINITROPH24	G/P	PAH	PAH	PAH	PAH
1,2-Diphenylhydrazine	293	NIH	G/P	DIPYLHYZ12	G/P	PAH	PAH	PAH	PAH
N,N-dimethylaniline	192	CDC	G	DMTYLANILNN	G	Benz	Benz	Benz	Benz
Epichlorohydrin	118	NIH	G	EPICHLORO	G	Benz	Benz	Benz	Benz
1,2-Epoxybutane	63	NIH	G	EPOXYBUTA12	G	Benz	Benz	Benz	Benz
Ethylene dibromide	131	CDC	G	ETHDIBROM	G	Benz	Benz	Benz	Benz
Ethyleneimine	56	CDC	G	ETHENIMINE	G	Benz	Benz	Benz	Benz
Ethylene glycol	197	CDC	G	ETHGLYCOL	G	Benz	Benz	Benz	Benz

Chem.				NATA					
	Boiling Point					Matching Chemical Modeled in HAPEM[d]			
Name	Value (°C)[a]	Source[b]	Phase[c]	Name	Phase[c]	P	NP	M-OR	M-NR
Ethylidene dichloride	-17	CDC	G	ETHIDDICHLD	G	Benz	Benz	Benz	Benz
Ethylene thiourea	230	CDC	G	ETHTHUREA	G	Benz	Benz	Benz	Benz
Ethyl acrylate	99	CDC	G	ETHYLACRYL	G	Benz	Benz	Benz	Benz
Ethyl benzene	136	CDC	G	ETHYLBENZ	G	Benz	Benz	Benz	Benz
Ethyl carbamate	185	NIH	G	ETHYLCARBA	G	Benz	Benz	Benz	Benz
Ethyl chloride	-139	NIH	G	ETHYLCHLRD	G	Benz	Benz	Benz	Benz
Ethylene oxide	11	CDC	G	ETOX	G	Benz	Benz	Benz	Benz
Formaldehyde	-21	CDC	G	FORMALD	G	Benz	Benz	Benz	Benz
1,2-Dimethoxyethane	82	NIH	G	GLYCOLETHR	G	Benz	Benz	Benz	Benz
2-(Hexyloxy)ethanol	258	NIH	G						
2-Butoxyethyl acetate	192	CDC	G						
2-Propoxyethyl Acetate	184	CS	G						
Butyl carbitol acetate	245	NIH	G						
Carbitol acetate	219	NIH	G						
Cellosolve Acetate	145	CDC	G						
Cellosolve Solvent	124	CDC	G						
Diethylene glycol diethyl ether	189 E	CS	G						
Diethylene glycol dimethyl ether	161 E	CS	G						
Diethylene glycol ethyl methyl ether	168 P	CS	G						
Diethylene glycol monobutyl ether	230	NIH	G						
Diethylene glycol monoethyl ether	196	NIH	G						
Diethylene glycol monomethyl ether	194 E	CS	G						
Ethoxytriglycol	256	NIH	G						
Ethylene glycol methyl ether	124	CDC	G						
Ethylene Glycol Monomethyl Ether Acetate	145	CDC	G						
Ethylene glycol mono-sec-butyl ether	192	CS	G						
Glycol ethers	120–240	http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_012d/0901b8038012d976.pdf?filepath=oxysolvents/pdfs/noreg/110-00977.pdf&fromPage=GetDoc	G						
Methoxytriglycol	249	http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_012d/0901b8038012d976.pdf?filepath=oxysolvents/pdfs/noreg/110-00977.pdf&fromPage=GetDoc	G						
N-Hexyl carbitol	260 E	CS	G						
Phenyl cellosolve	245 E	CS	G						
Propyl cellosolve	150	http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_012d/0901b8038012d976.pdf?filepath=oxysolvents/pdfs/noreg/110-00977.pdf&fromPage=GetDoc	G						
Triethylene Glycol Dimethyl Ether	215 E	CS	G						
Triglycol monobutyl ether	278	NIH	G/P						
Hydrochloric acid	-85	CDC	G	HCL	G	Benz	Benz	Benz	Benz
Heptachlor	392	CS	G/P	HEPTACHLOR	G/P	PAH	PAH	PAH	PAH
Hexamethylene Diisocyanate	212	NIH	G	HEXAMTHLE	G	Benz	Benz	Benz	Benz
Hexane	69	CDC	G	HEXANE	G	Benz	Benz	Benz	Benz

Chem.				NATA					
	Boiling Point					Matching Chemical Modeled in HAPEM[d]			
Name	Value (°C)[a]	Source[b]	Phase[c]	Name	Phase[c]	P	NP	M-OR	M-NR
Hexachloroethane	187	CDC	G	HEXCHLETHN	G	Benz	Benz	Benz	Benz
Hexachlorocyclopentadiene	238	CDC	G	HEXCHLPNTD	G	Benz	Benz	Benz	Benz
Hexachlorobutadiene	215	CDC	G	HEXCHLRBT	G	Benz	Benz	Benz	Benz
Hexachlorobenzene	325	NIH	G/P	HEXCHLROBZ	G/P	PAH	PAH	PAH	PAH
Hexamethylphosphoramide	233	NIH	G	HEXMTHPHO	G	Benz	Benz	Benz	Benz
Hydrogen Fluoride	19	CDC	G	HF	G	Benz	Benz	Benz	Benz
Mercury	356	CDC	G/P	HGSUM	G/P	PAH	PAH	PAH	PAH
1,2,3,4,5,6-Hexachlorocyclohexane	323	CDC	G/P	HXCCL123456	G/P	PAH	PAH	PAH	PAH
Hydrazine	113	CDC	G	HYDRAZINE	G	Benz	Benz	Benz	Benz
Hydroquinone	285	CDC	G/P	HYDROQUIN	G/P	PAH	PAH	PAH	PAH
Isophorone	215	CDC	G	ISOPHORONE	G	Benz	Benz	Benz	Benz
LEAD	1,740	CDC	P	LEAD	P	Cr6	Cr6	Ni	Ni
Maleic anhydride	202	CDC	G	MALANHYD	G	Benz	Benz	Benz	Benz
Manganese	1,962	CDC	P	MANGANESE	P	Cr6	Cr6	Ni	Ni
4,4'-Methylenebis(2-Chloraniline)	209	NIH	G	MB2CLRAN44P	G	Benz	Benz	Benz	Benz
Methylene chloride	39	CDC	G	MECL	G	Benz	Benz	Benz	Benz
Methanol	64	CDC	G	METHANOL	G	Benz	Benz	Benz	Benz
Methoxychlor	89	NIH	G	METHOXYCHL	G	Benz	Benz	Benz	Benz
Methyl bromide	3	CDC	G	METHYLBROM	G	Benz	Benz	Benz	Benz
Methyl isobutyl ketone	116	CDC	G	MIBK	G	Benz	Benz	Benz	Benz
Fine Mineral Fibers	NA	http://www.usg.com/content/dam/USG_Marketing_Communications/united_states/product_promotional_materials/finished_assets/usg-mineral-wool-300a-msds-en-75850002.pdf	P	MINFIB	P	Cr6	Cr6	Ni	Ni
Methyl methacrylate	101	CDC	G	MMETACRYLAT	G	Benz	Benz	Benz	Benz
Methyl tert-butyl ether	55	NIH	G	MTBE	G	Benz	Benz	Benz	Benz
4,4'-Methylenedianiline	397	CDC	G/P	MTHYDIAN44P	G/P	PAH	PAH	PAH	PAH
Methyl chloride	-98	CDC	G	MTHYLCHLRD	G	Benz	Benz	Benz	Benz
Methyl Chloroform	74	CDC	G	MTHYLCHLRF	G	Benz	Benz	Benz	Benz
4,4'-Methylenediphenyl Diisocyanate	313	CS	G/P	MTHYLDPNLDS	G/P	PAH	PAH	PAH	PAH
Methylhydrazine	88	CDC	G	MTHYLHYZIN	G	Benz	Benz	Benz	Benz
Methyl iodide	43	CDC	G	MTHYLIODIDE	G	Benz	Benz	Benz	Benz
Methyl isocyanate	39	CDC	G	MTHYLISOCY	G	Benz	Benz	Benz	Benz
Naphthalene	260	CDC	G	NAPHTH	G	Benz	Benz	Benz	Benz
Nickel	2,913	CDC	P	NICKEL	P	Cr6	Cr6	Ni	Ni
Nickel oxide	1,955	NIH	P						
Nickel refinery dust	2,730	http://www.cdc.gov/niosh/docs/81-123/pdfs/0445.pdf	P						
4-Nitrobiphenyl	340	CDC	G/P	NITROBIPHL4	G/P	PAH	PAH	PAH	PAH
Nitrobenzene	211	CDC	G	NITROBNZNE	G	Benz	Benz	Benz	Benz
4-Nitrophenol	279	NIH	G/P	NITROPHENL4	G/P	PAH	PAH	PAH	PAH
2-Nitropropane	121	CDC	G	NITROPROPA2	G	Benz	Benz	Benz	Benz
N-Nitrosodimethylamine	152	CDC	G	NNITROSDIM	G	Benz	Benz	Benz	Benz
N-Nitrosomorpholine	224	NIH	G	NNITROSMPH	G	Benz	Benz	Benz	Benz
N-Nitroso-n-methylurea	164 P	CS	G	NNITROSURE	G	Benz	Benz	Benz	Benz
o-Anisidine	225	CDC	G	o-Anisidine	G	Benz	Benz	Benz	Benz
o-Toluidine	200	CDC	G	O-TOLUIDINE	G	Benz	Benz	Benz	Benz
Anthracene	342	NIH	G/P	PAH_000E0	G/P	PAH	PAH	PAH	PAH
Phenanthrene	340	NIH	G/P						
Pyrene	404	NIH	P						
3-Methylcholanthrene	178	http://www.speclab.com/compound/c50328.htm	G	PAH_101E2	G	Benz	Benz	Benz	Benz

Chem.				NATA					
	Boiling Point					Matching Chemical Modeled in HAPEM[d]			
Name	Value (°C)[a]	Source[b]	Phase[c]	Name	Phase[c]	P	NP	M-OR	M-NR
7,12-Dimethylbenz[a]anthracene	122	http://www.sigmaaldrich.com/catalog/product/supelco/442425?lang=en&region=US	G	PAH_114E1	G	Benz	Benz	Benz	Benz
Dibenzo[a,h]pyrene	308 E	CS	G/P	PAH_176E2	P	Cr6	Cr6	Ni	Ni
Dibenzo[a,i]pyrene	552 P	CS	P						
Dibenzo[a,l]pyrene	552 P	CS	P						
5-Methylchrysene	449 P	CS	P	PAH_176E3	P	Cr6	Cr6	Ni	Ni
7H-Dibenzo[c,g]carbazole	544 P	CS	P						
Benzo[a]pyrene	360	http://www.speclab.com/compound/c50328.htm	G/P						
Coal tar	>250	http://www.inchem.org/documents/icsc/icsc/eics1415.htm	G/P						
Dibenzo[a,e]pyrene	552 P	CS	P						
Methylchrysene	449 P	CS	P						
1-Nitropyrene	445 P	CS	P	PAH_176E4	P	Cr6	Cr6	Ni	Ni
Benz[a]anthracene	438	NIH	P						
Benzo[b]fluoranthene	4,665 P	CS	P						
Benzo[j]fluoranthene	480 E	CS	P						
Dibenz[a,h]acridine	534 P	CS	P						
Dibenzo[a,j]Acridine	534 P	CS	P						
Indeno[1,2,3-c,d]pyrene	530	http://www.speclab.com/compound/c193395.htm	P						
Benzo[k]fluoranthene	480	http://www.speclab.com/compound/c207089.htm	P	PAH_176E5	P	Cr6	Cr6	Ni	Ni
Carbazole	355	http://www.sigmaaldrich.com/catalog/product/sigma/c5132?lang=en&region=US	G/P						
Chrysene	448	http://www.speclab.com/compound/c218019.htm	P						
Dibenzo[a,h]anthracene	262	http://www.sigmaaldrich.com/catalog/product/supelco/48574?lang=en&region=US	G/P	PAH_192E3	G/P	PAH	PAH	PAH	PAH
12-Methylbenz(a)anthracene	410 P	CS	P	PAH_880E5	G/P	PAH	PAH	PAH	PAH
1-Methylnaphthalene	240	NIH	G						
1-Methylphenanthrene	359	http://www.nature.nps.gov/hazardssafety/toxic/phen1met.pdf	G/P						
1-Methylpyrene	372	http://www.chemicalbook.com/ChemicalProductProperty_EN_CB7421679.htm	G/P						
2-Chloronaphthalene	256	http://www.chemicalbook.com/ChemicalProductProperty_EN_CB8854627.htm	G						
2-Methylnaphthalene	241	http://www.speclab.com/compound/c91576.htm	G						
2-Methylphenanthrene	339	CS	G/P						
9-Methyl Anthracene	196	CS	G						
Acenaphthene	279	NIH	G/P						
Acenaphthylene	265	NIH	G/P						
Benzo(a)fluoranthene	295	NIH	G/P						
Benzo(c)phenanthrene	430 P	CS	P						
Benzo(g,h,i)fluoranthene	406 P	CS	P						
Benzo[e]pyrene	465 P	CS	P						

Chem.				NATA					
	Boiling Point					Matching Chemical Modeled in HAPEM[d]			
Name	Value (°C)[a]	Source[b]	Phase[c]	Name	Phase[c]	P	NP	M-OR	M-NR
Benzo[g,h,i,]Perylene	550	NIH	P						
Benzofluoranthenes	406 P	CS	P						
Extractable Organic Matter (EOM)	NA	NA	NA						
Fluoranthene	384	NIH	G/P						
Fluorene	295	NIH	G/P						
Methylanthracene	360 P	CS	G/P						
Methylbenzopyrene	479 P	CS	G/P						
PAH, total	240–400	http://www.epa.gov/reg3hwmd/bf-lr/regional/analytical/semi-volatile.htm	G/P						
Perylene	276	http://www.sigmaaldrich.com/catalog/product/aldrich/394475?lang=en&region=US	G/P						
Parathion	375	CDC	G/P	PARATHION	G/P	PAH	PAH	PAH	PAH
2,4,4'-Trichlorobiphenyl (PCB-28)	164	CS	G	PCB	G/P	PAH	PAH	PAH	PAH
4,4'-Dichlorobiphenyl (PCB-15)	144	CS	G						
Decachlorobiphenyl (PCB-209)	460 P	CS	P						
Heptachlorobiphenyl	415 P	CS	P						
Hexachlorobiphenyl	396 P	CS	G/P						
Pentachlorobiphenyl	365 E	CS	G/P						
Polychlorinated biphenyls	365 E	CS	G/P						
Tetrachlorobiphenyl	360 P	CS	G/P						
p-Dioxane	101	CDC	G	P-DIOXANE	G	Benz	Benz	Benz	Benz
Tetrachloroethylene	121	CDC	G	PERC	G	Benz	Benz	Benz	Benz
Phenol	182	CDC	G	PHENOL	G	Benz	Benz	Benz	Benz
p-Phenylenediamine	267	CDC	G/P	PHNYLNDIAMI	G/P	PAH	PAH	PAH	PAH
Phosgene	8	CDC	G	PHOSGENE	G	Benz	Benz	Benz	Benz
Phosphine	88	CDC	G	PHOSPHINE	G	Benz	Benz	Benz	Benz
Phosphorus	280	CDC	G/P	PHOSPHORS	G/P	PAH	PAH	PAH	PAH
Phthalic anhydride	295	CDC	G/P	PHTHANHYDR	G/P	PAH	PAH	PAH	PAH
Pentachloronitrobenzene	328	NIH	G/P	PNTCHLNBZ	G/P	PAH	PAH	PAH	PAH
Pentachlorophenol	309	CDC	G/P	PNTCLPHENOL	G/P	PAH	PAH	PAH	PAH
Propylene dichloride	97	CDC	G	PROPDICLR	G	Benz	Benz	Benz	Benz
Propionaldehyde	48	NIH	G	PROPIONAL	G	Benz	Benz	Benz	Benz
1,3-Propanesultone	180	NIH	G	PROPNESLT13	G	Benz	Benz	Benz	Benz
Propoxur	D	CDC	NA	PROPOXUR	NA	EF=1	EF=1	EF=1	EF=1
Propylene oxide	34	CDC	G	PROPYLENEOX	G	Benz	Benz	Benz	Benz
1,2-Propylenimine	66	NIH	G	PROPYLENIMI	G	Benz	Benz	Benz	Benz
Quinoline	238	NIH	G	QUINOLINE	G	Benz	Benz	Benz	Benz
Quinone	S	CDC	NA	QUINONE	NA	EF=1	EF=1	EF=1	EF=1
Selenium	685	CDC	P	SELENIUM	P	Cr6	Cr6	Ni	Ni
Styrene	145	CDC	G	STYRENE	G	Benz	Benz	Benz	Benz
Styrene oxide	194	http://www.sigmaaldrich.com/catalog/product/aldrich/s5006?lang=en&region=US	G	STYROXIDE	G	Benz	Benz	Benz	Benz
Titanium tetrachloride	136	http://www.sigmaaldrich.com/catalog/product/aldrich/697079?lang=en&region=US	G	TITATETRA	G	Benz	Benz	Benz	Benz
2,4-Toluene diisocyanate	251	NIH	G	TOL_DIIS	G	Benz	Benz	Benz	Benz
Toluene-2,4-Diamine	292	CDC	G/P	TOLDIAM24	G/P	PAH	PAH	PAH	PAH
Toluene	111	CDC	G	TOLUENE	G	Benz	Benz	Benz	Benz
Toxaphene	D	CDC	NA	TOXAPHENE	NA	EF=1	EF=1	EF=1	EF=1
2,4,5-Trichlorophenol	247	NIH	G	TRCLPHNL245	G	Benz	Benz	Benz	Benz

Chem.				NATA					
	Boiling Point					Matching Chemical Modeled in HAPEM[d]			
Name	Value (°C)[a]	Source[b]	Phase[c]	Name	Phase[c]	P	NP	M-OR	M-NR
2,4,6-Trichlorophenol	246	NIH	G	TRCLPHNL246	G	Benz	Benz	Benz	Benz
1,2,4-Trichlorobenzene	213	CDC	G	TRICBZ124	G	Benz	Benz	Benz	Benz
1,1,2-Trichloroethane	114	CDC	G	TRICLA112	G	Benz	Benz	Benz	Benz
Triethylamine	89	CDC	G	TRIETHLAMN	G	Benz	Benz	Benz	Benz
Trifluralin	140	http://www.speclab.com/compound/c1582098.htm	G	TRIFLURALIN	G	Benz	Benz	Benz	Benz
2,2,4-Trimethylpentane	99	NIH	G	TRMEPN224	G	Benz	Benz	Benz	Benz
1,1,2,2-Tetrachloroethane	147	CDC	G	TTCLE1122	G	Benz	Benz	Benz	Benz
Vinyl chloride	-14	CDC	G	VINYCHLRI	G	Benz	Benz	Benz	Benz
Vinyl acetate	72	CDC	G	VINYLACET	G	Benz	Benz	Benz	Benz
Vinyl bromide	16	CDC	G	VINYLBROM	G	Benz	Benz	Benz	Benz
Vinylidene chloride	32	CDC	G	VINYLIDCLOR	G	Benz	Benz	Benz	Benz
m-Xylene	139	CDC	G	XYLENES	G	Benz	Benz	Benz	Benz
o-Xylene	144	CDC	G						
p-Xylene	138	CDC	G						
Xylenes (Mixed Isomers)	139	NIH	G						

Note: Information under the "Chem" header indicates chemicals for which EPA developed emissions data; we identified boiling points and HAPEM phase designations for these chemicals. When EPA ultimately conducted air-concentration modeling, for use then in exposure and risk modeling, they grouped some chemicals together as indicated in the information under the "NATA" header (note the occasional many-to-one relationship between the "Name" column under "Chem" and the "Name" column under "NATA"). Assigning phase designations to groups of chemicals required professional judgment, as discussed in Section 2.2.

[a] D=decomposes; E=experimental; NA=not available; P=predicted; S=sublimes; V=varies depending on compound.

[b] CDC=http://www.cdc.gov/niosh/npg; CS=http://www.chemspider.com; NIH=http://pubchem.ncbi.nlm.nih.gov/.

[c] G=gaseous; G/P=gaseous or particulate depending on conditions; P=particulate; NA=unknown.

[d] Source Types: P =point; NP=non-point; M-OR=mobile on-road; M-NR=mobile non-road.

Matching Chemicals: Benz=benzene; Buta=1,3-butadiene; Coke=Coke Oven Emissions; PAH=PAH, total; Ni=Nickel; Cr6=Chromium (VI); DPM = diesel particulate matter; "EF=1" means no surrogate assignment, so the exposure factor is set to 1 (before any truncations are then applied), meaning all exposure concentrations are set equal to ambient outdoor concentrations.

Table 2. Boiling-point Definitions Used to Classify HAPs for HAPEM7 Modeling for the 2014 NATA

HAPEM7 HAP Phase	Boiling-point Range (°C)
G (Gaseous)	< 240-260
G/P (Either gaseous or particulate depending on conditions)	240-260 to 400-480
P (Particulate)	> 400-480

Source: Adapted from the "Classification of Inorganic Pollutants" table at EPA's Volatile Organic Compound web page (available as of 23 October 2017 at https://www.epa.gov/indoor-air-quality-iaq/technical-overview-volatile-organic-compounds), as adapted from: World Health Organization, 1989. "Indoor air quality: organic pollutants." Report on a WHO Meeting, Berlin, 23-27 August 1987. Euro Reports and Studies 111. Copenhagen, World Health Organization Regional Office for Europe.

Table 3. HAPs Modeled in HAPEM7 for the 2014 NATA

NATA HAP	HAPEM7 HAP Phase[a]	Modeled in HAPEM7[b]			
		P	NP	M-OR	M-NR
Benzene	G	✓	✓	✓	✓
1,3-butadiene	G	✓	✓	✓	✓
Coke Oven Emissions	G/P	✓			
PAH, Total (polycyclic aromatic hydrocarbons; aggregate mass of unspecified congeners)	G/P	✓	✓	✓	✓
Chromium (VI) (compounds of hexavalent chromium)	P	✓	✓		
DPM (diesel particulate matter)	P		✓	✓	✓
Nickel	P			✓	✓

Note: For chromium (VI), DPM, and nickel, EPA modeled air concentrations corresponding to emissions from all four source types, but per EPA direction we only generated exposure concentrations for the subset of source types shown in the table. See discussion at the bottom of Section 2.3.

[a] G=gaseous; G/P=gaseous or particulate depending on conditions; P=particulate.

[b] P =point; NP=non-point; M-OR=mobile on-road; M-NR=mobile non-road.

Table 4. Truncations Applied to Exposure Factors for the 2014 NATA

HAP	Source Type				
	Point	Non-point	Mobile On-road	Mobile Non-road	Total (Aggregate of all Source Types)
Benzene	1.00	0.89	1.09	0.89	0.97
1,3-butadiene	0.99	0.92	1.18	0.92	1.03
Coke oven emissions	0.87	NA	NA	NA	0.87
PAH, total	0.70	0.66	0.83	0.66	0.72
Chromium (VI)	0.60	0.94	NA	NA	0.45
Diesel PM	NA	1.27	0.60	0.48	0.53
Nickel	NA	NA	0.56	0.48	0.52

RTI INTERNATIONAL | Memorandum

DATE: November 16, 2022

SUBJECT: DRAFT Test Data for Sterilization Chamber Vents at Facilities in the Ethylene Oxide Commercial Sterilization Facilities Source Category - Proposal Review for Ethylene Oxide Commercial Sterilization Source Category
EPA Contract No. 68HERD20A0004; Task Order 29

FROM: Riley Vanek
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I. Introduction

Section 112 of the Clean Air Act (CAA) requires the U.S. Environmental Protection Agency (EPA) to establish technology-based standards for sources of hazardous air pollutants (HAP). These technology-based standards are often referred to as maximum achievable control technology (MACT) standards, which may be promulgated for major and area sources. For area sources, CAA section 112(d)(5) allows the EPA to set standards based on generally available control technology in lieu of MACT standards. The EPA established national emission standards for hazardous air pollutants (NESHAP) on December 6, 1994 (59 FR 62585) for the ethylene oxide (EtO) commercial sterilization source category as 40 CFR part 63, subpart O. Section 112(d)(6) contains provisions requiring the EPA to periodically review these standards. The EPA is conducting a rule review and considering emission standards for a number of currently unregulated emission sources under CAA sections 112(d)(2)-(3) or (d)(5). The EPA is also completing a residual risk review under CAA section 112(f)(2) and a technology review of current emission standards under CAA section 112(d)(6).

The current subpart O NESHAP applies to sources that use at least 1 ton of EtO in sterilization or fumigation operations in each consecutive 12-month period. Emission releases from the EtO commercial sterilization facilities include sterilizer chamber vents (SCV), aeration room vents (ARV), chamber exhaust vents (CEV), and room air emission sources. While there are current emission standards for some SCV and ARV emission sources, there are additional emission sources that are not subject to emission standards. Under the rule review, the EPA is completing a review of currently unregulated emission sources.

The purpose of this memorandum is to present the available performance and emission test data for SCV in the source category. These test data may be used in standards setting under CAA sections 112(d)(2)-(3) or (d)(5) for SCV emissions. These test data may also be used to inform CAA section 112(d)(6) technology reviews and section 112(f)(2) residual risk reviews for SCV emissions.

II. Sources of Performance and Emission Test Data

Under the rule review for the EtO commercial sterilization facilities source category, EPA discussed with EPA regional offices and state and local agencies the available information for facilities in the source category. The main sources of emission test data are those provided by EPA Regions and state and local agencies and are from responses to the CAA section 114 requests sent to industry. The December 2019 CAA section 114 request was issued to a few select companies to gather information, and the September 2021 information collection request, under CAA section 114, was issued to gather information from all facilities in the EtO commercial sterilization category. (RTI 2022)

In the December 2019 and September 2021 requests, the EPA sent questionnaires to EtO commercial sterilization companies. The questionnaires were designed in the form of a Microsoft Excel® file, with the intention to collect information about sterilization chambers, CEVs, aeration rooms, EtO storage, and room air emission sources. Although the questionnaires did not require any new testing to be performed, the "APCD Summary" worksheet in the questionnaire requested all emission tests conducted in the last five years and asked each facility to submit complete copies of the test reports. In addition, EPA Regions and state and local agencies provided emission test data for facilities located in their area. The collection of test reports contained emission results for EtO from sterilization chambers, CEVs, aeration rooms, and room air emissions. The data compiled for this analysis for SCVs is from the most recent test available for each facility. Copies of the SCV performance and emission test reports collected are included in Docket ID No. EPA-HQ-OAR-2019-0178.

Some performance and emission tests include data from testing that was conducted solely while one type of emission source was venting (e.g., only for SCV), while other tests include data where more than one emission source type was venting during testing (e.g., both SCV and ARV were venting simultaneously during the testing). The test data that reflect the emissions from one emission source type are summarized. The available performance and emission tests for combined streams where more than one emission source type was venting during the test, or where we could not determine whether only one emission source type was vented during the test, are provided separately.

The EPA reviewed the available data and information for SCV for the following point sources:

- SCV at facilities where EtO use is at least 40 tpy,
- SCV at facilities where EtO use is at least 10 but less than 40 tpy,
- SCV at facilities where EtO use is at least 1 but less than 10 tpy,
- SCV at facilities where EtO use is less than 1 tpy.

A. SCV at facilities where EtO use is at least 40 tpy.

There are a total of 36 facilities where EtO use is at least 40 tpy. All 36 facilities have SCV emission sources and have APCDs in place. See **Appendix A, Table A.1** for the full list of facilities where EtO use is at least 40 tpy and have SCVs. There are 26 facilities that have available SCV emission test data. Some of these tests included combined streams for multiple emission source types. There are 22 facilities with emission test measurements available solely for SCVs, and these data are provided in **Appendix A, Table A.2**. There are another 4 facilities that conducted testing of combined source types (e.g., SCV and ARV); these data are provided in **Appendix A, Table A.3**.

B. SCV at facilities where EtO use is at least 10 but less than 40 tpy.

There are a total of 11 facilities where EtO use is at least 10 but less than 40 tpy. All 11 facilities have SCV emission sources and have APCDs in place. See **Appendix B, Table B.1** for the full list of facilities where EtO use is at least 10 but less than 40 tpy and have SCVs. There are 8 facilities that have available SCV emission test data. Some of these tests included combined streams for multiple emission source types. There are 6 facilities with emission test measurements available solely for SCVs, and these data are provided in **Appendix B, Table B.2**. There are other facilities that conducted testing for multiple combined sources (e.g., SCV and ARV); these data are provided in **Appendix B, Table B.3**.

C. SCV at facilities where EtO use is at least 1 but less than 10 tpy.

There are a total of 18 facilities where EtO use is at least 1 but less than 10 tpy, and all 18 facilities have SCV emission sources and have APCDs in place. See **Appendix C, Table C.1** for the full list of facilities. There are 9 facilities that have available SCV emission test data. Some of these tests included combined streams for multiple emission source types. There are 8 facilities with emission test measurements available solely for SCVs, and these data are provided in **Appendix C, Table C.2**. There are other facilities that conducted testing for multiple combined sources (e.g., SCV and ARV); these facilities are provided in **Appendix C, Table C.3**.

D. SCV at facilities where EtO use is less than 1 tpy.

There are a total of 20 facilities where EtO use is less than 1 tpy. All 20 facilities have SCV emission sources, 19 facilities have APCDs in place for SCVs, and 1 has an uncontrolled SCV. See **Appendix D, Table D.1** for the full list of 20 facilities where EtO use is less than 1 tpy and that have SCVs. (Another 12 facilities that are believed to conduct EtO sterilization for research and development purposes and are not included as part of the source category are also provided in **Table D.1** for informational purposes.) Of the 19 facilities with APCDs, there are 2 that have available SCV emission test data, both of which have emission test measurements available solely for SCVs, and these data are provided in **Appendix D, Table D.2**. There are no test data available for the facility with an uncontrolled SCV. (Of the other 12 facilities that have not been included in the EtO commercial sterilization facilities source category, 2 of the facilities have available test data; the data for these facilities are provided in **Appendix D, Table D.3**.)

III. Data Compiled and Calculations Conducted from Test Reports

From each emission test report, the following inlet and outlet parameters and emissions data for each test run as available were compiled into a master run-by-run spreadsheet:

- Emission source and air pollution control device type
- Flow rate, in actual cubic feet per minute (acfm)
- Flow rate, in dry standard cubic feet per minute (dscfm)
- Sample volume, in dry standard cubic feet (dscf)
- Sample volume, in dry standard cubic meter (dscm)
- Stack moisture, in percent (%)
- Stack gas temperature, in degrees Fahrenheit (˚F)
- Oxygen content of stack gas, in percent (%)
- Pollutant concentration, in parts per million volume (ppmv)
- Pollutant emission rate, in pounds per hour (lb/hr)
- Destruction and Removal Efficiency (DRE), in percent (%)

Once the data were compiled, the following calculations were conducted in the master run-by-run spreadsheet if the data were not provided in the test report:

- Converted reported concentrations to micrograms per dry standard cubic meter (µg/dscm)
- Calculated concentrations on dry basis if values were reported as wet and moisture was provided

As part of the test data review, the stack moisture collected for each test run was evaluated. Several emission test reports did not provide stack moisture and/or did not clarify whether the EtO concentration results were on a wet or dry basis. If test data are provided without moisture data or clarity, the default moisture content of 2 percent (%) was assumed and, the outlet EtO concentration was adjusted to ppmv dry (ppmvd).

IV. Quality Assurance/Quality Control Checks

After the test data had been compiled and calculated in the master run-by-run spreadsheet, there were internal QA/QC reviews from RTI and the EPA. There was a review of what specific emission sources were included during the emission test, and there was a review of the reported detection limit. Test data determined to be unacceptable or not appropriate after the QA/QC checks were removed from the run-by-run spreadsheet and were not included in the SCV emission standards analysis. Appendix A shows the analysis for SCV at facilities where EtO use is at least 40 tpy, and Appendix B includes the analysis for SCV at facilities where EtO use is at least 10 but less than 40 tpy. Appendix C shows the analysis for SCV at facilities where EtO use is at least 1 but less than 10 tpy, and Appendix D includes the analysis for SCV at facilities where EtO use is less than 1 tpy. The first table of each appendix shows all facilities with the emission source type within the subcategory. The second table in each appendix contains the run-by-run test data that were available in the analysis with measurements solely for SCV emissions. The third table in each appendix includes the list of test data that were removed from the run-by-run spreadsheet following the QA/QC reviews, e.g., because the measurements during the test were conducted when multiple emission source types were venting simultaneously.

A. Multiple Emission Sources

At some facilities, multiple emissions source types were operating simultaneously and ducted together to one or more outlet stacks being tested. Where the SCVs were tested separately, this is annotated as such in the run-by-run spreadsheets. At some facilities, multiple emission source types (sterilization chambers, aeration room vents, CEVs, and room air emission sources) were routed together to one APCD during the emission test. These test runs were not included in the data set for setting SCV emission standards as SCV-specific data were not available. See appendix Tables A.3, B.3, C.3, and D.3 for the list of test runs not included.

B. Non-Detects

The detection limit varied based on the test method and analytical equipment used by the testing firm. For individual test runs that had values flagged as being below detection limit (BDL), then the method detection limit (MDL) or other reporting limit if an MDL was not available was used as the concentration for that test run. The concentration, emission rate, and emission factor were then calculated for each test run, as appropriate.

If all the test data for a run were flagged as BDL, then the emission test data was considered BDL. If there was a mix of test data flagged as BDL and above detection limit (ADL), then the emission test data were considered detection level limited. If all test data for a run were flagged as ADL, then the run was considered ADL. (Westlin and Merrill 2011)

Some test reports that use EPA Reference Method 18 (M18) or CARB Method 431 (CARB 431) reported MDL considerably lower than the generally accepted MDL for the test method. For M18 and CARB 431, 0.2 ppmv is the Representative Detection Level (RDL). Test run data provided in the test reports of 0.15 ppmv or more are considered to be reasonable. For any test run values that are less than 0.15 ppmv, however, the 0.2 ppmv RDL was used to calculate the concentration and emission rate for that run. Some available test reports used either EPA Reference Method 320 or TO-15 (modified) to analyze for EtO with sufficiently low detection limits. As such, no adjustment to the MDL was necessary for these data.

C. Anomalous Data

One test report indicated that the data for a single test run was determined to be anomalous by the facility and responsible permitting authority. The data were excluded from consideration and listed in Appendix C.3.

V. References

RTI 2022. *Documentation of Database Containing Information from Responses to the December 2019 Questionnaire and the September 2021 Section 114 for the Ethylene Oxide Commercial Sterilization NESHAP Review*. Memorandum from R. Vanek, RTI International. November 2022.

Westlin, P., and R. Merrill. 2011. *Data and procedure for handling below detection level data in analyzing various pollutant emissions databases for MACT and RTR emissions limits*.

Memorandum from Peter Westlin, SPPD/MPG and Raymond Merrill, AQAD/MTG, to SPPD management and MACT rule writers. December 13, 2011 (Revised April 5, 2012).

Test Report References for Appendices

Abbott 2016. *Results of Annual Ethylene Oxide Source Testing and Leak Testing*, for Abbott Vascular Facility in Temecula, California. Performance testing for SCV and ARV on April 7, 2016. Test Report summary memo and tables dated April 2016.

Abbott 2017. *Results of Annual Ethylene Oxide Source Testing and Leak Testing*, for Abbott Vascular Facility in Temecula, California. Performance testing for SCV and ARV on May 23, 2017. Test Report summary memo and tables dated May 2017.

Abbott 2018. *Results of Annual Ethylene Oxide Source Testing and Leak Testing*, for Abbott Vascular Facility in Temecula, California. Performance testing for SCV and ARV on May 17, 2018. Test Report summary memo and tables dated May 2018.

Abbott 2019. *Results of Annual Ethylene Oxide Source Testing and Leak Testing*, for Abbott Vascular Facility in Temecula, California. Performance testing for SCV on May 29, 2019. Test Report summary memo and tables dated May 2019.

Abbott 2020. *Results of Annual Ethylene Oxide Source Testing and Leak Testing*, for Abbott Vascular Facility in Temecula, California. Performance testing for SCV and ARV on May 21, 2020. Test Report summary memo and tables dated May 2020.

ACS 2013. *Report of Air Pollution Source Testing of an Ethylene Oxide Emission-Control System*, for American Contract Systems Facility in Houston, Texas. Performance testing for SCV on June 24, 2013. Test Report dated July 2013.

Alcon 2019. Data tables from *WVDEP DAQ Permit to Modify R13-2820D Compliance Test Report*, for Covidien Facility in Lesage, West Virginia. Performance testing for SCV and ARV on April 24, 2019. Test Report summary tables dated June 2019.

Arthrex 2018. *Ethylene Oxide Sterilization MACT Emissions Testing*, for Arthrex Manufacturing in Ave Maria, Florida. Performance testing for SCV and ARV on December 12, 2017. Test report dated January 2018.

Auris Health 2014. Source Test Report Summary, for Auris Health Facility in San Jose, California. Performance testing for SCV on August 1, 2014. Test Report summary memo dated October 2014.

Auris Health 2015. Source Test Report Summary, for Auris Health Facility in San Jose, California. Performance testing for SCV on July 10, 2015. Test Report summary memo dated July 2015.

Baxter Healthcare 2021. Source Test Report Summary for Baxter Healthcare Facility in Mountain Home, Arkansas. Performance testing for SCV on February 25-26, 2020. Test Report Summary dated August 2021.

B. Braun Medical 2021. *40 CFR 63 Subpart O PADEP Plan Approval Compliance Emissions Test Report*, for B. Braun Medical in Allentown, Pennsylvania. Performance testing for SCV and ARV on December 15, 2020. Test report dated February 2021.

BD 2017. *Source Emissions Testing Report* for Becton Dickinson Facility in Sandy, Utah. Performance testing for SCV and ARV on August 2, 2017. Test report dated October 2017.

BD 2018. Source Test Report Summary for Becton Dickinson Facility in Madison, Georgia. Performance testing for SCV and ARV on January 25-26, 2018. Test report summary dated March 2018.

BD 2019. *Report of Air Pollution Source Testing of an Ethylene Oxide Emission-Control System* for Becton Dickinson Facility in Covington, Georgia. Performance testing for SCV and ARV on September 11-12, 2019. Test report dated October 2019.

BD 2020. *Source Test Report* for Becton Dickinson Facility in Columbus, Nebraska. Performance testing for SCV on July 8, 2020. Test report dated July 2020.

Blue Line 2017. *Results of Ethylene Oxide Source Testing and Leak Testing*, for Blue Line Sterilization Services Facility in Novato, California. Performance testing for SCV on August 28 and October 10, 2017. Test Report summary dated October 2017.

Blue Line 2018. *Results of Ethylene Oxide Source Testing and Leak Testing*, for Blue Line Sterilization Services Facility in Novato, California. Performance testing for SCV on October 23, 2018. Test Report summary dated October 2018.

Blue Line 2019. *Results of Ethylene Oxide Source Testing and Leak Testing*, for Blue Line Sterilization Services Facility in Novato, California. Performance testing for SCV on August 28, 2019. Test Report summary dated August 2019.

Blue Line 2021. *Results of Ethylene Oxide Source Testing*, for Blue Line Sterilization Services Facility in Novato, California. Performance testing for SCV on October 27, 2021. Test Report summary dated October 2021.

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Boston Scientific 2019-5. Source Test Summary Memo, for Boston Scientific/Cardiac Pacemakers Facility (Bldg 5) in Arden Hills, Minnesota. Performance testing for SCV on September 20, 2019. Test Report dated October 2019.

Boston Scientific 2019-9. Source Test Summary Memo, for Boston Scientific/Cardiac Pacemakers Facility (Bldg 9) in Arden Hills, Minnesota. Performance testing for SCV on May 31, 2019. Test Report dated June 2019.

Boston Scientific 2020-C. Source Test Summary Memo, for Boston Scientific/Cardiac Pacemakers Facility (Bldg C) in Arden Hills, Minnesota. Performance testing for SCV on September 5, 2020. Test Report dated September 2020.

Boston Scientific 2020-5. Source Test Summary Memo, for Boston Scientific/Cardiac Pacemakers Facility (Bldg 5) in Arden Hills, Minnesota. Performance testing for SCV on November 30, 2020. Test Report dated December 2020.

Boston Scientific 2020-9. Source Test Summary Memo, for Boston Scientific/Cardiac Pacemakers Facility (Bldg 9) in Arden Hills, Minnesota. Performance testing for SCV on June 23, 2020. Test Report dated July 2020.

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Appendix A

Ethylene Oxide Commercial Sterilization Source Category

SCV at Facilities where EtO Use is at least 40 tpy

Table A.1 Full List of Facilities with SCV, at Facilities where EtO Use is at least 40 tpy

See filename *"EtO_AppA.1_SCV(40+)_proposal.xlsx"*

Table A.2 Final Run-by-Run Values for SCV, at Facilities where EtO Use is at least 40 tpy

See filename *"EtO_AppA.2_ SCV(40+)_proposal.xlsx"*

Table A.3 Test Data Not Included for SCV, at Facilities where EtO Use is at least 40 tpy

See filename *"EtO_AppA.3_ SCV(40+)_proposal.xlsx"*

Appendix B

Ethylene Oxide Commercial Sterilization Source Category

SCV at Facilities where EtO Use is at least 10 but less than 40 tpy

Table B.1 Full List of Facilities with SCV, at Facilities where EtO Use is at least 10 but less than 40 tpy

See filename *"EtO_AppB.1_SCV(10-40)_proposal.xlsx"*

Table B.2 Final Run-by-Run Values for SCV, at Facilities where EtO Use is at least 10 but less than 40 tpy

See filename *"EtO_AppB.2_SCV(10-40)_proposal.xlsx"*

Table B.3 Test Data Not Included for SCV, at Facilities where EtO Use is at least 10 but less than 40 tpy

See filename *"EtO_AppB.3_SCV(10-40)_proposal.xlsx"*

Appendix C

Ethylene Oxide Commercial Sterilization Source Category

SCV at Facilities where EtO Use is at least 1 but less than 10 tpy

Table C.1 Full List of Facilities with SCV, at Facilities where EtO Use is at least 1 but less than 10 tpy

See filename *"EtO_AppC.1_SCV(1-10)_proposal.xlsx"*

Table C.2 Final Run-by-Run Values for SCV, at Facilities where EtO Use is at least 1 but less than 10 tpy

See filename *"EtO_AppC.2_SCV(1-10)_proposal.xlsx"*

Table C.3 Test Data Not Included for SCV, at Facilities where EtO Use is at least 1 but less than 10 tpy

See filename *"EtO_AppC.3_SCV(1-10)_proposal.xlsx"*

Appendix D

Ethylene Oxide Commercial Sterilization Source Category

SCV at Facilities where EtO Use is less than 1 tpy

Table D.1 Full List of Facilities with SCV, at Facilities where EtO Use is less than 1 tpy

See filename *"EtO_AppD.1_SCV(less than 1)_proposal.xlsx"*

Table D.2 Final Run-by-Run Values for SCV, at Facilities where EtO Use is less than 1 tpy

See filename *"EtO_AppD.2_SCV(less than 1)_proposal.xlsx"*

Table D.3 Test Data Not Included for SCV, at Facilities where EtO Use is less than 1 tpy

See filename *"EtO_AppD.3_SCV(less than 1)_proposal.xlsx"*

Table A.1. Full List of Facilities with SCV, at Facilities where EtO Use is at least 40 tpy

PFID	Facility Name	City	State	Configuration	Actual EtO Use (tpy)	Allowable EtO Use (tpy)	SCV Present?	SCV Control	SCV Perf Test Data Available?	Separate SCV Test Data Available
1	Boston Scientific Corporation	Coventry	RI	Separate, CEV	96.99	267.75	Y	Controlled	N	N
3	STERIS Corporation	Northborough	MA	Separate, CEV	125.74	200.00	Y	Controlled	Y	N
13	Edwards Lifesciences Technology Sàrl	Añasco	PR	Separate, CEV	43.92	110.00	Y	Controlled	Y	Y
17	STERIS AST South Plainfield NJ	South Plainfield	NJ	Separate, CEV	99.01	125.00	Y	Controlled	Y	Y
22	Sterigenics US LLC Queensbury	Queensbury	NY	Separate, CEV	189.16	275.00	Y	Controlled	Y	Y
23	Steri-Tech, Inc.	Salinas	PR	Separate, No CEV	44.17	58.40	Y	Controlled	Y	Y
28	B. Braun Medical Inc. Allentown	Allentown	PA	Separate, CEV	54.16	196.74	Y	Controlled	Y	Y
42	Sterilization Services of Virginia	Richmond	VA	Separate, CEV	210.27	445.45	Y	Controlled	N	N
51	Becton Dickinson	Madison	GA	Separate, CEV	139.43	302.50	Y	Controlled	Y	Y
52	Becton Dickinson	Covington	GA	Separate, CEV	163.12	267.00	Y	Controlled	Y	Y
55	International Sterilization Laboratory	Groveland	FL	Separate, CEV	49.93	70.00	Y	Controlled	Y	Y
56	STERIS Corporation	Spartanburg	SC	Separate, No CEV	81.46	150.00	Y	Controlled	N	N
61	Royal Sterilization Systems	New Tazewell	TN	Separate, CEV	133.50	348.58	Y	Controlled	N	N
62	Sterigenics US LLC Charlotte	Charlotte	NC	Separate, CEV	361.05	400.00	Y	Controlled	N	N
63	Sterigenics US LLC Atlanta	Atlanta	GA	Separate, CEV	146.43	312.50	Y	Controlled	Y	Y
64	Sterilization Services of Tennessee	Memphis	TN	Separate, CEV	72.76	158.78	Y	Controlled	N	N
65	Sterilization Services of Georgia	Atlanta	GA	Separate, CEV	51.61	75.00	Y	Controlled	Y	Y
72	STERIS AST	Coon Rapids	MN	Separate, CEV	71.02	71.02	Y	Controlled	Y	N
73	Medline North Point Services (NPS)	Waukegan	IL	Separate, CEV	229.20	375.00	Y	Controlled	Y	N
81	Baxter Healthcare Corporation	Mountain Home	AR	Separate, CEV	205.22	300.00	Y	Controlled	Y	Y
83	Ethicon	San Angelo	TX	Separate, No CEV	43.58	100.00	Y	Controlled	Y	Y
84	STERIS Corporation	Grand Prairie	TX	Combination, CEV	243.10	460.00	Y	Controlled	Y	Y
85	STERIS Corporation	El Paso I	TX	Separate, No CEV	152.19	291.50	Y	Controlled	N	N
86	STERIS Corporation	El Paso II	TX	Separate, CEV	350.40	700.80	Y	Controlled	N	N
88	Midwest Sterilization Corporation	Laredo	TX	Separate, CEV	630.18	1278.78	Y	Controlled	Y	Y
90	Sterigenics, LLC - Grand Prairie	Grand Prairie	TX	Separate, CEV	299.13	445.50	Y	Controlled	Y	Y
91	Sterigenics US LLC Santa Teresa	Santa Teresa	NM	Separate, CEV	544.88	846.00	Y	Controlled	Y	Y
92	Steritec, Inc.	Athens	TX	Separate, No CEV	53.66	107.31	Y	Controlled	N	N
95	BD Pharmaceuticals Systems	Columbus	NE	Separate, No CEV	43.30	227.93	Y	Controlled	Y	Y
96	Midwest Sterilization Corporation	Jackson	MO	Separate, CEV	289.38	456.31	Y	Controlled	Y	Y
98	BD Medical Sandy	Sandy	UT	Separate, No CEV	80.92	228.00	Y	Controlled	Y	N
99	Sterigenics Salt Lake City	Salt Lake City	UT	Separate, CEV	150.18	210.30	Y	Controlled	Y	Y
100	Terumo BCT	Lakewood	CO	Separate, CEV	102.51	225.30	Y	Controlled	N	N
113	Steris	San Diego	CA	Combination	198.94	718.43	Y	Controlled	Y	Y
122	Sterigenics US LLC Los Angeles - Gifford Ave	Los Angeles	CA	Separate, CEV	41.64	166.99	Y	Controlled	Y	Y
111112	STERIS AST	Temecula	CA	Separate, CEV	66.60	240.00	Y	Controlled	Y	Y
118119	Sterigenics US LLC Ontario	Ontario	CA	Separate, CEV	428.97	657.00	Y	Controlled	N	N
120121	Sterigenics US LLC Los Angeles 50th St	Los Angeles	CA	Separate, CEV	79.50	219.00	Y	Controlled	Y	Y

Facility IDs 85 and 86 are co-located sites and are permitted together.
Facility IDs 122 and 120121 are co-located sites and are permitted together.

FACID (PFID)	Company	Plant Location (City)	Plant Location State	Det based on EtO Usage	Det based on EtO Emission	Emission Source	Data Reference	Test Date	Run	APCD ID	APCD Name	APCD Type	APCD Yr Installed	Source ID	Sources Controlled by APCD (Configuration)	Test Methods	EtO Used During Test (lbs)	Production Rate Source	INLET Flow Actual (acfm, wet)	INLET Flow Dry Standard (dscfm)	INLET Sample Volume (dscf)	INLET Sample Volume (dscm)	INLET Moisture (avg %vol)	INLET Assumed Moisture (avg %vol)	INLET Temp Stack Gas (deg F)	INLET Oxygen (avg %vol db)	INLET EtO Concentration from Test Report	INLET units	INLET EtO Concentration Converted to (µg/dscm)	INLET EtO Emission (lb/hr)	OUTLET Flow Actual (acfm, wet)	OUTLET Flow Dry Standard (dscfm)	OUTLET Sample Volume (dscf)	OUTLET Sample Volume (dscm)	OUTLET Tested Moisture (% vol)	OUTLET Assumed Moisture (% vol)	OUTLET Temp Stack Gas (deg F)	OUTLET Oxygen (avg %vol db)	OUTLET DRE (%)	OUTLET EtO Concentration from Test Report	OUTLET Tested Units	OUTLET EtO Concentration Calculated from Assumed Moisture	OUTLET Calculated Units	Test run flag	Use this Outlet EtO Concentration	OUTLET EtO Concentration Converted to (µg/dscm)	OUTLET EtO Emission (lb/hr)
13	Edwards Lifesciences Technology Sàrl	Añasco	PR	Source using 10+ ton	Synthetic Area	6 SCV	Test Report September 2022	7/29/2022	1	NA	AAT Wet Gas Scrubber / Dry Bed Reactor System #3	Wet acid scrubber and dry bed reactor	NA	SCV 4-9	6 SCVs	M1, M2, M3A, M4, CRDS alternate test method	193.0	p. 16 of 265	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	304.7	254	226	NA	NA	3.22%	NA	NA	21.14	99.999999847%	0.000305	ppmvd	NA	NA	ADL	**0.00031**	**0.589**	4.70E-07
13	Edwards Lifesciences Technology Sàrl	Añasco	PR	Source using 10+ ton	Synthetic Area	6 SCV	Test Report September 2022	7/29/2022	2	NA	AAT Wet Gas Scrubber / Dry Bed Reactor System #3	Wet acid scrubber and dry bed reactor	NA	SCV 4-9	6 SCVs	M1, M2, M3A, M4, CRDS alternate test method	185.8	p. 16 of 265	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	285.8	250	221	NA	NA	3.73%	NA	NA	20.95	99.999999987%	0.000244	ppmvd	NA	NA	ADL	**0.00024**	**0.447**	3.70E-07
13	Edwards Lifesciences Technology Sàrl	Añasco	PR	Source using 10+ ton	Synthetic Area	6 SCV	Test Report September 2022	7/30/2022	3	NA	AAT Wet Gas Scrubber / Dry Bed Reactor System #3	Wet acid scrubber and dry bed reactor	NA	SCV 4-9	6 SCVs	M1, M2, M3A, M4, CRDS alternate test method	188.0	p. 16 of 265	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	304.9	251	226	NA	NA	2.91%	NA	NA	20.96	99.999999975%	0.000499	ppmvd	NA	NA	ADL	**0.00050**	**0.914**	7.70E-07
17	STERIS AST South Plainfield NJ	South Plainfield	NJ	Source using 10+ ton	Synthetic Area	SCV	No SCV test available. July 30, 2003 NJDEP memo re. test correction provides test data.	2/13/2003	NA	NA	NA	SCV Scrubber	NA	NA	SCV	Unknown [Assume either M18 or CARB 431 was used]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.99%	NA	NA	NA	NA	NA	NA	NA	NA	0.02
22	Sterigenics US LLC Queensbury	Queensbury	NY	Source using 10+ ton	Synthetic Area	SCV	Test Report December 2017	10/23/2017	1	NA	Ceilcote Model SPT-42-120	Packed tower acid scrubber	NA	NA	Tested 1 of 11 SCVs	M1, M2: [Assume either M18 or CARB 431 was used]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	101.51	NA	66.7	NA	NA	2.0%	NA	80.1	NA	99.84%	358	ppmv	**365.3**	ppmvd	ADL	**365.3**	**669,040**	0.164
22	Sterigenics US LLC Queensbury	Queensbury	NY	Source using 10+ ton	Synthetic Area	SCV	Test Report December 2017	10/23/2017	2	NA	Ceilcote Model SPT-42-120	Packed tower acid scrubber	NA	NA	Tested 1 of 11 SCVs	M1, M2: [Assume either M18 or CARB 431 was used]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	294.00	NA	66.5	NA	NA	2.0%	NA	82.0	NA	99.9997%	1.995	ppmv	**2.04**	ppmvd	ADL	**2.036**	**3,728.31**	0.00091
22	Sterigenics US LLC Queensbury	Queensbury	NY	Source using 10+ ton	Synthetic Area	SCV	Test Report December 2017	10/23/2017	3	NA	Ceilcote Model SPT-42-120	Packed tower acid scrubber	NA	NA	Tested 1 of 11 SCVs	M1, M2: [Assume either M18 or CARB 431 was used]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	96.00	NA	66.5	NA	NA	2.0%	NA	82.2	NA	99.9954%	9.672	ppmv	**9.87**	ppmvd	ADL	**9.869**	**18,075.3**	0.0044
23	Steri-Tech, Inc.	Salinas	PR	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2000	12/1/1999	1-1	NA	NAO Thermal Oxidizer	Thermal oxidizer	NA	NA	Tested 1 of 4 SCVs. First evacuation of SCV.	M1, M2, M3, M18	50	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	65.38	1,598	426.31	0.404	NA	1.15%	NA	1,486	13.00%	**99.999%**	0.2	ppmv	0.2	ppmv	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00058
23	Steri-Tech, Inc.	Salinas	PR	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2000	12/1/1999	1-2	NA	NAO Thermal Oxidizer	Thermal oxidizer	NA	NA	Tested 1 of 4 SCVs. First evacuation of SCV.	M1, M2, M3, M18	50	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	68.81	2,190	584.83	0.378	NA	1.23%	NA	1,483	13.60%	**99.999%**	0.2	ppmv	0.2	ppmv	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00080
23	Steri-Tech, Inc.	Salinas	PR	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2000	12/2/1999	1-3	NA	NAO Thermal Oxidizer	Thermal oxidizer	NA	NA	Tested 1 of 4 SCVs. First evacuation of SCV.	M1, M2, M3, M18	50	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	68.32	2,306	612.53	0.406	NA	1.15%	NA	1,494	14.00%	**99.999%**	0.2	ppmv	0.2	ppmv	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00084
23	Steri-Tech, Inc.	Salinas	PR	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2000	12/1/1999	2-1	NA	NAO Thermal Oxidizer	Thermal oxidizer	NA	NA	Tested 1 of 4 SCVs. Last evacuation of SCV.	M1, M2, M3, M18	50	NA	NA	NA	0.272	NA	NA	NA	NA	NA	106.00	ppm	NA	0.000125	1,383	383.87	0.313	NA	1.48%	NA	1,405	13.00%	**99.811%**	0.2	ppmv	0.2	ppmv	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00053
23	Steri-Tech, Inc.	Salinas	PR	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2000	12/1/1999	2-2	NA	NAO Thermal Oxidizer	Thermal oxidizer	NA	NA	Tested 1 of 4 SCVs. Last evacuation of SCV.	M1, M2, M3, M18	50	NA	NA	NA	0.296	NA	NA	NA	NA	NA	87.80	ppm	NA	0.000107	1,388	384.72	0.322	NA	1.44%	NA	1,408	13.60%	**99.772%**	0.2	ppmv	0.2	ppmv	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00053
23	Steri-Tech, Inc.	Salinas	PR	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2000	12/2/1999	2-3	NA	NAO Thermal Oxidizer	Thermal oxidizer	NA	NA	Tested 1 of 4 SCVs. Last evacuation of SCV.	M1, M2, M3, M18	50	NA	NA	NA	0.295	NA	NA	NA	NA	NA	104.00	ppm	NA	0.000138	1,373	379.85	0.285	NA	1.63%	NA	1,407	14.00%	**99.808%**	0.2	ppmv	0.2	ppmv	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00052
28	B. Braun Medical Inc. Allentown	Allentown	PA	Source using 10+ ton	Synthetic Area	SCV	Test Report Feb 2021	12/15/2020	1	C004	Angull System: Catalytic oxidizer (CARULITE 500) with Peak Shaver	Peak Shaver in series with a Catalytic Oxidizer	NA	ID No. 107	Tested 1 of 8 SCVs.	M1, M2, M3A, M4, M25A	134.42	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	19,196	15,727	350,364	NA	1.26%	NA	180.0	20.31%	99.97808%	0.7356	ppmvd	NA	NA	ADL	**0.7356**	**1,347.18**	0.07936
28	B. Braun Medical Inc. Allentown	Allentown	PA	Source using 10+ ton	Synthetic Area	SCV	Test Report Feb 2021	12/15/2020	2	C004	Angull System: Catalytic oxidizer (CARULITE 500) with Peak Shaver	Peak Shaver in series with a Catalytic Oxidizer	NA	ID No. 107	Tested 1 of 8 SCVs.	M1, M2, M3A, M4, M25A	142.65	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	19,317	15,663	352,188	NA	2.15%	NA	181.0	20.33%	99.97726%	0.8055	ppmvd	NA	NA	ADL	**0.8055**	**1,475.23**	0.08655
28	B. Braun Medical Inc. Allentown	Allentown	PA	Source using 10+ ton	Synthetic Area	SCV	Test Report Feb 2021	12/15/2020	3	C004	Angull System: Catalytic oxidizer (CARULITE 500) with Peak Shaver	Peak Shaver in series with a Catalytic Oxidizer	NA	ID No. 107	Tested 1 of 8 SCVs.	M1, M2, M3A, M4, M25A	137.43	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	22,272	18,129	388,643	NA	2.03%	NA	180.0	20.32%	99.97466%	0.7836	ppmvd	NA	NA	ADL	**0.7836**	**1,435.12**	0.09745
51	Becton Dickinson	Madison	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report March 2018	1/26/2018	1	RTO-1	Thermal oxidizer	Regenerative thermal oxidizer	NA	Chamber 3	Tested 3 of 7 SCVs (1 SCV per run).	[Assume either M18 or CARB 431 was used]	74.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	233.68	NA	18,002	NA	NA	3.0%	NA	237.9	NA	**99.9894%**	0.2	ppm	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.02470
51	Becton Dickinson	Madison	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report March 2018	1/26/2018	2	RTO-1	Thermal oxidizer	Regenerative thermal oxidizer	NA	Chamber 4	Tested 3 of 7 SCVs (1 SCV per run).	[Assume either M18 or CARB 431 was used]	73.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	220.50	NA	18,738	NA	NA	3.0%	NA	221.3	NA	**99.9883%**	0.2	ppm	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.02571
51	Becton Dickinson	Madison	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report March 2018	1/26/2018	3	RTO-1	Thermal oxidizer	Regenerative thermal oxidizer	NA	Chamber 6	Tested 3 of 7 SCVs (1 SCV per run).	[Assume either M18 or CARB 431 was used]	73.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	232.11	NA	18,558	NA	NA	3.0%	NA	209.6	NA	**99.9890%**	0.2	ppm	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.02546
52	Becton Dickinson	Covington	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report Oct 2019	9/12/2019	1	RTO-1	Regenerative thermal oxidizer	Thermal oxidizer	NA	Chamber 2	Tested 3 of 5 SCVs vented to APCD. (1 SCV each run)	M1, M2; CARB 431	75.1	NA	NA	NA	NA	NA	NA	131	NA	NA	NA	NA	NA	214.57	NA	11,615	NA	NA	3.0%	NA	338.7	NA	**99.9926%**	0.2	ppm	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.01594
52	Becton Dickinson	Covington	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report Oct 2019	9/12/2019	2	RTO-1	Regenerative thermal oxidizer	Thermal oxidizer	NA	Chamber 3	Tested 3 of 5 SCVs vented to APCD. (1 SCV each run)	M1, M2; CARB 431	75.8	NA	NA	NA	NA	NA	NA	130	NA	NA	NA	NA	NA	206.73	NA	11,752	NA	NA	3.0%	NA	326.2	NA	**99.9922%**	0.2	ppm	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.01612
52	Becton Dickinson	Covington	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report Oct 2019	9/12/2019	3	RTO-1	Regenerative thermal oxidizer	Thermal oxidizer	NA	Chamber 4	Tested 3 of 5 SCVs vented to APCD. (1 SCV each run)	M1, M2; CARB 431	74.2	NA	NA	NA	NA	NA	NA	130	NA	NA	NA	NA	NA	212.00	NA	11,808	NA	NA	3.0%	NA	321.7	NA	**99.9924%**	0.2	ppm	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.01620
55	International Sterilization Laboratory	Groveland	FL	Source using 10+ ton	Synthetic Area	SCV	Test Report June 2006	6/7/2006	1	NA	Sulfuric acid scrubber	Wet scrubber	NA	Chamber A	Tested 2 of 4 SCV vented to APCD. (2 SCV tested across 3 runs - A, B, then A&B)	M18	85.0	NA	NA	NA	330.0	NA	NA	NA	NA	NA	NA	NA	NA	141.67	320.00	NA	NA	NA	NA	2.0%	NA	NA	99.90%	2,370	ppm	**2,418**	ppmvd	ADL	**2,418**	**4,429,118**	0.148
55	International Sterilization Laboratory	Groveland	FL	Source using 10+ ton	Synthetic Area	SCV	Test Report June 2006	6/7/2006	2	NA	Sulfuric acid scrubber	Wet scrubber	NA	Chamber B	Tested 2 of 4 SCV vented to APCD. (2 SCV tested across 3 runs - A, B, then A&B)	M18	80.2	NA	NA	NA	421.0	NA	NA	NA	NA	NA	NA	NA	NA	80.20	421.00	NA	NA	NA	NA	2.0%	NA	NA	99.90%	1,630	ppm	**1,663**	ppmvd	ADL	**1,663**	**3,046,187**	0.078
55	International Sterilization Laboratory	Groveland	FL	Source using 10+ ton	Synthetic Area	SCV	Test Report June 2006	6/7/2006	3	NA	Sulfuric acid scrubber	Wet scrubber	NA	Chambers A & B	Tested 2 of 4 SCV vented to APCD. (2 SCV tested across 3 runs - A, B, then A&B)	M18	168.6	NA	NA	NA	481.0	NA	NA	NA	NA	NA	NA	NA	NA	252.90	479.00	NA	NA	NA	NA	2.0%	NA	NA	99.81%	5,950	ppm	**6,071**	ppmvd	ADL	**6,071**	**11,119,516**	0.489
63	Sterigenics US LLC Atlanta	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report July 2020	6/25/2020	1	EC3, EC2	Ceilcote scrubber to AAT scrubber	Wet scrubber, wet/dry scrubber, polishing beds (series)	NA	NA	6 of 10 SCV tested. (Run 1= 1 chamber, Run 2= 2 chambers, Run 3= 3 chambers.)	M1, M2, M3, M4, M320	37.70	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	62.83	8,975	8,097	NA	NA	2.63%	NA	92	17.5%	99.99997%	**0.02980**	ppmvw	**0.0306**	ppmvd	DLL	**0.0306**	**56.05**	0.00213
63	Sterigenics US LLC Atlanta	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report July 2020	6/25/2020	2	EC3, EC2	Ceilcote scrubber to AAT scrubber	Wet scrubber, wet/dry scrubber, polishing beds (series)	NA	NA	6 of 10 SCV tested. (Run 1= 1 chamber, Run 2= 2 chambers, Run 3= 3 chambers.)	M1, M2, M3, M4, M320	186.00	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	328.24	8,928	7,996	NA	NA	2.61%	NA	96	20.9%	99.999998%	**0.0121**	ppmvw	**0.0124**	ppmvd	DLL	**0.0124**	**22.75**	0.00086
63	Sterigenics US LLC Atlanta	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report July 2020	6/25/2020	3	EC3, EC2	Ceilcote scrubber to AAT scrubber	Wet scrubber, wet/dry scrubber, polishing beds (series)	NA	NA	6 of 10 SCV tested. (Run 1= 1 chamber, Run 2= 2 chambers, Run 3= 3 chambers.)	M1, M2, M3, M4, M320	169.00	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	206.94	8,911	7,877	NA	NA	2.62%	NA	104	20.9%	99.999997%	**0.00560**	ppmvw	**0.00575**	ppmvd	DLL	**0.0058**	**10.53**	0.00040
65	Sterilization Services of Georgia	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report April 2021	2/23/2021	1-1	1SC	Chemroxx Scrubber	Wet scrubber	NA	Chamber 1	SCV vented to APCD. (1 SCV tested)	Unknown	67.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	150.67	NA	62	NA	NA	1.60%	NA	59.2	NA	99.999%	4.58	ppmvd	NA	NA	DLL	**4.580**	**8,388.04**	0.00007
65	Sterilization Services of Georgia	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report April 2021	2/23/2021	1-2	1SC	Chemroxx Scrubber	Wet scrubber	NA	Chamber 1	SCV vented to APCD. (1 SCV tested)	Unknown	67.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	81.36	NA	75	NA	NA	1.52%	NA	71.8	NA	99.997%	5.25	ppmvd	NA	NA	ADL	**5.246**	**9,607.78**	0.00010
65	Sterilization Services of Georgia	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report April 2021	2/23/2021	1-3	1SC	Chemroxx Scrubber	Wet scrubber	NA	Chamber 1	SCV vented to APCD. (1 SCV tested)	Unknown	67.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	156.46	NA	58	NA	NA	1.25%	NA	73.9	NA	99.997%	10.34	ppmvd	NA	NA	ADL	**10.34**	**18,937.2**	0.00015
65	Sterilization Services of Georgia	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report April 2021	2/23/2021	2-1	1SC	Chemroxx Scrubber	Wet scrubber	NA	Chamber 2	SCV vented to APCD. (1 SCV tested)	Unknown	42.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	95.11	NA	112	NA	NA	1.58%	NA	63.6	NA	99.940%	69.09	ppmvd	NA	NA	ADL	**69.09**	**126,535**	0.00196
65	Sterilization Services of Georgia	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report April 2021	2/23/2021	2-2	1SC	Chemroxx Scrubber	Wet scrubber	NA	Chamber 2	SCV vented to APCD. (1 SCV tested)	Unknown	43.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	215.00	NA	78	NA	NA	1.36%	NA	71.8	NA	99.980%	79.32	ppmvd	NA	NA	ADL	**79.32**	**145,271**	0.00158
65	Sterilization Services of Georgia	Atlanta	GA	Source using 10+ ton	Synthetic Area	SCV	Test Report April 2021	2/23/2021	2-3	1SC	Chemroxx Scrubber	Wet scrubber	NA	Chamber 2	SCV vented to APCD. (1 SCV tested)	Unknown	42.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	85.60	NA	96	NA	NA	1.26%	NA	61.7	NA	99.940%	75.14	ppmvd	NA	NA	ADL	**75.14**	**137,615**	0.00184

FACID (PFID)	Company	Plant Location (City)	Plant Location State	Det based on EtO Usage	Det based on EtO Emission	Emission Source	Data Reference	Test Date	Run	APCD ID	APCD Name	APCD Type	APCD Yr Installed	Source ID	Sources Controlled by APCD (Configuration)	Test Methods	EtO Used During Test (lbs)	Production Rate Source	INLET Flow Actual (acfm, wet)	INLET Flow Dry Standard (dscfm)	INLET Sample Volume (dscf)	INLET Sample Volume (dscm)	INLET Moisture (avg %vol)	INLET Assumed Moisture (avg %vol)	INLET Temp Stack Gas (deg F)	INLET Oxygen (avg %vol db)	INLET EtO Concentration from Test Report	INLET units	INLET EtO Concentration Converted to (µg/dscm)	INLET EtO Emission (lb/hr)	OUTLET Flow Actual (acfm, wet)	OUTLET Flow Dry Standard (dscfm)	OUTLET Sample Volume (dscf)	OUTLET Sample Volume (dscm)	OUTLET Tested Moisture (% vol)	OUTLET Assumed Moisture (% vol)	OUTLET Temp Stack Gas (deg F)	OUTLET Oxygen (avg %vol db)	OUTLET DRE (%)	OUTLET EtO Concentration from Test Report	OUTLET Tested Units	OUTLET EtO Concentration Calculated from Assumed Moisture	OUTLET Calculated Units	Test run flag	Use this Outlet EtO Concentration	OUTLET EtO Concentration Converted to (µg/dscm)	OUTLET EtO Emission (lb/hr)
81	Baxter Healthcare Corporation	Mountain Home	AR	Source using 10+ ton	Synthetic Area	SCV	Test Report Summary August 2021	2/25/2020	1	SN-101	Acid-Water Scrubber	Wet scrubber	NA	SCV 2	1 of 7 SCV tested (SCV 2)	Unknown	26.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6,224	NA	NA	NA	2.0%	NA	NA	99.96%	0.5	ppm	**0.51020**	ppmvd	ADL	0.5102	934.41	0.021
81	Baxter Healthcare Corporation	Mountain Home	AR	Source using 10+ ton	Synthetic Area	SCV	Test Report Summary August 2021	2/25/2020	2	SN-101	Acid-Water Scrubber	Wet scrubber	NA	SCV 6	1 of 7 SCV tested (SCV 6)	Unknown	50.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6,224	NA	NA	NA	2.0%	NA	NA	99.96%	0.48	ppm	**0.48980**	ppmvd	ADL	0.4898	897.04	0.021
81	Baxter Healthcare Corporation	Mountain Home	AR	Source using 10+ ton	Synthetic Area	SCV	Test Report Summary August 2021	2/25/2020	3	SN-101	Acid-Water Scrubber	Wet scrubber	NA	SCV 4 & 5	2 of 7 SCV tested (SCV 4 and SCV 5)	Unknown	82.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6,224	NA	NA	NA	2.0%	NA	NA	99.99%	0.52	ppm	**0.53061**	ppmvd	ADL	0.5306	971.79	0.021
81	Baxter Healthcare Corporation	Mountain Home	AR	Source using 10+ ton	Synthetic Area	SCV	Test Report Summary August 2021	2/26/2020	1	SN-101	Acid-Water Scrubber	Wet scrubber	NA	SCV 2 & 4	2 of 7 SCV tested (SCV 2 and SCV 4)	Unknown	192.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6,302	NA	NA	NA	2.0%	NA	NA	99.99%	0.345	ppm	**0.35204**	ppmvd	ADL	0.3520	644.75	0.013
81	Baxter Healthcare Corporation	Mountain Home	AR	Source using 10+ ton	Synthetic Area	SCV	Test Report Summary August 2021	2/26/2020	2	SN-101	Acid-Water Scrubber	Wet scrubber	NA	SCV 1 & 3	2 of 7 SCV tested (SCV 1 and SCV 3)	Unknown	53.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6,304	NA	NA	NA	2.0%	NA	NA	99.98%	0.017	ppm	**0.01735**	ppmvd	ADL	0.0173	31.77	0.017
81	Baxter Healthcare Corporation	Mountain Home	AR	Source using 10+ ton	Synthetic Area	SCV	Test Report Summary August 2021	2/26/2020	3	SN-101	Acid-Water Scrubber	Wet scrubber	NA	SCV 5	1 of 7 SCV tested (SCV 5)	Unknown	172.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6,296	NA	NA	NA	2.0%	NA	NA	99.99%	0.017	ppm	**0.01735**	ppmvd	ADL	0.0173	31.77	0.017
83	Ethicon	San Angelo	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report November 2003	9/16/2003	1-1	East	Damas Model 1000-2-6-HE-SR; East Scrubber	Wet scrubbers	NA	Sterilizer O	6 SCV vented to 2 different APCD (1 SCV tested)	M1, M2, M18	30.36	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	28.0	NA	3.20	NA	NA	NA	NA	NA	NA	99.99%	21	ppmvd	NA	NA	ADL	**21.00**	**38,460**	0.0005
83	Ethicon	San Angelo	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report November 2003	9/16/2003	2-1	West	Damas Model 1000-2-6-HE-SR; West Scrubber	Wet scrubbers	NA	Sterilizer T	6 SCV vented to 2 different APCD (1 SCV tested)	M1, M2, M18	30.58	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	32.2	NA	3.72	NA	NA	NA	NA	NA	NA	99.99%	69	ppmvd	NA	NA	ADL	**69.00**	**126,370**	0.0018
83	Ethicon	San Angelo	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report November 2003	9/17/2003	2-2	West	Damas Model 1000-2-6-HE-SR; West Scrubber	Wet scrubbers	NA	Sterilizer T	6 SCV vented to 2 different APCD (1 SCV tested)	M1, M2, M18	28.38	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	18.9	NA	2.31	NA	NA	NA	NA	NA	NA	99.99%	88	ppmvd	NA	NA	ADL	**88.00**	**161,168**	0.0014
83	Ethicon	San Angelo	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report November 2003	9/17/2003	2-3	West	Damas Model 1000-2-6-HE-SR; West Scrubber	Wet scrubbers	NA	Sterilizer U	6 SCV vented to 2 different APCD (1 SCV tested)	M1, M2, M18	30.14	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	36.2	NA	4.17	NA	NA	NA	NA	NA	NA	99.99%	122	ppmvd	NA	NA	ADL	**122.00**	**223,437**	0.0035
84	STERIS Grand Prairie	Grand Prairie	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report September 2011	8/18/2011	1	NA	Glygen 2001 acid wash scrubber (each SCV), sulfuric acid packed tower (common)	Acid wash scrubber (each SCV) followed by sulfuric acid packed tower (common)	NA	Chamber 10	Tested 1 of 10 SCV.	M1, M2, M18	168.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	297	NA	1,112	NA	NA	NA	2%	95.7	NA	99.942%	22.59	ppm	**23.05**	ppmvd	ADL	**23.0510**	**42,217**	0.1723
84	STERIS Grand Prairie	Grand Prairie	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report September 2011	8/18/2011	2	NA	Glygen 2001 acid wash scrubber (each SCV), sulfuric acid packed tower (common)	Acid wash scrubber (each SCV) followed by sulfuric acid packed tower (common)	NA	Chamber 10	Tested 1 of 10 SCV.	M1, M2, M18	165.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	292	NA	1,131	NA	NA	NA	2%	101.6	NA	99.956%	16.62	ppm	**16.96**	ppmvd	ADL	**16.96**	**31,060**	0.1289
84	STERIS Grand Prairie	Grand Prairie	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report September 2011	8/18/2011	3	NA	Glygen 2001 acid wash scrubber (each SCV), sulfuric acid packed tower (common)	Acid wash scrubber (each SCV) followed by sulfuric acid packed tower (common)	NA	Chamber 10	Tested 1 of 10 SCV.	M1, M2, M18	163.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	289	NA	1,104	NA	NA	NA	2%	100.9	NA	99.964%	13.54	ppm	**13.82**	ppmvd	ADL	**13.82**	**25,304**	0.1026
88	Midwest Sterilization Corporation	Laredo	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2022	12/15/2021	1	NA	2 Croll-Reynolds wet gas scrubbers and 1 AAT wet gas scrubber	Wet Scrubber system	NA	SCV 1, 2, 3, 4	10 SCV and 10 CEVs vented to APCD (4 SCVs were tested)	M1, M2, M3, M4, M18	608.2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	4,410.3	NA	3.02%	NA	75.9	NA	99.9991%	4.5	ppm	**4.6**	ppmvd	ADL	**4.64**	**8,498**	0.00228
88	Midwest Sterilization Corporation	Laredo	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2022	12/15/2021	2	NA	2 Croll-Reynolds wet gas scrubbers and 1 AAT wet gas scrubber	Wet Scrubber system	NA	SCV 5, 6, 7, 8	10 SCV and 10 CEVs vented to APCD (4 SCVs were tested)	M1, M2, M3, M4, M18	604.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	5,510.6	NA	4.32%	NA	87.6	NA	99.9929%	28.8	ppm	**30.1**	ppmvd	ADL	**30.10**	**55,127**	0.01814
88	Midwest Sterilization Corporation	Laredo	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report January 2022	12/15/2021	3	NA	2 Croll-Reynolds wet gas scrubbers and 1 AAT wet gas scrubber	Wet Scrubber system	NA	SCV 9, 10, 1, 2	10 SCV and 10 CEVs vented to APCD (4 SCVs were tested)	M1, M2, M3, M4, M18	608.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	5,242.5	NA	4.35%	NA	87.3	NA	99.9973%	11.7	ppm	**12.2**	ppmvd	ADL	**12.23**	**22,402**	0.00704
90	Sterigenics, LLC - Grand Prairie	Grand Prairie	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report Dec 2003	12/16/2003	1	NA	AAT Safe Cell I system	Wet Scrubber	NA	NA	3 SCV vented to APCD (all 3 tested simultaneously).	M2, M18	763.80	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1,239	NA	390	NA	NA	2.10%	NA	56.5	NA	99.9963%	17.06	ppm	**17.43**	ppmvd	ADL	**17.43**	**31,915**	0.0456
90	Sterigenics, LLC - Grand Prairie	Grand Prairie	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report Dec 2003	12/16/2003	2	NA	AAT Safe Cell I system	Wet Scrubber	NA	NA	3 SCV vented to APCD (all 3 tested simultaneously).	M2, M18	767.50	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1,279	NA	404	NA	NA	2.10%	NA	64.1	NA	99.9942%	26.83	ppm	**27.41**	ppmvd	ADL	**27.41**	**50,192**	0.0744
90	Sterigenics, LLC - Grand Prairie	Grand Prairie	TX	Source using 10+ ton	Synthetic Area	SCV	Test Report Dec 2003	12/16/2003	3	NA	AAT Safe Cell I system	Wet Scrubber	NA	NA	3 SCV vented to APCD (all 3 tested simultaneously).	M2, M18	765.10	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1,275	NA	371	NA	NA	2.10%	NA	63.9	NA	99.9937%	31.34	ppm	**32.01**	ppmvd	ADL	**32.01**	**58,629**	0.0798
91	Sterigenics US LLC Santa Teresa	Santa Teresa	NM	Source using 10+ ton	Synthetic Area	SCV	Test Report Jan 2013	12/12/2012	1	NA	Celicote Wet Scrubber	Wet Scrubber	NA	NA	13 SCVs vent to APCD (1 unique SCV tested each run)	M1, M2. [Assume either M18 or CARB 431 was used]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.954%	NA	NA	NA	NA	NA	NA	NA	NA
91	Sterigenics US LLC Santa Teresa	Santa Teresa	NM	Source using 10+ ton	Synthetic Area	SCV	Test Report Jan 2013	12/12/2012	2	NA	Celicote Wet Scrubber	Wet Scrubber	NA	NA	13 SCVs vent to APCD (1 unique SCV tested each run)	M1, M2. [Assume either M18 or CARB 431 was used]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.954%	NA	NA	NA	NA	NA	NA	NA	NA
91	Sterigenics US LLC Santa Teresa	Santa Teresa	NM	Source using 10+ ton	Synthetic Area	SCV	Test Report Jan 2013	12/12/2012	3	NA	Celicote Wet Scrubber	Wet Scrubber	NA	NA	13 SCVs vent to APCD (1 unique SCV tested each run)	M1, M2. [Assume either M18 or CARB 431 was used]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.954%	NA	NA	NA	NA	NA	NA	NA	NA
95	BD Pharmaceuticals Systems	Columbus	NE	Source using 10+ ton	Synthetic Area	SCV	Test Report July 2020	7/8/2020	1	NA	Lesni Balancer/abator	Balancer/abator	NA	NA	1 of 3 SCV and ARV tested. (Total of 3 SCV and ARV)	M1, M2, M4 [outlet only], M18	NA	NA	5,562	4,760	NA	NA	3.1%	NA	94.30	NA	521.0	ppmvd	**954,185**	17.0	6,327	4,800	NA	NA	3.1%	NA	176.2	NA	99.96%	0.18	ppmvw	**0.19**	ppmvd	BDL	**0.1858**	**340.21**	0.0061
95	BD Pharmaceuticals Systems	Columbus	NE	Source using 10+ ton	Synthetic Area	SCV	Test Report July 2020	7/8/2020	2	NA	Lesni Balancer/abator	Balancer/abator	NA	NA	1 of 3 SCV and ARV tested. (Total of 3 SCV and ARV)	M1, M2, M4 [outlet only], M18	NA	NA	5,644	4,815	NA	NA	2.8%	NA	97.80	NA	898.8	ppmvd	**1,646,107**	29.7	6,033	4,556	NA	NA	2.8%	NA	180.8	NA	99.98%	0.18	ppmvw	**0.19**	ppmvd	BDL	**0.1852**	**339.16**	0.0058
95	BD Pharmaceuticals Systems	Columbus	NE	Source using 10+ ton	Synthetic Area	SCV	Test Report July 2020	7/8/2020	3	NA	Lesni Balancer/abator	Balancer/abator	NA	NA	1 of 3 SCV and ARV tested. (Total of 3 SCV and ARV)	M1, M2, M4 [outlet only], M18	NA	NA	5,578	4,768	NA	NA	2.7%	NA	97.20	NA	1,490.2	ppmvd	**2,729,226**	48.7	6,143	4,605	NA	NA	2.7%	NA	186.4	NA	99.99%	0.18	ppmvw	**0.18**	ppmvd	BDL	**0.1850**	**338.81**	0.0058
96	Midwest Sterilization Corporation	Jackson	MO	Source using 10+ ton	Synthetic Area	SCV	Test Report October 2019	10/3/2019	1	CD-01 and CD-03	Croll Reynolds Scrubbers	Wet Scrubber system	NA	SCV 1, 7, 11, 13	4 SCV tested. 13 SCV vent to APCD in series (CD-01 and CD-03).	M1, M2, M3, M4, M18	381.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	317.19	NA	NA	3,809.5	NA	NA	4.5%	NA	NA	99.9988%	3.0	ppm	**3.14**	ppmvd	ADL	**3.1420**	**5,754**	0.00368
96	Midwest Sterilization Corporation	Jackson	MO	Source using 10+ ton	Synthetic Area	SCV	Test Report October 2019	10/3/2019	2	CD-01 and CD-03	Croll Reynolds Scrubbers	Wet Scrubber system	NA	SCV 1, 7, 11, 13	4 SCV tested. 13 SCV vent to APCD in series (CD-01 and CD-03).	M1, M2, M3, M4, M18	380.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	313.20	NA	NA	3,676.5	NA	NA	3.5%	NA	NA	99.9988%	3.0	ppm	**3.11**	ppmvd	ADL	**3.1072**	**5,691**	0.00390
96	Midwest Sterilization Corporation	Jackson	MO	Source using 10+ ton	Synthetic Area	SCV	Test Report October 2019	10/3/2019	3	CD-01 and CD-03	Croll Reynolds Scrubbers	Wet Scrubber system	NA	SCV 1, 7, 11, 13	4 SCV tested. 13 SCV vent to APCD in series (CD-01 and CD-03).	M1, M2, M3, M4, M18	381.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	313.87	NA	NA	3,838.9	NA	NA	2.6%	NA	NA	99.9987%	2.6	ppm	**2.67**	ppmvd	ADL	**2.6694**	**4,889**	0.00405
99	Sterigenics Salt Lake City	Salt Lake City	UT	Source using 10+ ton	Synthetic Area	SCV	Test Report May 2016	4/19/2016	1	NA	Celicote packed tower scrubber	Wet Scrubber	NA	Chamber #4	10 SCV vented to APCD (1 SCV was tested)	M1, M2, M18	41.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	274	NA	141	NA	NA	2.8%	NA	68.7	NA	99.999996%	0.2	ppmv	0.2	ppmvd	(<) BDL. Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00001
99	Sterigenics Salt Lake City	Salt Lake City	UT	Source using 10+ ton	Synthetic Area	SCV	Test Report May 2016	4/19/2016	2	NA	Celicote packed tower scrubber	Wet Scrubber	NA	Chamber #2	10 SCV vented to APCD (1 SCV was tested)	M1, M2, M18	39.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	218	NA	140	NA	NA	2.8%	NA	75.2	NA	99.999996%	0.2	ppmv	0.2	ppmvd	(<) BDL. Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00001

FACID (PFID)	Company	Plant Location (City)	Plant Location State	Det based on EtO Usage	Det based on EtO Emission	Emission Source	Data Reference	Test Date	Run	APCD ID	APCD Name	APCD Type	APCD Yr Installed	Source ID	Sources Controlled by APCD (Configuration)	Test Methods	EtO Used During Test (lbs)	Production Rate Source	INLET Flow Actual (acfm, wet)	INLET Flow Dry Standard (dscfm)	INLET Sample Volume (dscf)	INLET Sample Volume (dscm)	INLET Moisture (avg %vol)	INLET Assumed Moisture (avg %vol)	INLET Temp Stack Gas (deg F)	INLET Oxygen (avg %vol db)	INLET EtO Concentration from Test Report	INLET units	INLET EtO Concentration Converted to (µg/dscm)	INLET EtO Emission (lb/hr)
99	Steri genics Salt Lake City	Salt Lake City	UT	Source using 10+ ton	Synthetic Area	SCV	Test Report May 2016	4/19/2016	3	NA	Celcote packed tower scrubber	Wet Scrubber	NA	Chamber #6	10 SCV vented to APCD (1 SCV was tested)	M1, M2, M18	39.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	197
113	Steris	San Diego	CA	Source using 10+ ton	Synthetic Area	SCV	DRE obtained from 2018 NOV	3/27/2018	NA	NA	Glygen 2001 acid wash scrubbers (9), packed bed scrubber (1)	Wet Scrubber, acid packed bed scrubber	NA	NA	9 SCV; unknown how many tested in 2018. (1 Glygen per SCV, then 1 common acid packed bed scrubber)	[Assume CARB 431 was used based on previous tests from 2004-2015]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
122	Steri genics US LLC Los Angeles - Gifford Ave (49th St)	Los Angeles	CA	Source using 10+ ton	Synthetic Area	SCV	Test Report February 2012	10/26/2011	1	NA	Chemrox packed tower scrubber	Wet Scrubber	NA	Chambers 4, 8, & 9	8 SCV vented to APCD (Run 1 tested 3 sterilizers, Runs 2 and 3 each tested 1)	CARB 1, M2C, CARB 431	71.6	NA	NA	NA	NA	NA	3%	NA	NA	NA	NA	NA	NA	159
122	Steri genics US LLC Los Angeles - Gifford Ave (49th St)	Los Angeles	CA	Source using 10+ ton	Synthetic Area	SCV	Test Report February 2012	10/26/2011	2	NA	Chemrox packed tower scrubber	Wet Scrubber	NA	Chamber 7	8 SCV vented to APCD (Run 1 tested 3 sterilizers, Runs 2 and 3 each tested 1)	CARB 1, M2C, CARB 431	31.2	NA	NA	NA	NA	NA	3%	NA	NA	NA	NA	NA	NA	85
122	Steri genics US LLC Los Angeles - Gifford Ave (49th St)	Los Angeles	CA	Source using 10+ ton	Synthetic Area	SCV	Test Report February 2012	10/26/2011	3	NA	Chemrox packed tower scrubber	Wet Scrubber	NA	Chamber 5	8 SCV vented to APCD (Run 1 tested 3 sterilizers, Runs 2 and 3 each tested 1)	CARB 1, M2C, CARB 431	28.1	NA	NA	NA	NA	NA	3%	NA	NA	NA	NA	NA	NA	80
111112	STERIS AST	Temecula	CA	Source using 10+ ton	Synthetic Area	SCV	Test Report February 2020	2/20/2020	1-3	NA	Anguil Peak Shaver, Donaldson Abator	Balancer/abator	NA	NA	SCV vented to APCD	CARB 431	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	122.2	ppmv	NA	NA
120121	Steri genics US LLC Los Angeles (50th St)	Los Angeles	CA	Source using 10+ ton	Synthetic Area	SCV	Test Report February 2012	10/27/2011	1	NA	Chemrox packed tower scrubber	Wet scrubber	NA	Chambers A, B, & C	6 SCV vented to APCD (Run 1 tested 3 sterilizers, Runs 2 and 3 each tested 1)	CARB 1, M2C, CARB 431	173.7	NA	NA	NA	NA	NA	3%	NA	NA	NA	NA	NA	NA	347
120121	Steri genics US LLC Los Angeles (50th St)	Los Angeles	CA	Source using 10+ ton	Synthetic Area	SCV	Test Report February 2012	10/27/2011	2	NA	Chemrox packed tower scrubber	Wet scrubber	NA	Chamber D	6 SCV vented to APCD (Run 1 tested 3 sterilizers, Runs 2 and 3 each tested 1)	CARB 1, M2C, CARB 431	56.1	NA	NA	NA	NA	NA	3%	NA	NA	NA	NA	NA	NA	112
120121	Steri genics US LLC Los Angeles (50th St)	Los Angeles	CA	Source using 10+ ton	Synthetic Area	SCV	Test Report February 2012	10/27/2011	3	NA	Chemrox packed tower scrubber	Wet scrubber	NA	Chamber F	6 SCV vented to APCD (Run 1 tested 3 sterilizers, Runs 2 and 3 each tested 1)	CARB 1, M2C, CARB 431	57.4	NA	NA	NA	NA	NA	3%	NA	NA	NA	NA	NA	NA	132

FACID (PFID)	OUTLET Flow Actual (acfm, wet)	OUTLET Flow Dry Standard (dscfm)	OUTLET Sample Volume (dscf)	OUTLET Sample Volume (dscm)	OUTLET Tested Moisture (%vol)	OUTLET Assumed Moisture (%vol)	OUTLET Temp Stack Gas (deg F)	OUTLET Oxygen (avg %vol db)	OUTLET DRE (%)	OUTLET EtO Concentration from Test Report	OUTLET Tested Units	OUTLET EtO Concentration Calculated from Assumed Moisture	OUTLET Calculated Units	Test run flag	Use this Outlet EtO Concentration	OUTLET EtO Concentration Converted to (µg/dscm)	OUTLET EtO Emission (lb/hr)
99	NA	140	NA	NA	2.8%	NA	76.0	NA	99.999995%	0.2	ppmv	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.00001
113	NA	NA	NA	NA	NA	NA	NA	NA	99.2%	NA	NA	NA	NA	NA	NA	NA	NA
122	NA	3,625	NA	NA	3%	NA	76.5	NA	99.9984%	0.1026	ppm	**0.106**	ppmvd	DLL	**0.1058**	**193.72**	0.00255
122	NA	3,616	NA	NA	3%	NA	77.8	NA	99.984%	0.5394	ppm	**0.556**	ppmvd	DLL	**0.5561**	**1,018**	0.01338
122	NA	3,609	NA	NA	3%	NA	77.7	NA	99.983%	0.5513	ppm	**0.568**	ppmvd	DLL	**0.5684**	**1,041**	0.013644
111112	NA	11,858	NA	NA	NA	2%	298	NA	99.989%	0.2	ppmv	0.2	ppmvd	(<) BDL Applied RDL value of 0.2 ppmv to the test run.	**0.2**	**366.29**	0.000816
120121	NA	2,695	NA	NA	3%	NA	75.9	NA	99.90%	27.23	ppm	**28.07**	ppmvd	ADL	**28.07**	**51,413**	0.50324
120121	NA	2,650	NA	NA	3%	NA	76.4	NA	99.80%	13.14	ppm	**13.55**	ppmvd	ADL	**13.55**	**24,810**	0.23880
120121	NA	2,640	NA	NA	3%	NA	80.3	NA	99.98%	1.174	ppm	**1.21**	ppmvd	ADL	**1.210**	**2,217**	0.021252

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Office of Air Quality Planning and Standards Research Triangle Park NC 27711
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October 1992

Air

EPA

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations

DRAFT EIS

Background Information for Proposed Standards

NESHAP

001

ETHYLENE OXIDE EMISSIONS FROM COMMERCIAL STERILIZATION/FUMIGATION OPERATIONS --

BACKGROUND INFORMATION FOR PROPOSED STANDARDS

Final

ETHYLENE OXIDE EMISSIONS FROM COMMERCIAL STERILIZATION/FUMIGATION OPERATIONS -- BACKGROUND INFORMATION FOR PROPOSED STANDARDS

Emission Standards Division

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina 27711

March 1993

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Publication No. EPA-435/D-93-016

ENVIRONMENTAL PROTECTION AGENCY

Background Information
and Draft
Environmental Impact Statement
for Commercial Sterilization/Fumigation Operations

Prepared by:

for Bruce Jordan
Director, Emission Standards Division
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

6-7-93
(Date)

1. The proposed national emission standard would limit emissions of ethylene oxide from existing and new commercial sterilization/fumigation operations. The proposed standards implement Section 112 of the Clean Air Act as amended in 1990 and are based on the Administrator's determination of July 16, 1992 (57 FR 31576) that commercial sterilization sources generate a large amount of ethylene oxide, a hazardous air pollutant listed in Section 112(b) of the Act.

2. Copies of this document have been sent to the following Federal Departments: Labor, Health and Human Services, Defense, Transportation, Agriculture, Commerce, Interior, and Energy; the National Science Foundation; the Council on Environmental Quality; members of the State and Territorial Air Pollution Program Administrators; the Association of Local Air Pollution Control Officials; EPA Regional Administrators; Office of Management and Budget; and other interested parties.

3. The comment period for review of this document is 60 days. Mr. David Markwordt, Chemicals and Petroleum Branch, telephone (919) 541-0837, may be contacted regarding the date of the comment period.

4. For additional information contact:

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5. Copies of this document may be obtained from:

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1.0 SUMMARY

1.1 STATUTORY AUTHORITY

National emission standards for hazardous air pollutants are established in accordance with Section 112(b)(1)(B) of the Clean Air Act (42 U.S.C. 7412), as amended. Emission standards under Section 112 apply to new and existing sources of a substance that has been listed as a hazardous air pollutant. This study examines emissions of ethylene oxide (EO) from commercial sterilization and fumigation industries.

1.2 REGULATORY ALTERNATIVES

Five regulatory alternatives representing selected combinations of control options were developed to evaluate the environmental and cost impacts of differing control strategies.

Regulatory Alternative A represents the maximum level of control with 99 percent of the EO emissions from all emissions points associated with commercial sterilization operations captured and controlled. Regulatory Alternative B represents the maximum level of control of all emissions points that exceed an EO use cutoff. Regulatory Alternative C represents control of the sterilizer vent, vacuum pump drain, and aeration room emissions at this same level of EO use. Additional controls on chamber exhaust emissions are not anticipated under this alternative. Regulatory Alternative D represents control of only the sterilizer vent and vacuum pump drain emissions for facilities using 270 kilograms per year (kg/yr) (600 pounds per year [lb/yr]) or more of EO. Regulatory Alternative E represents control of these same two emissions points for facilities using 900 kg/yr (2,000 lb/yr) or more of EO. Regulatory Alternative E

represents the maximum achievable control technology (MACT) floor determination.

1.3 ENVIRONMENTAL IMPACT

Table 1-1 summarizes the environmental impacts of the regulatory alternatives. At the MACT floor (Regulatory Alternative E), the nationwide EO emissions are estimated at 120 megagrams per year (Mg/yr) (132 tons per year [tons/yr]). The lower EO use cutoff proposed under Regulatory Alternative D reduces the estimated nationwide EO emissions to 109 Mg/yr (120 tons/yr). The control options under Regulatory Alternative C reduce the nationwide emissions to 68 Mg/yr (75 tons/yr). Under Regulatory Alternatives B and A, the control options proposed would reduce the nationwide emissions of EO to 30 Mg/yr and 11 Mg/yr (33 tons/yr and 12 tons/yr), respectively.

The potential impacts of these regulatory alternatives on wastewater, solid waste, and energy are also shown in Table 1-1. It is expected that the wastewater and solid waste impacts will be insignificant because of the recycling of ethylene glycol and reactant.

1.4 COST IMPACT

The nationwide cost impacts of the regulatory alternatives are summarized in Table 1-2. The costs associated with Regulatory Alternative E (MACT floor regulation) may require a nationwide capital investment of about $3.8 million. The control measures in Regulatory Alternatives D, C, B, and A may each require a nationwide capital investment of about $4.3 million, $6.4 million, $9.2 million, and $12 million respectively. These cost figures were determined using fourth quarter 1987 dollars.

1.5 ECONOMIC IMPACT

The economic impacts associated with the regulation of commercial sterilizers are not significant. In general, sterilization costs represent a small fraction of total production costs for facilities in industries in which sterilization is not the main source of revenue. Thus, any cost increases caused by the regulation will not significantly increase total production costs. Furthermore, because total

TABLE 1-1. POTENTIAL NATIONWIDE PERCENT EMISSIONS REDUCTION AND NATIONWIDE AIR, WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS

Regulatory Alternative	Nationwide emission reduction, %	EO air emission reduction Mg/yr (tons/yr)	Total annual wastewater production, m^3 (gal)[a,b]	Total annual solid waste production, Mg/(tons)[c,d]	Total annual electricity consumption, Kw/h (000's)
A	99	1,061 (1,170)	2,150 (569,000)	190 (209)	4,600
B	97	1,042 (1,148)	2,140 (566,000)	137 (151)	2,700
C	94	1,004 (1,107)	2,140 (566,000)	137 (151)	2,700
D	90	963 (1,062)	2,140 (566,000)	0	0
E	89	952 (1,049)	2,120 (561,000)	0	0

[a]Actual impacts anticipated to be zero because of recycling of ethylene glycol.
[b]Approximately 60 percent (by volume) of wastewater is composed of ethylene glycol.
[c]Actual impacts anticipated to be zero because of recycling of reactant.
[d]Based on the use of gas/solid reactor.

Source: U. S. EPA Ethylene Oxide Commercial Sterilization Data Base, 1986, 1988.

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TABLE 1-2. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS

Regulatory Alternative	Emission reduction, %	Total annual costs, $/MM	Emission reduction, Mg/yr (tons/yr)	Cost effectiveness $/Mg ($/ton)	Incremental cost effectiveness, $/Mg ($/ton)
A	99	12	1,061 (1,170)	11,300 (10,300)	147,000 (133,000)
B	97	9.2	1,042 (1,149)	8,800 (8,000)	74,000 (67,000)
C	94	6.4	1,004 (1,107)	6,400 (5,800)	51,000 (46,000)
D	90	4.3	963 (1,062)	4,500 (4,050)	45,000 (41,000)
E	89	3.8	952 (1,049)	4,000 (3,600)	N/A

[a]Ethylene oxide use cutoff same as for sterilizer vent.
[b]Status quo means that baseline chambers exhaust emissions are not exceeded.

production costs will not increase substantially, the price increases required to recover control also will be low.

In the contract sterilization industry, sterilization is nearly the entire product, and thus is the main source of revenue. Therefore, increased sterilization costs due to the regulation may cause total production costs and prices to increase significantly. However, as a result of the regulation, these facilities should experience an increase in demand for their services through facilities switching from in-house sterilization to contract sterilization. This increase in demand should allow them to recover control costs and may even increase profits for facilities in the contract sterilization industry. Thus, contract sterilizers are not adversely impacted by the regulation of commercial sterilizers.

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2.0 INTRODUCTION

2.1 BACKGROUND AND AUTHORITY FOR STANDARDS

According to industry estimates, more than 2.4 billion pounds of toxic pollutants were emitted to the atmosphere in 1988 ("Implementation Strategy for the Clean Air Act Amendments of 1990," Environmental Protection Agency [EPA] Office of Air and Radiation, January 15, 1991). These emissions may result in a variety of adverse health effects, including cancer, reproductive effects, birth defects, and respiratory illnesses. Title III of the 1990 Amendments to the Clean Air Act provides the tools for controlling emissions of these pollutants. Emissions from both large and small facilities that contribute to air toxics problems in urban and other areas will be regulated. The primary consideration in establishing national industry standards must be demonstrated technology. Before national emission standards for hazardous air pollutants (NESHAP) are proposed as Federal regulations, air pollution prevention and control methods are examined in detail with respect to their feasibility, environmental impacts, and costs. Various control options based on different technologies and degrees of efficiency are examined, and a determination is made regarding whether the various control options apply to each emissions source or if dissimilarities exist between the sources. In most cases, regulatory alternatives are subsequently developed and are then studied by EPA as a prospective basis for a standard. The alternatives are investigated in terms of their impacts on the environment, the economics and well-being of the industry, the national economy, and energy and other impacts. This document summarizes the information obtained through these studies so that interested

persons will be able to evaluate the information considered by EPA in developing the proposed standards.

National emission standards for hazardous air pollutants for new and existing sources are established under Section 112 of the Clean Air Act as amended in 1990 [42 U.S.C. 7401 et seq., as amended by PL 101-549, November 15, 1990], hereafter referred to as the Act. Section 112 directs the EPA Administrator to promulgate standards that "require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition of such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reductions, and any non-air quality health and environmental impacts and energy requirements, determines is achievable ... ." The Act allows the Administrator to set standards that "distinguish among classes, types, and sizes of sources within a category or subcategory."

The Act differentiates between major sources and area sources. A major source is defined as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." The Administrator, however, may establish a lesser quantity cutoff to distinguish between major and area sources. The level of the cutoff is based on the potency, persistence, or other characteristics or factors of the air pollutant. An area source is defined as "any stationary source of hazardous air pollutants that is not a major source." For new sources, the 1990 Amendments state that the "maximum degree of reduction in emissions that is deemed achievable for new sources in a category or subcategory shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator." Emission standards for existing sources "may be less stringent than the standards for new sources in the same

category or subcategory but shall not be less stringent, and may be more stringent than--

(A) the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information), excluding those sources that have, within 18 months before the emission standard is proposed or within 30 months before such standard is promulgated, whichever is later, first achieved a level of emission rate or emission reduction which complies, or would comply if the source is not subject to such standard, with the lowest achievable emission rate (as defined by Section 171) applicable to the source category and prevailing at the time, in the category or subcategory for categories and subcategories with 30 or more sources, or

(B) the average emission limitation achieved by the best performing five sources (for which the Administrator has or could reasonably obtain emissions information) in the category or subcategory for categories or subcategories with fewer than 30 sources."

The Federal standards are also known as "MACT" standards and are based on the maximum achievable control technology previously discussed. The MACT standards may apply to both major and area sources, although the existing source standards may be less stringent than the new source standards, within the constraints presented above. The MACT is considered to be the basis for the standard, but the Administrator may promulgate more stringent standards that have several advantages. First, they may help achieve long-term cost savings by avoiding the need for more expensive retrofitting to meet possible future residual risk standards, which may be more stringent (discussed in Section 2.6). Second, Congress was clearly interested in providing incentives for improving technology. Finally, in the 1990 Amendments, Congress gave EPA a clear mandate to reduce the health and environmental risk of air toxics emissions as quickly as possible.

For area sources, the Administrator may "elect to promulgate standards or requirements applicable to sources in such categories or subcategories which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants." These area source standards are also known as "GACT" (generally available control technology) standards, although MACT may be applied at the Administrator's discretion, as discussed previously.

The standards for hazardous air pollutants (HAP's), like the new source performance standards (NSPS) for criteria pollutants required by Section 111 of the Act (42 U.S.C. 7411), differ from other regulatory programs required by the Act (such as the new source review program and the prevention of significant deterioration program) in that NESHAP and NSPS are national in scope (versus site-specific). Congress intended for the NESHAP and NSPS programs to provide a degree of uniformity to State regulations to avoid situations where some States may attract industries by relaxing standards relative to other States. States are free under Section 116 of the Act to establish standards more stringent than Section 111 or 112 standards.

Although NESHAP are normally structured in terms of numerical emissions limits, alternative approaches are sometimes necessary. In some cases, physically measuring emissions from a source may be impossible or at least impracticable due to technological and economic limitations. Section 112(h) of the Act allows the Administrator to promulgate a design, equipment, work practice, or operational standard, or combination thereof, in those cases where it is not feasible to prescribe or enforce an emissions standard. For example, emissions of volatile organic compounds (many of which may be HAP's, such as benzene) from storage vessels for volatile organic liquids are greatest during tank filling. The nature of the emissions (i.e, high concentrations for short periods during filling and low concentrations for longer periods during storage) and the configuration of storage tanks make direct emission measurement

impractical. Therefore, the MACT or GACT standards may be based on equipment specifications.

Under Section 112(h)(3), the Act also allows the use of alternative equivalent technological systems: "If, after notice and opportunity for comment, the owner or operator of any source establishes to the satisfaction of the Administrator that an alternative means of emission limitation" will reduce emissions of any air pollutant at least as much as would be achieved under the design, equipment, work practice, or operational standard, the Administrator shall permit the use of the alternative means.

Efforts to achieve early environmental benefits are encouraged in Title III. For example, source owners and operators are encouraged to use the Section 112(i)(5) provisions, which allow a 6-year compliance extension of the MACT standard in exchange for the implementation of an early emission reduction program. The owner or operator of an existing source must demonstrate a 90-percent emission reduction of HAP's (or 95 percent if the HAP's are particulates) and meet an alternative emission limitation, established by permit, in lieu of the otherwise applicable MACT standard. This alternative limitation must reflect the 90- (95-) percent reduction and is in effect for a period of 6 years from the compliance date for the otherwise applicable standard. The 90- (95-) percent early emission reduction must be achieved before the otherwise applicable standard is first proposed, although the reduction may be achieved after the standard's proposal (but before January 1, 1994) if the source owner or operator makes an enforceable commitment before the proposal of the standard to achieve the reduction. The source must meet several criteria to qualify for the early reduction standard, and Section 112(i)(5)(A) provides that the State may require additional reductions.

2.2 SELECTION OF POLLUTANTS AND SOURCE CATEGORIES

As amended in 1990, the Act includes a list of 189 HAP's. Petitions to add or delete pollutants from this list may be submitted to EPA. Using this list of pollutants, EPA will publish a list of source categories (major and area sources) for

which emission standards will be developed. Within 2 years of enactment (November 1992), EPA will publish a schedule establishing dates for promulgating these standards. Petitions also may be submitted to EPA to remove source categories from the list. The schedule for standards for source categories will be determined according to the following criteria:

"(A) the known or anticipated adverse effects of such pollutants on public health and the environment;

(B) the quantity and location of emissions or reasonably anticipated emissions of hazardous air pollutants that each category or subcategory will emit; and

(C) the efficiency of grouping categories or subcategories according to the pollutants emitted, or the processes or technologies used."

After the source category has been chosen, the types of facilities within the source category to which the standard will apply must be determined. A source category may have several facilities that cause air pollution, and emissions from these facilities may vary in magnitude and control cost. Economic studies of the source category and applicable control technology may show that air pollution control is better served by applying standards to the more severe pollution sources. For this reason, and because there is no adequately demonstrated system for controlling emissions from certain facilities, standards often do not apply to all facilities at a source. For the same reasons, the standards may not apply to all air pollutants emitted. Thus, although a source category may be selected to be covered by standards, the standards may not cover all pollutants or facilities within that source category.

2.3 PROCEDURE FOR DEVELOPMENT OF NESHAP

Standards for major and area sources must (1) realistically reflect MACT or GACT; (2) adequately consider the cost, the non-air quality health and environmental impacts, and the energy requirements of such control; (3) apply to new and existing sources; and (4) meet these conditions for all variations of industry operating conditions anywhere in the country.

The objective of the NESHAP program is to develop standards to protect the public health by requiring facilities to control emissions to the level achievable according to the MACT or GACT guidelines. The standard-setting process involves three principal phases of activity: (1) gathering information, (2) analyzing the information, and (3) developing the standards.

During the information-gathering phase, industries are questioned through telephone surveys, letters of inquiry, and plant visits by EPA representatives. Information is also gathered from other sources, such as a literature search. Based on the information acquired about the industry, EPA selects certain plants at which emissions tests are conducted to provide reliable data that characterize the HAP emissions from well-controlled existing facilities.

In the second phase of a project, the information about the industry, the pollutants emitted, and the control options are used in analytical studies. Hypothetical "model plants" are defined to provide a common basis for analysis. The model plant definitions, national pollutant emissions data, and existing State regulations governing emissions from the source category are then used to establish "regulatory alternatives." These regulatory alternatives may be different levels of emissions control or different degrees of applicability or both.

The EPA conducts studies to determine the cost, economic, environmental, and energy impacts of each regulatory alternative. From several alternatives, EPA selects the single most plausible regulatory alternative as the basis for the NESHAP for the source category under study.

In the third phase of a project, the selected regulatory alternative is translated into standards, which, in turn, are written in the form of a Federal regulation. The Federal regulation limits emissions to the levels indicated in the selected regulatory alternative.

As early as is practical in each standard-setting project, EPA representatives discuss the possibilities of a standard and the form it might take with members of the National Air Pollution

Control Techniques Advisory Committee, which is composed of representatives from industry, environmental groups, and State and local air pollution control agencies. Other interested parties also participate in these meetings.

The information acquired in the project is summarized in the background information document (BID). The BID, the proposed standards, and a preamble explaining the standards are widely circulated to the industry being considered for control, environmental groups, other government agencies, and offices within EPA. Through this extensive review process, the points of view of expert reviewers are taken into consideration as changes are made to the documentation.

A "proposal package" is assembled and sent through the offices of EPA Assistant Administrators for concurrence before the proposed standards are officially endorsed by the EPA Administrator. After being approved by the EPA Administrator, the preamble and the proposed regulation are published in the Federal Register.

The public is invited to participate in the standard-setting process as part of the Federal Register announcement of the proposed regulation. The EPA invites written comments on the proposal and also holds a public hearing to discuss the proposed standards with interested parties. All public comments are summarized and incorporated into a second volume of the BID. All information reviewed and generated in studies in support of the standards is available to the public in a "docket" on file in Washington, D.C. Comments from the public are evaluated, and the standards may be altered in response to the comments.

The significant comments and EPA's position on the issues raised are included in the preamble of a promulgation package, which also contains the draft of the final regulation. The regulation is then subjected to another round of internal EPA review and refinement until it is approved by the EPA Administrator. After the Administrator signs the regulation, it is published as a "final rule" in the Federal Register.

2.4 CONSIDERATION OF COSTS

The requirements and guidelines for the economic analysis of proposed NESHAP are prescribed by Presidential Executive Order 12291 (EO 12291) and the Regulatory Flexibility Act (RFA). The EO 12291 requires preparation of a Regulatory Impact Analysis (RIA) for all "major" economic impacts. An economic impact is considered to be major if it satisfies any of the following criteria:

1. An annual effect on the economy of $100 million or more;
2. A major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions; or
3. Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

An RIA describes the potential benefits and costs of the proposed regulation and explores alternative regulatory and nonregulatory approaches to achieving the desired objectives. If the analysis identifies less costly alternatives, the RIA includes an explanation of the legal reasons why the less costly alternatives could not be adopted. In addition to requiring an analysis of the potential costs and benefits, EO 12291 specifies that EPA, to the extent allowed by the Act and court orders, demonstrate that the benefits of the proposed standards outweigh the costs and that the net benefits are maximized.

The RFA requires Federal agencies to give special consideration to the impact of regulations on small businesses, small organizations, and small governmental units. If the proposed regulation is expected to have a significant impact on a substantial number of small entities, a regulatory flexibility analysis must be prepared. In preparing this analysis, EPA takes into consideration such factors as the availability of capital for small entities, possible closures among small entities, the increase in production costs due to compliance, and a comparison

of the relative compliance costs as a percent of sales for small versus large entities.

The prime objective of the cost analysis is to identify the incremental economic impacts associated with compliance with the standards based on each regulatory alternative compared to baseline. Other environmental regulatory costs may be factored into the analysis wherever appropriate. Air pollutant emissions may cause water pollution problems, and captured potential air pollutants may pose a solid waste disposal problem. The total environmental impact of an emission source must, therefore, be analyzed and the costs determined whenever possible.

A thorough study of the profitability and price-setting mechanisms of the industry is essential to the analysis so that an accurate estimate of potential adverse economic impacts can be made for proposed standards. It is also essential to know the capital requirements for pollution control systems already placed on plants so that the additional capital requirements necessitated by these Federal standards can be placed in proper perspective. Finally, it is necessary to assess the availability of capital to provide the additional control equipment needed to meet the standards.

2.5 CONSIDERATION OF ENVIRONMENTAL IMPACTS

Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969 requires Federal agencies to prepare detailed environmental impact statements on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment. The objective of NEPA is to build into the decision-making process of Federal agencies a careful consideration of all environmental aspects of proposed actions.

In a number of legal challenges to standards for various industries, the United States Court of Appeals for the District of Columbia Circuit has held that environmental impact statements need not be prepared by EPA for proposed actions under the Act. Essentially, the Court of Appeals has determined that the best system of emissions reduction requires the Administrator to take into account counterproductive environmental effects of proposed

standards as well as economic costs to the industry. On this basis, therefore, the Courts established a narrow exemption from NEPA for EPA determinations.

In addition to these judicial determinations, the Energy Supply and Environmental Coordination Act (ESECA) of 1974 (PL-93-319) specifically exempted proposed actions under the Act from NEPA requirements. According to Section 7(c)(1), "No action taken under the Clean Air Act shall be deemed a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969" (15 U.S.C. 793(c)(1)).

Nevertheless, EPA has concluded that preparing environmental impact statements could have beneficial effects on certain regulatory actions. Consequently, although not legally required to do so by Section 102(2)(C) of NEPA, EPA has adopted a policy requiring that environmental impact statements be prepared for various regulatory actions, including NESHAP developed under Section 112 of the Act. This voluntary preparation of environmental impact statements, however, in no way legally subjects the EPA to NEPA requirements.

To implement this policy, a separate section is included in this document that is devoted solely to an analysis of the potential environmental impacts associated with the proposed standards. Both adverse and beneficial impacts in such areas as air and water pollution, increased solid waste disposal, and increased energy consumption are discussed.

2.6 RESIDUAL RISK STANDARDS

Section 112 of the Act provides that 8 years after MACT standards are established (except for those standards established 2 years after enactment, which have 9 years), standards to protect against the residual health and environmental risks remaining must be promulgated, if necessary. The standards would be triggered if more than one source in a category or subcategory exceeds a maximum individual risk of cancer of 1 in 1 million. These residual risk regulations would be based on the concept of providing an "ample margin of safety to protect public health."

The Administrator may also consider whether a more stringent standard is necessary to prevent--considering costs, energy, safety, and other relevant factors--an adverse environmental effect. In the case of area sources controlled under GACT standards, the Administrator is not required to conduct a residual risk review.

3.0 ETHYLENE OXIDE STERILIZATION/FUMIGATION PROCESSES AND EMISSIONS

3.1 BACKGROUND INFORMATION

The commercial sterilization (CS) source category covers the use of ethylene oxide (EO) as a sterilant/fumigant in the production of medical equipment supplies and in miscellaneous sterilization and fumigation operations. Commercial sterilization facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. These materials may be sterilized at the facility that produces or uses the product or by contract sterilizers (i.e., firms under contract to sterilize products manufactured by other companies). Libraries and museums use EO to fumigate books and other historical items. State departments of agriculture control diseases of bees by fumigating beehives with EO.

Information about facilities that use EO as a sterilant/fumigant was obtained from two sources: (1) a survey of medical equipment suppliers (Health Industry Manufacturers' Association [HIMA] members) conducted by HIMA in November 1985 and (2) an information collection request (ICR) submitted by EPA under Section 114 of the Act to miscellaneous sterilizers and fumigators (identified during an extensive survey of potential users) in July 1986. A total of 203 CS facilities responded to the HIMA survey and the July 1986 EPA information request to complete the 1986 data base.[1,2]

Additional information to the 1986 data base was obtained from two Section 114 letters (July 1988 and July 1989). The July 1988 Section 114 letter was sent to 44 (9 parent companies) of the 203 facilities represented in the 1986 data base.[3] These 44 facilities were chosen because they represent the diversity of sterilizer chamber sizes, annual EO use, and industries associated with the commercial sterilization category. Although these facilities represent only 22 percent of the number of facilities in the CS data base, the emissions from these facilities account for 64 percent of the total emissions from commercial sterilization facilities. The July 1988 Section 114 letter was used to obtain detailed operating parameters for a short-term health risk assessment analysis; data on vacuum pumps, gas types, control devices, and aeration rooms were also obtained from this ICR. The July 1989 Section 114 letter was sent to 39 of the 203 facilities in the 1986 data base (i.e., those with a maximum individual risk [MIR] of cancer incidence greater than 10^{-3}).[4] The purpose of this Section 114 letter was to update EPA's Air Toxics Exposure and Risk Information System (ATERIS) data base. The July 1989 Section 114 letter was also used to obtain updated information regarding EO use, emission controls, and vacuum pumps. The responses to the July 1989 Section 114 letter indicated that 7 of the 39 facilities had ceased EO use. Therefore, 196 facilities comprise the EPA 1989 CS data base.

As shown in Table 3-1, the facilities represented in the EPA commercial sterilization data base are located in 41 States and Puerto Rico. These facilities were grouped by Standard Industrial Classification (SIC) into the following categories:

1. medical equipment suppliers;
2. pharmaceuticals;
3. other health-related industries;
4. spice manufacturers;
5. contract sterilizers;
6. libraries, museums, and archives;

TABLE 3-1. LOCATIONS OF FACILITIES--EPA COMMERCIAL STERILIZATION DATA BASE[1-4]

State	No. of facilities	State	No. of facilities
Arizona	3	Missouri	5
Arkansas	2	New Hampshire	2
California	19	New Jersey	17
Colorado	3	New York	13
Connecticut	6	North Carolina	7
Delaware	2		
Florida	5	Ohio	2
Georgia	4	Pennsylvania	9
Illinois	8	Puerto Rico	14
Indiana	4	Rhode Island	2
Iowa	3	South Carolina	2
Maryland	5	Tennessee	3
Massachusetts	9	Texas	12
Michigan	8	Utah	1
Minnesota	6	Virginia	5
Mississippi	2	Washington	2
Subtotal	89	Subtotal	96

The commercial sterilization data base includes one facility located in each of the following States: Alabama, Hawaii, Kentucky, Maine, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Wisconsin, and West Virginia.

Subtotal	11
Total No. of facilities	196

7. laboratories (research, testing, and animal breeding); and

8. State departments of agriculture.[5]

Table 3-2 shows the number of facilities in the EPA commercial sterilization data base for the eight categories listed above and the SIC codes represented by these industry categories.

3.2 PROCESS DESCRIPTION

There are two main types of EO sterilization processes: (1) bulk sterilization and (2) single-item sterilization. These processes are described below followed by discussions about spice fumigators, library and museum fumigators, and beehive fumigators used by State departments of agriculture. (In addition to using the bulk sterilization process, one facility also sterilizes within 55-gallon drums.[2] This process, which is neither bulk nor single-item sterilization, is not discussed.)

3.2.1 Bulk Sterilization

Bulk sterilization is the more commonly used EO sterilization process; 98 percent of the commercial sterilization facilities represented in the EPA data base use this process.[1-4] The products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas at a predetermined temperature, humidity level, and pressure. The equipment, sterilant gases, and sterilization cycle used for bulk sterilization processes are described below.

3.2.1.1 Equipment. A schematic of a gas sterilizer is shown in Figure 3-1. The main components of the sterilizer are the chamber and vacuum pump. Chambers used by commercial sterilization facilities typically range in volume from 2.8 cubic meters (m^3) (100 cubic feet [ft^3]) to 28 m^3 (1,000 ft^3).[1,2] Table 3-3 presents size data for the chambers in the EPA commercial sterilization data base.

A vacuum pump is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete. In the past, once-through, water-ring vacuum pumps were used. However, many facilities are converting to full sealant recovery (i.e., oil-sealed or

TABLE 3-2. NUMBER OF FACILITIES AND STANDARD INDUSTRIAL CLASSIFICATION (SIC) PER INDUSTRY CATEGORY--EPA COMMERCIAL STERILIZATION DATA BASE[5]

Industry category	No. of facilities	SIC
Medical equipment suppliers	61	3841, 3842
Pharmaceuticals	39	2834, 5122, 2831, 2833
Other health-related industries	24	3079, 3693, 5086, 2211, 2821, 2879, 3069, 3569, 3677, 3999
Spice manufacturers	23	2099, 5149, 2034, 2035, 2046
Contract sterilizers	17	7399, 7218, 8091
Libraries, museums, and archives	13	8411, 8231
Laboratories (research, testing and animal breeding)	11	0279, 7391, 8071, 8922, 7397
State departments of agriculture	8	9641
Total	196	

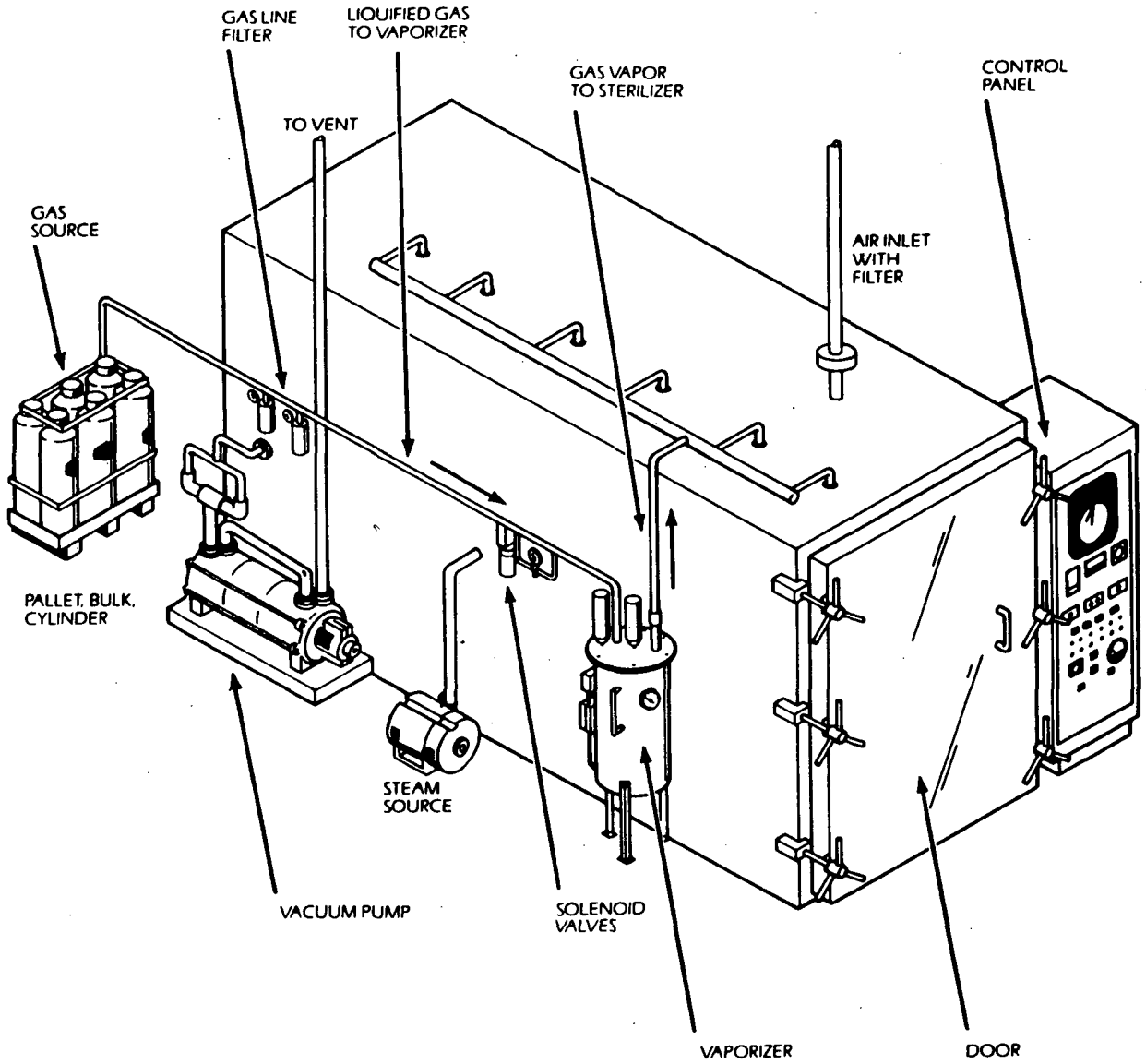

Figure 3-1. Schematic of a gas sterilizer.
(Courtesy of Union Carbide Corporation, Linde Division.)[7]

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TABLE 3-3. CHAMBER SIZES--EPA COMMERCIAL STERILIZATION DATA BASE[1,2]

Size range, m^3 (ft^3)	No. of chambers	Percent	Cumulative No. of chambers	Cumulative percent
≤1.4 (≤50)	83	20	83	20
1.5-2.8 (51-100)	29	7	112	28
2.9-14 (101-500)	113	28	225	55
15-28 (501-1,000)	116	29	341	84
29-57 (1,001-2,000)	55	14	396	98
≥58 (≥2,001)	11	2	407[a]	100

[a]This number excludes four single-item sterilization units, one 55-gal drum user, and two facilities that did not report a chamber size.

recirculating water) vacuum pumps in order to meet the 1 part per million by volume (1 ppmv) Occupational Safety and Health Administration (OSHA) worker exposure standard for EO and proposed State regulations.[3,6]

3.2.1.2 Sterilant Gases. Ethylene oxide is an extremely effective sterilant gas. The EO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping.

The most widely used sterilant gas is a mixture of 12 percent by weight EO and 88 percent by weight dichlorodifluoromethane (CFC-12), referred to as 12/88. Two other commonly used sterilant gases are (1) pure EO (i.e., 100 percent EO) and (2) a mixture of 10 percent by weight EO and 90 percent by weight carbon dioxide (CO_2), referred to as 10/90. Other sterilant gas mixtures that are used include 20/80, 30/70, and 80/20 (weight percents EO/CO_2).[1,2,4] Gas mixtures that contain 20 percent or greater EO (by weight) are considered flammable. The 80/20 (EO/CO_2) mixture has the same flammability range as pure EO.[7] Physical and chemical properties of EO, CFC-12, and CO_2 are given in Table 3-4. Table 3-5 shows the number of commercial sterilization facilities represented in the EPA data base that use a particular gas type and the amount of EO used for each gas type. Since many commercial sterilization facilities operate more than one sterilization chamber, the gas usage rates in Table 3-5 also are presented on a chamber basis.[1,2,4] The data presented in Table 3-5 are based on information from the 1985 HIMA survey and the 1986 EPA ICR.[1,2] Gas type data were collected for the 44 facilities that responded to the 1988 Section 114 letter; however, this information was not updated for the remaining facilities represented in the 1989 CS data base. Since 1986, the increased price of CFC-12 (due to EPA regulation of CFC production) could have affected the number of facilities that use 12/88.

TABLE 3-4. PHYSICAL AND CHEMICAL PROPERTIES OF ETHYLENE OXIDE, DICHLORODIFLUOROMETHANE, AND CARBON DIOXIDE [8-11]

	Ethylene oxide	Dichlorodifluoromethane	Carbon dioxide
Other designations	1,2-epoxyethane, oxirane, dimethylene oxide	CFC-12, refrigerant 12, propellant 12	Carbonic acid gas, carbonic anhydride
Appearance	Colorless liqud or gas	Colorless gas, readily liquified under pressure and/or cooling	Colorless gas
Chemical formula	C_2H_4O	CCl_2F_2	CO_2
Molecular weight	44.0	120.9	44.0
Vapor pressure at 20°C (68°F)	146.0 kPa (21.2 psia)	567.6 kPa (82.3 psia)	5,731.0 kPa (831 psia)
Boiling point at 101.3 kPa (14.7 psi)	10.4°C (50.7°F)	-29.8°C (-21.6°F)	-78.5°C (-109.3°F)
Flammability limits in air	Lower 3 percent by volume Upper 80+ percent by volume[a]	Nonflammable	Nonflammable
Water solubility	Completely miscible	Low solubility	--
Heat of combustion, vapor at 25°C (77°F)	1,306 kJ/mol (12,760 Btu/lb)	111 kJ/mol (396 Btu/lb)	--
Threshold limit value (TLV) 8-hr time weighted average (TWA)	1 ppmv	1,000 ppmv	5,000 ppmv

[a]Pure EO explodes by decomposition at 560°C (1040°F) with ignition.

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TABLE 3-5. STERILANT GAS TYPE USAGE--EPA COMMERCIAL STERILIZATION DATA BASE [1-4]

Sterilant gas	No. of facilities[a]	Percent of facilities	No. of chambers[b]	Percent of chambers	EO use, Mg/yr[c]	Percent of total EO use
12/88 (EO/CFC-12)	151	77	282	64	639	33
Pure EO	40	20	113	26	1,027	54
10/90 (EO/CO_2)	14	7	19	4	4	<0.01
Other mixtures[d]	16	8	25	6	249	13

[a]There are 196 commercial sterilization facilities in the EPA data base. Approximately 10 percent of these facilities use more than one type of sterilant gas.

[b]There are 434 operational sterilization "chambers" (the four single-item sterilization systems are counted as chambers) in the EPA commercial sterilization data base. More than one type of sterilant gas is used in 5 percent of these chambers.

[c]Amount of EO in the sterilant gas mixture.

[d]Includes mixture of EO and CO_2 with a weight percent of EO ranging from 20 to 80 percent and custom mixes.

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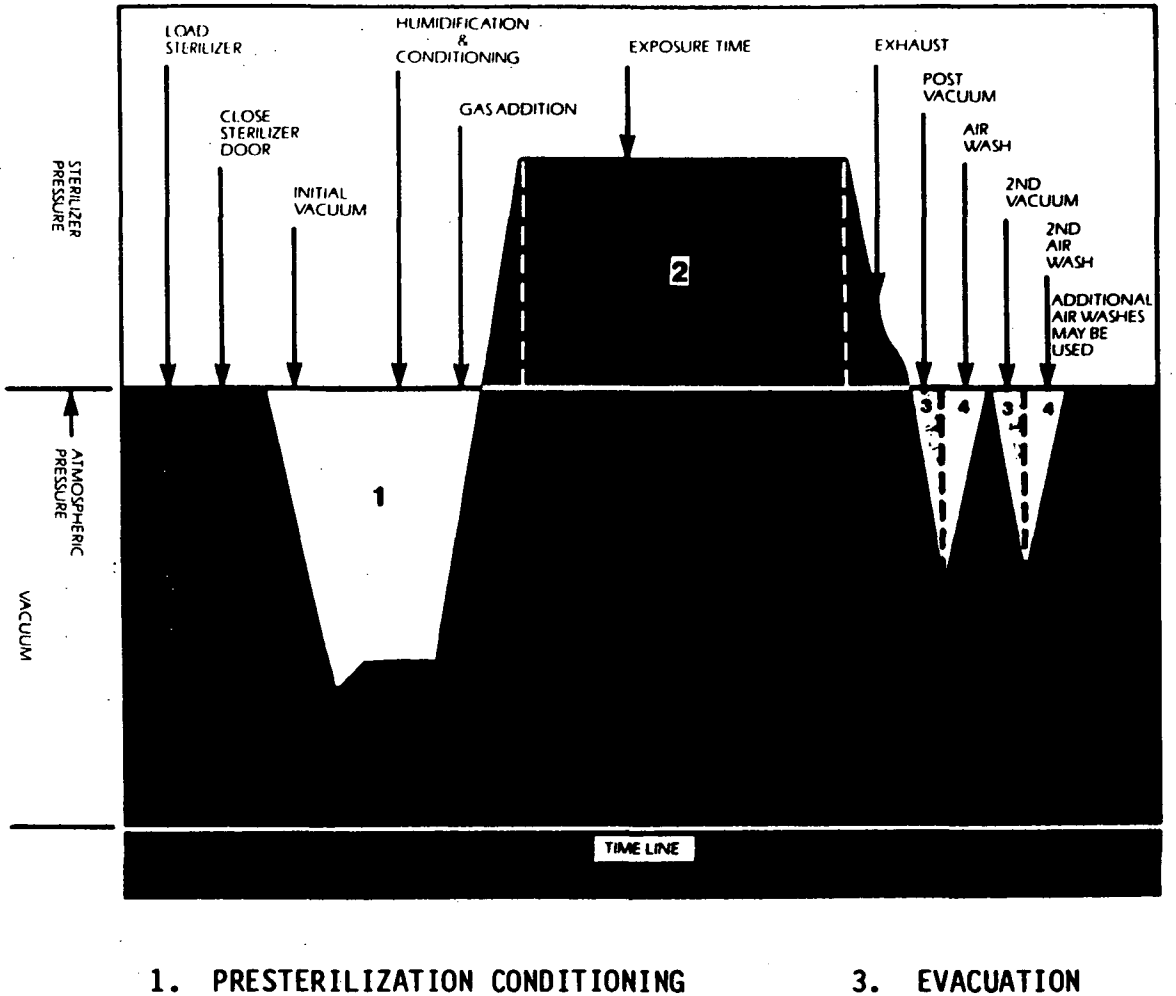
The 12/88 mixture is popular for several reasons. Unlike pure EO, 12/88 is nonflammable and nonexplosive. Therefore, the use of 12/88 does not require explosion-proof rooms and additional safety precautions that are necessary when pure EO is used. The 10/90 mixture also is nonflammable and nonexplosive.[7] But, because 10/90 is only 10 percent EO by volume whereas 12/88 is 27.3 percent EO by volume, 10/90 requires higher operating pressures to obtain an EO concentration that is sufficient for effective sterilization (approximately 304 kilopascals [kPa], or 44 pounds per square inch absolute [psia], for 10/90, as compared to 170 kPa [24.7 psia] for 12/88).[12] The chambers used for 10/90 sterilization must be ASME-rated pressure vessels, (i.e., manufactured in accordance with Section VIII, Division I, of the American Society of Mechanical Engineers [ASME] Pressure Vessel Code) and are, therefore, more expensive to construct than the chambers used with 12/88. However, because of insurance requirements, many commercial sterilization facilities use chambers that meet requirements for ASME-rated pressure vessels when sterilizing with 12/88 or with explosive mixtures below ambient pressure.[13]

3.2.1.3 Sterilization Cycle. The typical sterilization cycle consists of five phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, (4) air wash, (5) chamber exhaust, and (6) aeration. Figures 3-2 and 3-3 show pressure/time curves for the first four phases of the 12/88 sterilization cycle and the pure EO sterilization cycle, respectively. Steps 1 through 4 typically require about 8 hours.

3.2.1.3.1 Presterilization conditioning. After the products have been loaded into the chamber and the airtight door sealed, a partial vacuum is drawn inside the chamber. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable sterilant gases are used, the removal of air reduces the potential for ignition.[7] The chamber pressure is reduced to a pressure of about 6.9 to 69 kPa (1 to 10 psia) for 12/88 and 3 kPa (0.4 psia) for pure EO. The initial drawdown takes from about 5 to 45 minutes, depending on the product being



1. PRESTERILIZATION CONDITIONING
2. STERILIZATION
3. EVACUATION
4. AIR WASH

Figure 3-2. Sterilization cycle for 12/88.
(Courtesy of Union Carbide Corporation, Linde Division.)[7]

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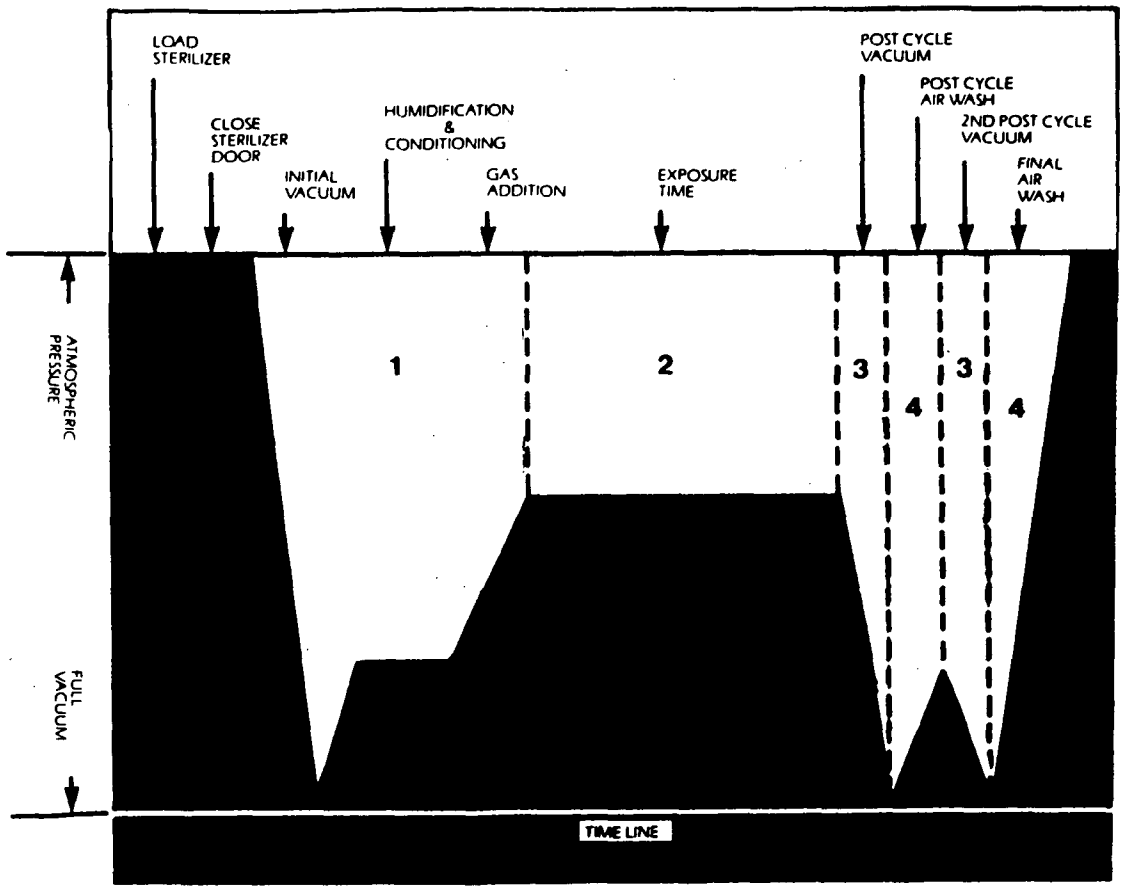

1. PRESTERILIZATION CONDITIONING
2. STERILIZATION
3. EVACUATION
4. AIR WASH

Figure 3-3. Sterilization cycle for pure EO.
(Courtesy of Union Carbide Corporation, Linde Division.)[7]

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sterilized. Certain products require a longer drawdown time because they are damaged by sudden pressure changes. The chamber temperature is then adjusted to between 38° and 54°C (100° and 130°F). A higher temperature increases the diffusion rate of EO into the products and, thus, reduces the time the products must be exposed to the sterilant gas to ensure proper sterilization. Finally, the relative humidity is raised to about 45 percent by injecting steam. Proper humidification is important to the process because the susceptibility of microorganisms to the sterilant gas is increased under moist conditions.[7]

3.2.1.3.2 Sterilization. The sterilant, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration of EO (600 parts per million [ppm]).[7] The chamber pressure depends on the type of sterilant gas used. Pure EO is used under vacuum pressures of about 51 kPa (7.35 psia); the 12/88 mixture is used at pressures of about 170 kPa (24.7 psia). The pressure is held for about 4 to 6 hours. This exposure time is dependent on the temperature, pressure, humidity level, type of sterilant gas, and products being sterilized. For example, porous products require shorter exposures than nonporous products. Also, some bacteria are more resistant to EO and take longer to destroy.

3.2.1.3.3 Evacuation. Following sufficient exposure time, the sterilant gas is evacuated from the chamber with a vacuum pump. (If sterilization is performed at a pressure greater than atmospheric, the chamber is often allowed to vent to atmospheric pressure before using the vacuum pump to evacuate the chamber.) Typical evacuation pressures are 13 kPa (1.9 psia) for 12/88 gas and 3 kPa (0.4 psia) for pure EO. This postcycle vacuum phase typically lasts about 10 minutes.

3.2.1.3.4 Air wash. The pressure in the chamber is brought to atmospheric pressure by introducing air (when nonflammable sterilant gases are used) or either nitrogen or CO_2 (when flammable sterilant gases are used). The combination of evacuation and air wash phases is repeated from two to four times

to remove as much of the EO from the product as possible. Each air wash typically lasts 2 to 15 minutes.

The purpose of the air wash is to allow residual EO to diffuse from the product. Removal of EO from the product during the air wash helps meet Food and Drug Administration (FDA) guidelines on residual EO levels for medical devices, EPA residual tolerances for agricultural products, and the OSHA standard for exposure in the workplace.

3.2.1.3.5 Chamber exhaust. Prior to unloading the sterilizer, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust is an exhaust system that evacuates EO-laden air from the chamber prior to unloading and while the chamber is being unloaded (and reloaded). The chamber exhaust typically consists of a butterfly valve in the ductwork that opens automatically and a roof-mounted blower that automatically switches on and pulls fresh air through the chamber. A chamber face velocity of 30.5 m/min (100 ft/min) is generally maintained, producing a chamber exhaust flow rate of 28 to 85 m^3/min (1,000 to 3,000 ft^3/min), depending on chamber size. This process usually begins 15 minutes prior to unloading and continues during loading and reloading.[14]

The chamber exhaust is responsible for removing EO from the void space in the sterilizer chamber, not the product. Use of the chamber exhaust assists some facilities in meeting the EO worker exposure levels set by OSHA. Facilities that use conveyors to load and unload the chamber, as well as facilities that do not have problems meeting OSHA worker exposure levels, may not use chamber exhausts.

3.2.1.3.6 Aeration. After the last air wash, the sterile products are placed in an aeration room and kept there for several hours to days depending on the product. The purpose of aeration is to allow further diffusion of residual EO from the products prior to shipping in order to comply with the FDA and EPA residual EO guidelines. Ethylene oxide concentrations in the aeration room are maintained at relatively low levels by ventilating the room at a rate of about 20 air changes per hour.

Recent information from industry contacts indicates that some commercial sterilization facilities are aerating some or all of the sterile products in heated enclosed aeration units. In comparison to traditional warehouse-type aeration rooms, these units are smaller in volume (<70 m^3 [2500 ft^3]) with much lower ventilation rates. Consequently, the EO concentrations are usually higher than the 1 ppmv OSHA standard. However, worker exposure is reduced by not opening the door until the EO concentration drops and by limiting the frequency of opening the aeration room door. The main purpose of this type of aeration process is to increase the diffusion rate of EO out of the sterile product (by increasing the temperature) and, thus, reduce the aeration time.

Facilities that sterilize products infrequently may aerate in the sterilization chamber. Two basic chamber aeration processes are used. The first process involves cycling the chamber between atmospheric pressure and a slight vacuum pressure (i.e., a pressure of about 94 kPa [13.7 psia]) several times over a 12- to 24-hour period. The length of these cycles depends on the chamber size and vacuum pump capacity. The second process involves drawing an extreme vacuum (about 0.6 kPa [0.1 psia]) in the chamber and holding the vacuum for 24 to 48 hours.

Some commercial sterilization facilities with small sterilizers (less than 1 m^3 [40 ft^3]) use aeration chambers (or cabinets), which are similar to the sterilization chambers in size and design. These facilities typically aerate products for about 24 hours.

3.2.2 Single-Item Sterilization System

Four of the 196 commercial sterilization facilities represented in the 1989 EPA CS data base (2 percent) reported the use of a single-item sterilization system.[1,2] Three of these facilities use the Sterijet® system manufactured by H. W. Andersen Products; one facility uses another patented system that is similar to the Sterijet® system.[2] In contrast to the bulk sterilization chambers used by most commercial sterilization facilities, these systems are designed to sterilize

small individual items (such as medical equipment supplies) in sealed pouches. Marketing of these systems is primarily focused on hospital sterilization.[15]

These single-item sterilization systems consist of (1) a machine that delivers the sterilant gas through a nozzle, (2) flexible plastic pouches, and (3) an aeration cabinet. The process involves the following steps. The product to be sterilized is placed in a plastic pouch. With the open ends of the pouch sealed around the nozzle, a slight vacuum is drawn in the pouch followed by injection of a premeasured quantity of sterilant gas. The amount of sterilant gas injected depends on the size of the pouch. After the gas is injected, the nozzle is automatically withdrawn, and the pouch is heat sealed. The sealed pouches are placed directly into an aeration cabinet or temperature-controlled aeration room. The enclosed product is sterilized prior to the escape of the gas through the pouch, which is designed to retain the EO long enough to ensure proper sterilization. The products are sterilized for approximately 12 hours at about 50°C (122°F) and aerated for 36 hours.[15]

Another type of single item sterilization system consists of (1) ampule-delivered EO sterilant gas, (2) flexible plastic pouches, (3) a sterilization cabinet, and (4) an optional aeration cabinet.[16] This process involves the following steps. The product to be sterilized is wrapped in gas permeable packaging and placed in a plastic pouch along with an ampule containing the sterilant gas. The pouch is placed in the sterilization cabinet, and the ampule is broken to release the sterilant gas. The pouch is then sealed, and the cabinet closed to allow sufficient time for sterilization of the materials. After the sterilization cycle is complete, the cabinet door and plastic pouch are opened, and the materials are unloaded. Depending on the characteristics of the materials sterilized, they may be placed in an aeration cabinet to allow for the offgassing of residual EO. The products are typically sterilized for approximately 12 hours at room temperature and atmospheric

pressure, and aerated for approximately 12 hours at 50°C (122°F) at atmospheric pressure (if an aeration cabinet is used).[16]

At least one vendor does offer an optional or retrofit ventilation hood to control worker exposure to EO when loading/unloading the sterilizer, and while sterilization occurs. This device causes fresh air to be pulled past the chamber by a roof-mounted blower; however, this system does not provide any evacuation of the sterilization cabinet itself.[16]

3.2.3 Spice Fumigators

The process for spice fumigators is essentially the same as bulk sterilization.[17] The spices are typically stored in fiber drums lined with a plastic insert, which is closed with twist tie; lids are then placed on the drums. Alternatively, the spices may be stored in large bags or totes. The drums, bags, or totes are loaded into the sterilization chamber on wooden pallets, typically via a conveyor. Depending on how densely packed the spice is, a long, hollow spike punctured with many holes may be driven into the spice to allow the EO to penetrate through the bag drum, or tote. Ethylene oxide is then added to the chamber. The length of the sterilization cycle depends on the product's susceptibility to adequate kill rates. Ethylene oxide's effectiveness is different for different spices. Following evacuation of the sterilization chamber, and subsequent air washes, the spices are removed from the sterilization chamber and placed in an aeration room. Aeration typically takes 2 hours.[17]

3.2.4 Library and Museum Fumigators

Library and museum fumigation is accomplished using essentially the same process as for bulk sterilization. However, the amount of ethylene oxide used each year by these facilities is much lower than that used by the typical bulk sterilizers. These library and museum fumigators are typically operated only one to two times a month.[18-21] Additionally, several museums and libraries are discontinuing their use of ethylene oxide for fumigation because of (1) the recent OSHA worker exposure regulations and (2) problems associated with the long aeration

times needed when fumigating organic materials with EO (most museums and libraries do not have the space needed for adequate aeration of organic materials, such as wood [up to 1 month], because these materials readily absorb much of the EO used in the fumigation process).[22-24] Some museums have switched to using sulfuryl fluoride as a fumigant.[22,23] Other museums are accepting objects from other museums and libraries to be fumigated with EO in their fumigator.[25]

3.2.5 Beehive Fumigators

The process for beehive fumigators is essentially the same as bulk sterilization; however, a unique feature of the fumigators warrants a separate discussion. Whereas the sterilization processes described above are performed at one location, the eight State departments of agriculture represented in the EPA sterilization data base use portable chambers to fumigate beehives at numerous and variable locations in each of the six States.[2] The State departments of agriculture use an EO/CO_2 sterilant gas mixture. Typically, a garden hose is connected to the fumigation chamber and is placed along the ground for venting the sterilant gas during the evacuation phase of the sterilization cycle. After the evacuation, the beehive is removed from the chamber and aerated in the open air.

3.3 EMISSION SOURCES

The four principal sources of EO emissions from sterilization/fumigation processes are (1) the sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator), (2) the sterilization chamber vacuum pump drain (assuming that a once-through, water-ring vacuum pump is used), (3) the chamber exhaust vent(s), and (4) the aeration room vent(s). A schematic of these emission sources is shown in Figure 3-4. Other potential emission sources are equipment leaks and storage and handling. (For the purposes of developing emission estimates, and because bulk sterilization processes are the main source of emissions, emission sources were assumed to be the same for all stationary sterilization processes [i.e., bulk and single-item and the 55-gallon drums]).

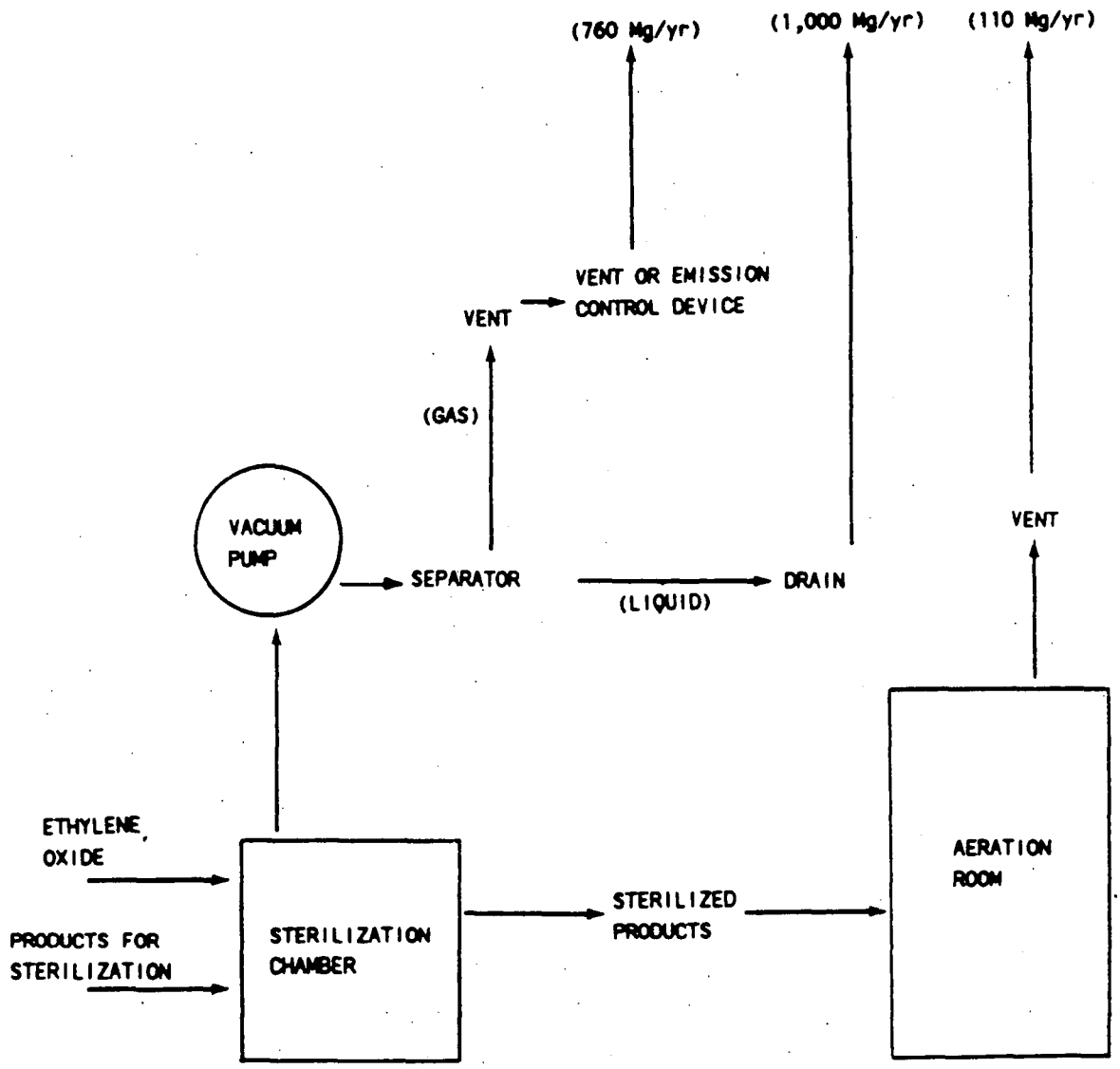

Figure 3-4. Schematic of emission sources at commercial sterilization facilities.

3.3.1 Sterilization Chamber Vents

Sterilization chamber vent emissions are dependent on the type of vacuum pump used to evacuate the sterilizer. Once-through, liquid-ring design vacuum pumps that use water as the working fluid discharge a mixture of chamber gas and water to a centrifugal gas/liquid separator. In the separator, gaseous EO is directed to a vent and emitted to the atmosphere. The liquids from the separator are discharged to a drain. (Full-sealant recovery [i.e., oil-sealed or recirculating water] vacuum pumps do not produce drain emissions of EO.) Sterilizer vent emissions also include emissions associated with venting the chamber from a positive pressure before evacuating with a vacuum pump.

3.3.2 Sterilization Chamber Vacuum Pump Drains

If a once-through, water-ring vacuum pump is used to evacuate the chamber, some of the EO evacuated from the chamber enters the liquid-phase separator line with the vacuum pump water. Although some EO may be hydrolyzed to ethylene glycol, the conversion rate at ambient temperatures is extremely slow, requiring weeks for completion (see Figure 3-5).[8] Also, EO is rapidly released from an aqueous solution when agitated.[26] Therefore, virtually all of the EO that dissolves in the vacuum pump water is emitted from the water. The absorbed EO may be released at the 1-inch air break between the liquid pipe and drain (required by local plumbing codes) or may diffuse into other areas of the building as the water passes through the drain system. Any remaining EO would desorb into the head space of the sewer pipes (possibly creating flammable mixtures with air) and be emitted as it passes through the sewer or waste treatment systems.[6,8]

3.3.3 Chamber Exhaust Vent

Chamber exhaust emissions consist of EO that remains in the sterilizer chamber void space (surrounding the product) after the sterilization cycle is completed. Product off-gassing in the sterilizer is a negligible contributor to this emission source.[27] Therefore, the chamber exhaust emissions are assumed to be only EO trapped in the sterilizer void space.

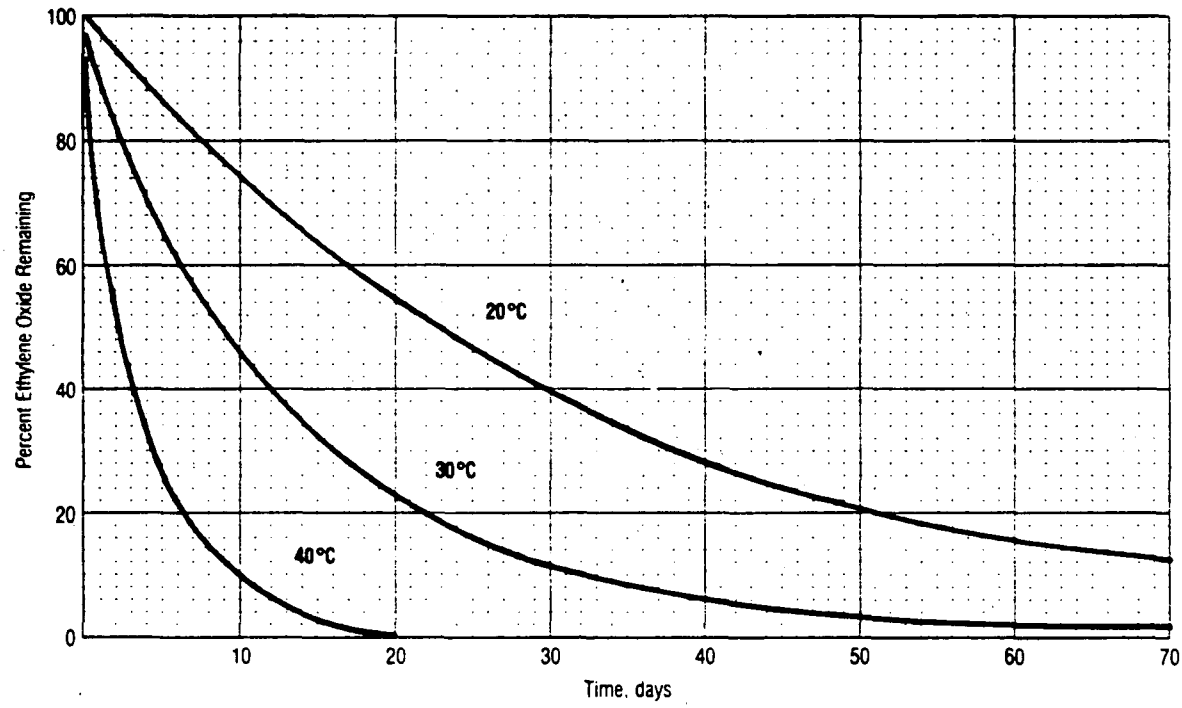

Figure 3-5. Hydrolysis rates of dilute, neutral aqueous solutions of ethylene oxide. (Courtesy of Union Carbide Corporation, Ethylene Oxide/Glycol Division.)[8]

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3.3.4 Aeration Room Vent

All emissions from residual EO in the product are referred to as aeration room vent emissions. As residual EO diffuses out of the sterile products in the aeration room or is emitted to the sterilization room when the chamber door is opened, it is emitted to the atmosphere via room ventilation. High ventilation airflow rates are used to maintain EO concentrations below the OSHA limit.

3.3.5 Equipment Leaks

Although equipment component counts (number of flanges, valves, etc.) were not obtained for the commercial sterilization facilities, observations made during site visits indicated that the number of components is small. However, control of equipment leaks may be important to meet the 1 ppmv OSHA standard. For the purposes of this analysis, equipment leak emissions are assumed to be negligible.

3.3.6 Storage and Handling

Ethylene oxide at commercial sterilization facilities is typically stored in pressurized cylinders rather than bulk containers. Therefore, material losses associated with loading and unloading bulk quantities of EO and storage tank breathing losses would not occur. Although bulk storage of sterilant gas at sterilization facilities is rare, at least one commercial sterilization facility stores bulk quantities of 12/88 in a pressure vessel. During transfer of the 12/88 from the tank truck to the pressure vessel, the vessel and the tank truck are vapor balanced. Therefore, emissions during transfer are expected to be negligible. Also, because the storage tank is a pressure vessel, no emissions should occur during routine operation. Consequently, commercial sterilization facilities are likely to have negligible storage and handling emissions.

3.4 EMISSION ESTIMATES

3.4.1 Commercial Sterilization Facilities

The emission estimate for commercial sterilization facilities is based on the facility-specific annual EO usages and emission control levels reported in the 196 responses to the HIMA survey, the 1986 EPA ICR, and the July 1989 Section 114

letter.[1,2] Eight of the 196 facilities are State departments of agriculture that operate a total of 10 mobile beehive fumigator units; these units are not included in these or subsequent analyses unless otherwise stated. (These 10 fumigation units use a total of 0.46 megagrams per year (Mg/yr) (1,015 pounds per year [lb/yr]) of EO, all of which is reportedly uncontrolled.) Average EO emissions from the remaining 188 commercial sterilization facilities, based on total sterilizer volume, are presented in Table 3-6. The total amount of EO used by these 188 commercial sterilization facilities is 1,920 Mg/yr (4.23 million lb/yr); approximately 42 percent (i.e., 809 Mg/yr [1.78 million lb/yr]) of this amount is controlled. Therefore, the EO emission estimate for the 188 facilities represented in the 1989 EPA CS data base is 1,111 Mg/yr (2.45 million lb/yr).[1-4] Of this amount, it is estimated that 667 Mg/yr (1.47 million lb/yr) are emitted from sterilizer vents; 312 Mg/yr (688,000 lb/yr) are emitted from sterilization chamber vacuum pump drains; 38 Mg/yr (84,000 lb/yr) are emitted from chamber exhaust vents; and 57 Mg/yr (126,000 lb/yr) are emitted from aeration room vents (see Figure 3-4). These estimates were developed using the HIMA survey, the EPA ICR responses, the Section 114 letter (July 1988 and July 1989) responses, and the following assumptions:

1. All of the EO used in the sterilization process is evacuated from the sterilization chamber or released from the product during postevacuation processes.

2. Within each facility, EO emissions are distributed among four emission points. The four emission points and the percentage of total EO emissions allocated to each are:

a. Sterilizer vent(s)--50 percent;

b. Sterilization chamber vacuum pump drain (if applicable)--45 percent;

c. Chamber exhaust vent(s)--2 percent; and

d. Aeration room vent(s)--3 percent.

This 50/45/2/3-percent split is based on industry estimates, limited test data, and engineering judgment.[28,29]

TABLE 3-6. AVERAGE EMISSIONS FROM COMMERCIAL STERILIZATION FACILITIES--EPA COMMERCIAL STERILIZATION DATA BASE[1-4]

Total chamber volume at facility, m^3 (ft^3)	No. of facilities	Mean EO use, kg/yr (lb/yr)	Mean EO emissions, kg/yr (lb/yr)[a] [b]
<11 (<400)	87	580 (1,300)	520 (1,200)
11-56 (400-2,000)	71	6,500 (14,000)	4,200 (9,300)
>56 (>2,000)	38	37,000 (82,000)	20,000 (45,000)

[a]Mean emissions are less than mean EO use because of existing controls.
[b]Emissions from all sources (i.e., sterilizer vent, vacuum pump drain, aeration).

3. For the uncontrolled sterilization chambers, all of the EO that enters the chamber (except 3 percent, if the aeration room is controlled) is released to the atmosphere. For the 79 sterilization chambers with emission control devices, the chamber vent emissions are assumed to be controlled at the following efficiencies:

a. 99.0 percent for acid/water scrubbers and catalytic oxidizers;

b. 99.0 percent for flares (given the chemical/ physical characteristics of ethylene oxide, its high combustability, and the extremely weak nature of the oxide bond, it is reasonable to assume that emissions of ethylene oxide will be controlled at an efficiency of 99 percent in flares rather than the generally EPA-accepted efficiency for flares of 98 percent); and

c. The facility-reported efficiency for other control devices.

4. All facilities that control sterilizer vent emissions with acid/water scrubbing, catalytic oxidation, flaring, or condensation/ reclamation control devices are assumed to have recirculating-fluid vacuum pumps and, thus, no drain emissions from those chambers. (One facility that uses a different control technology than those described above is assumed to have a once-through water-sealed pump). All uncontrolled facilities are assumed to have once-through water-sealed pumps unless data are available to indicate otherwise.

5. At facilities that have once-through water-sealed vacuum pumps, all of the EO that dissolves in the vacuum pump water subsequently enters the drain and is assumed to be emitted uncontrolled to the atmosphere at an outdoor ground-level drain near the facility. This assumption is consistent with test data that suggest EO is rapidly released from an aqueous solution when agitated.[26]

6. Facilities that have a total sterilizer volume greater than 7 m^3 (>250 ft^3) are assumed to have chamber exhausts on all sterilizers. Chamber exhaust emissions are assumed to equal

2 percent of the total EO use and to be released uncontrolled to the atmosphere.[29]

7. At each facility (except for three facilities that have aeration room controls), all of the EO that enters the aeration room(s) vent is released uncontrolled to the atmosphere.

3.5 CURRENT REGULATIONS

3.5.1 Occupational Safety and Health Administration Standard

In 1984, OSHA established a permissible exposure limit for occupational exposure to EO of 1 ppmv determined as an 8-hour time-weighted average (TWA) concentration. In addition, an action level of 0.5 ppmv as an 8-hour TWA was established as the level above which employers must monitor employee exposure.[30] In April 1988, OSHA established a short-term excursion limit (EL) for occupational exposure to EO emissions of 5 ppmv averaged over a 15-minute sampling period.[31]

3.5.2 State Regulations

Existing State regulations for EO are summarized in Table 3-7. Several States are currently regulating EO or developing air toxics programs.[32-38]

TABLE 3-7. STATE REGULATIONS FOR ETHYLENE OXIDE EMISSIONS[22-28]

State	Regulatory description
California[a]	• Control is based on annual EO usage

Annual usage, lb	Sterilizer control	Aeration control
<25	No control	No control
25-600	99%	No control
600-5,000	99.9%	95%
>5,000	99.9%	99%

State	Regulatory description
Colorado	• Regulate as a volatile organic compound (VOC).
	• Reasonably available control technology (RACT) required for new sources.
Connecticut	• Best available control technology (BACT) required for all new or modified sources exceeding a maximum allowable stack concentration (MASC).
	• MASC is calculated using exhaust gas flow rate, stack height, and the distance from the discharge point to the property line. MASC would be exceeded for industrial sterilizers using typical sterilization cycles. Therefore, BACT required on new or modified sources. Existing sources exceeding the maximum allowable ambient concentration of 0.01 ppm have 3 years to comply with orders given by the Connecticut Department of Environmental Protection.
Florida[a]	• Maximum risk level of 10^{-6} for new or modified sources.
Michigan[a]	• BACT for all new sources. Requires emissions be indectable or subjected to risk analysis (maximum allowable risk level is 10^{-6}). For industrial sterilizers using typical sterilization cycles, a control efficiency based on a risk assessment analysis would be greater than 99 percent by weight.
Missouri	• Regulate as a VOC.
New Jersey	• Regulate as a VOC.
	• BACT required for new or modified sources.
New York[b]	• New or modified sources must receive 99 percent control or greater, or BACT (also at permit reviews)
	• Maximum annual impact must not exceed guideline Acceptable Ambient Level (AAL) of 6.67 $\mu g/m^3$ (a revised AAL of 0.019 $\mu g/m^3$ is anticipated for the next edition of Air Guide-1 [to be released by 01/90].
	• Certificate of operation includes the following statement: "Should significant new scientific evidence from a recognized institution result in the decision by DEC that lower ambient levels must be established, it may be necessary to reduce emissions from this source prior to the expiration of this Certification of Operation."
Oklahoma	• Maximum ambient air concentration at property line is 1/100 of TLV.
Puerto Rico	• Regulate as a VOC.
	• Emission controls required for emissions greater than 3 lb/h or 15 lb/d.
Rhode Island[b]	• Maximum risk level of 10^{-6} for new and existing sources.
	• If BACT is used, may consider 10^{-5} risk level.
Tennessee	• Regulate under standards for process and nonprocess emissions.
Texas	• BACT required for all new sources.
Utah	• BACT required for all new or modified sources. BACT requirements to go into effect for existing sources.
	• Following the programs developed in New York.
Vermont	• Regulate as a VOC.
Virginia	• For any 24-hour concentration exceeding 1/100 of the TLV-TWA both existing and new facilities are required to control emissions as directed by the Virginia Air Pollution Control Board.
Wyoming	• BACT required for all new sources.
	• Controls must meet AAL at property line.

[a]Information obtained from State contacts in May 1990.
[b]Information obtained from State contacts in February 1989. All other information is from 1986 through 1987 data.

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4.0 EMISSION CONTROL TECHNIQUES

This chapter describes the techniques available to control ethylene oxide (EO) emissions from bulk sterilization and single-item sterilization processes. Alternatives to EO sterilization, retrofit considerations, and the impacts of chlorofluorocarbon (CFC) regulation on EO emission controls are also discussed.

4.1 BULK STERILIZATION PROCESSES

Discussed below are techniques available to control emissions of ethylene oxide (EO) from the four principal sources of emissions from bulk sterilization processes:

1. The sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
2. The sterilization chamber vacuum pump drain;
3. The chamber exhaust vent; and
4. The aeration room vent.

4.1.1 Sterilization Chamber Vent Emissions

Three primary techniques are used to control EO emissions from sterilizer vents: hydrolysis, oxidation, and condensation. Ethylene oxide is catalytically hydrolyzed to form ethylene glycol; thermal or catalytic oxidation decomposes EO into carbon dioxide and water; and condensation allows the recovery of the sterilant gas mixture. A fourth control technique for sterilizer vents is a gas/solid reactor system that chemically reacts with EO and binds it to the solid packing of the reactor.[1]

Table 4-1 shows the emission control techniques and devices for sterilizer vent emissions used by the controlled facilities represented in the EPA data base (refer to Chapter 3 for a description of the contents and origin of the data base). Forty of the 188 commercial sterilization facilities (21 percent) in

TABLE 4-1. ETHYLENE OXIDE EMISSION CONTROL DEVICES FOR STERILIZER VENTS--EPA COMMERCIAL STERILIZATION DATA BASE[2,3,5]

Emission control technique and device	Control efficiency, (percent)[a]	No. of facilities (percent)	No. of chambers (percent)	Cumulative chamber size, m^3 (ft^3)	EO usage/facility, Mg/yr (lb/yr)
Hydrolysis					
Packed scrubber	99.0[b]	21 (11)	78 (19)	7 - 274 (350 - 9,900)	0.8 - 84 (1,800 - 180,000)
Reaction/detoxification tower	99.0[b]	7 (4)	15(4)	8 - 45 (300 - 1,600)	2.1 - 49 (5,000 - 110,000)
Caustic scrubber	50	1 (0.5)	2 (0.5)	9 (320)	0.2 (400)
Oxidation					
Flare	98.0[c]	3 (2)	6 (1.5)	11 - 229 (400 - 8,180)	25 - 90 (54,000 - 197,000)
Catalytic oxidizer	99.0	2 (1)	2 (0.5)	4 - 18 (130 - 660)	0.5 - 7 (1,000 - 15,000)
Condensation					
Condensation/ reclamation system	50.0 - 83.0	6 (3)	16 (4)	32 - 132 (1,160 - 4,720)	7 - 127 (15,000 - 280,000)
Total		40 (21)[d]	119 (29)[e]		1,020 (2,240,000)[f]

[a]Control efficiencies are those reported by the 188 commercial sterilization facilities represented in the EPA data base and are not necessarily supported by EPA-sponsored test data.

[b]Although the 21 commercial sterilization facilities that use scrubbers reported control efficiencies ranging from 96.0 to 99.9 percent, a detailed review of the available test data for acid-water scrubbers indicates that 99.0 percent is the maximum removal efficiency that can be achieved on a continuous basis.[16]

[c]Although the two commercial sterilization facilities that use flares reported destruction efficiencies of 99.0 and 99.7 percent, the EPA's position is that flares operated within specified conditions of waste gas heat content and flare exit velocity will achieve at least 98 percent destruction efficiency.[25]

[d]Total number of facilities = 188.

[e]Total number of chambers = 404.

[f]Represents 53 percent of the total EO used by the 188 commercial sterilization facilities represented in the EPA data base.

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the data base reported the use of a control device for sterilizer vent emissions. Twenty-eight of these 40 facilities use one emission control device for multiple chambers by manifolding the chamber vents and staggering the evacuation of the sterilant gas from the chambers. The remaining 12 facilities control emissions from single chambers.[2-5]

Nine additional commercial sterilization facilities reported the use of a neutral-water scrubber to control EO vent emissions. Neutral-water scrubbers reduce EO vent emissions by "washing" a portion of the EO to the drain (facilities reported 20 to 100 percent of the total EO emissions from the sterilizer chamber were "controlled" by a neutral-water scrubber).[2-5] Some of the EO that is washed to the drain may be converted by hydrolysis to ethylene glycol; however, the conversion rate of EO to ethylene glycol in neutral water at ambient temperatures is extremely slow, requiring weeks for completion.[6] Since EO is rapidly released from an aqueous solution when agitated, the vast majority of the EO washed to the drain is expected to off-gas uncontrolled from the air break in the drain line, sewer lines, or the waste water treatment system.[6-8] Because the use of neutral-water scrubbers merely changes the EO emission source, these scrubbers are not discussed here as a control technique.

4.1.1.1 <u>Hydrolysis</u>. Hydrolysis is the most common EO emission control technique used by commercial sterilization facilities.[2-5] This technique is applicable for both pure EO and EO/inert gas mixtures such as 12/88 (12 percent by weight EO and 88 percent by weight dichlorodifluoromethane [CFC-12]) and 10/90 (10 percent by weight EO and 90 percent by weight carbon dioxide [CO_2]).

Ethylene oxide can be hydrolyzed under relatively mild conditions to ethylene glycol products (without affecting the inert gas) as shown in the following reaction:

$$C_2H_4O + H_2O \xrightarrow[H+ \text{ or } OH-]{} HOCH_2CH_2OH + HO(CH_2CH_2)_nOH$$

Ethylene oxide	Ethylene glycol	Polyethylene glycols

Ethylene oxide will hydrolyze in neutral water, but this reaction is very slow. (The half-life of EO in neutral water at ambient temperatures is approximately 14 days.)[8] The reaction rate is increased in an acidic or basic solution. The reaction is approximately two orders of magnitude faster under acidic conditions than under basic conditions, making acid hydrolysis the preferred method. Twenty-eight of the 188 commercial sterilization facilities represented in the EPA data base reported using acid-water scrubbers; one facility reported using caustic scrubbers to control EO emissions.[2-5]

4.1.1.1.1 Packed scrubbers. Figure 4-1 is a schematic of a packed scrubbing system used to control EO emissions. The system consists of a countercurrent packed tower, a reaction vessel, and a holding tank. In the countercurrent tower, the sterilant gas is contacted with an acidic water solution, generally aqueous sulfuric acid. Because EO is extremely water soluble, most of the EO is absorbed into the scrubber liquor. Next, the liquor is sent to the reactor vessel, which is a small storage tank operated at atmospheric pressure, to complete the hydrolysis of EO. After the reaction is complete, the liquor is sent to the storage vessel. The liquor in the storage vessel is recirculated to operate the tower until the concentration of the ethylene glycol in the liquor reaches a predetermined weight percentage, past which point the scrubber efficiency declines. Manufacturers of packed scrubbing systems suggest that the scrubbing liquor is spent when the solution is 30 to 40 percent by weight ethylene glycol.[9,10] Possible methods of determining when the liquor needs replacing include liquid level indicators or specific gravity detectors in the tank. (Both parameters increase as the amount of ethylene glycol increases.) Alternatively, the amount of EO charged to the sterilizer can be used to determine the liquor changeout point. The spent solution is neutralized and

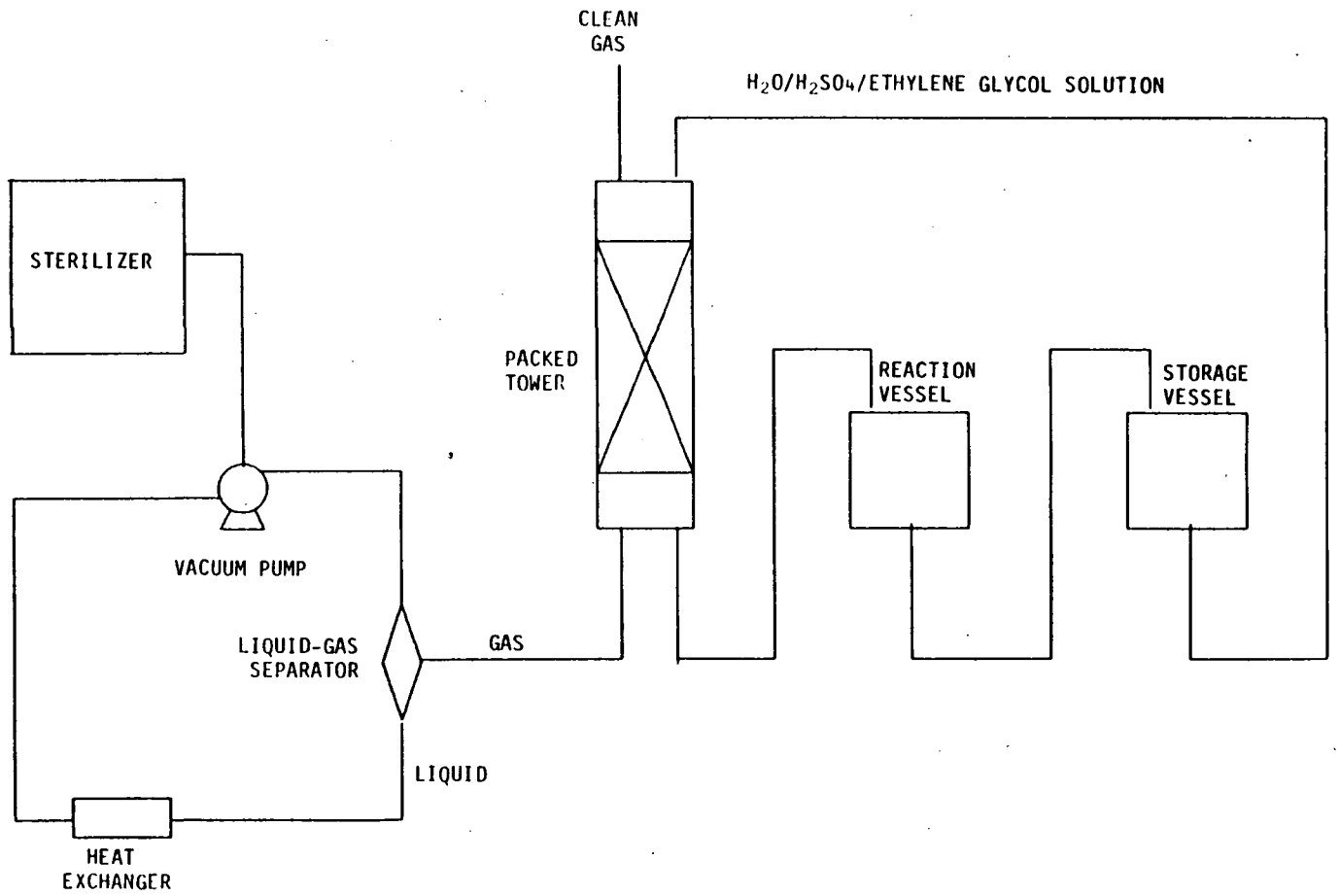

Figure 4-1. Countercurrent packed scrubbing system.

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then disposed or sold. (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Generally, sodium hydroxide is used to neutralize the glycol solution; sodium carbonate can also be used.

Countercurrent packed scrubbers are used by commercial sterilization facilities with sterilizers ranging from 1.1 cubic meters (m^3) (40 cubic feet [ft^3]) to 170 m^3 (6,000 ft^3). Ethylene oxide use at these commercial sterilization facilities ranges from 0.8 megagrams per year (Mg/yr) (2,000 pounds per year [lb/yr]) to 84 Mg/yr (180,000 lb/yr).[2,3,5]

Manufacturers of countercurrent packed scrubbers designed to control EO emissions from sterilizer vents claim EO removal efficiencies greater than 99 percent.[1,9,11] For a 12/88 sterilant-gas mixture, the average EO removal efficiency for three tests was 99.0 percent by weight (individual test results were 99.0, 98.7, and 99.4 percent).[12] These tests were conducted using a scrubber that was designed to achieve an EO removal efficiency of 99 percent. A representative from the manufacturer of the tested acid-water scrubber stated that the company can design scrubbers to achieve virtually any EO removal efficiency with any type of sterilant gas.[13] The results of an EPA-sponsored test on another acid-water scrubber designed by this company indicated an EO removal efficiency greater than 99.9 percent for 12/88.[14] For pure EO, the EO removal efficiency was greater than 99.98 percent for each of four tests performed at two facilities.[12,15] However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved on a continuous basis based on limited data at various EO concentrations.[16]

4.1.1.1.2 <u>Reaction/detoxification towers</u>. Another acid hydrolysis scrubbing technique for EO emission control is a reaction, or detoxification, tower. A schematic of this system is shown in Figure 4-2. The reaction/detoxification tank holds a sulfuric acid solution of pH 0.5 to 2.5. As the sterilant gas bubbles upward through the acidic liquor, EO is absorbed, and catalytically hydrolyzed to ethylene glycol. The gas stream then

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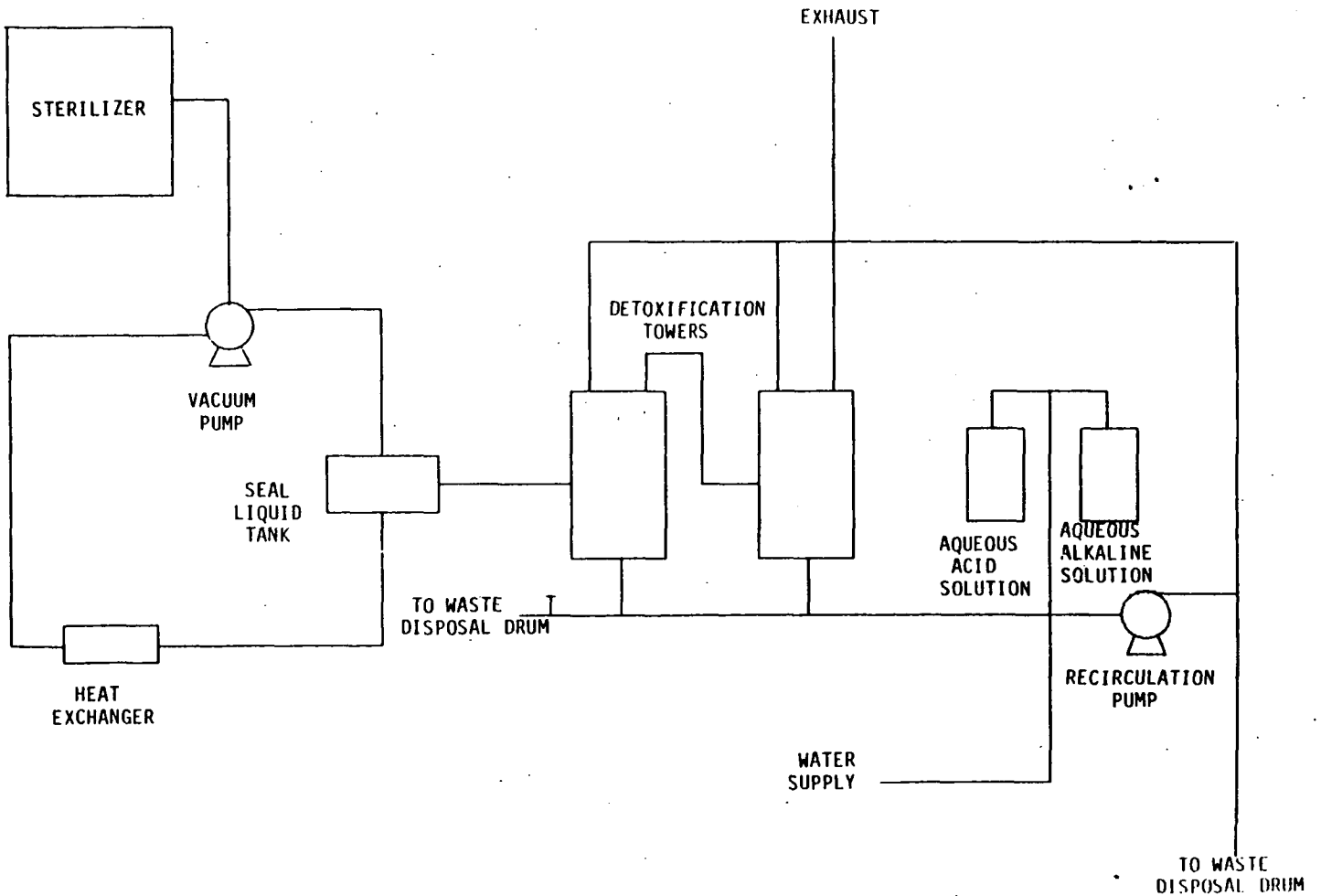

Figure 4-2. Detoxification tower control system.

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flows through the liquid surface and a demister. The demisting pad prevents acid mist from exiting with the scrubbed gas and provides a final hydrolysis reaction site for any EO remaining in the gas stream. Inert gases (i.e., CFC-12 and CO_2) are exhausted unreacted to the atmosphere. After ethylene glycol builds up in the stream to a maximum recommended level of 60 percent, the scrubber liquor is neutralized and disposed or sold.[17] (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Possible methods of determining the scrubbing liquor changeout point include (1) using liquid level indicators, (2) using specific gravity detectors, and (3) measuring the amount of EO charged to the sterilizer. Reaction towers have been installed for chambers ranging from 1.4 m^3 (50 ft^3) to 45 m^3 (1,600 ft^3).[18,19] Seven of the 188 commercial sterilization facilities represented in EPA's data base use reaction towers to control EO emissions from sterilizer vents. The sterilizers at these seven facilities range in volume from 4 m^3 (140 ft^3) to 27 m^3 (960 ft^3). Annual ethylene oxide use at these seven facilities ranges from 2.1 Mg (5,000 lb) to 49 Mg (110,000 lb).[2,3,5]

Manufacturers of reaction/detoxification towers claim 99+ percent EO removal efficiency by weight.[18,20] Third-party laboratory test results indicate that EO emission reductions greater than 99.8 percent can be achieved with reaction towers.[19] However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved by acid hydrolysis techniques on a continuous basis.[16]

4.1.1.1.3 <u>Waste disposal</u>. The spent liquor from acid hydrolysis of EO is typically 40 to 60 weight percent ethylene glycol and has a pH of 0.5 to 2.0. Because of the low pH, the solution is considered a hazardous waste and thus, requires special handling procedures for shipping. However, the spent liquor can easily be neutralized with sodium hydroxide (caustic) prior to disposal. Two recovery companies have been identified that are willing to purchase the aqueous ethylene glycol

solution.[21,22] Both of these companies require that sodium hydroxide be used for neutralization and will pick up the solution at the sterilization facility. A third recovery company will accept the spent scrubbing solution on a no cost/no payment basis, except for shipping charges.[23] Neutralized scrubbing solution may also be disposed to a landfill or incinerator.

4.1.1.2 Oxidation. Two methods of oxidizing EO are (1) thermal oxidation with flares and (2) catalytic oxidation with a solid-phase catalyst.

4.1.1.2.1 Thermal oxidation. Ethylene oxide, which has a high heating value, a relatively low ignition temperature, and a very wide range of mixtures combustible in air (see Table 3-4), can be easily and efficiently destroyed by thermal oxidation using flares. Thermal oxidation of EO produces carbon dioxide and water as follows:

$$2\ C_2H_4O + 5\ O_2 \xrightarrow[\text{thermal oxidation}]{} 4\ CO_2 + 4\ H_2O$$

Three of the 188 commercial sterilization facilities represented in the EPA data base reported using flares to control EO emissions when pure EO was used as a sterilant gas.[2,5] One of these facilities has one 76.7-m^3 (2,710-ft^3) chamber and uses 26 Mg (57,000 lb) of EO per year. Another facility has three chambers ranging in size from 75.2 to 76.9 m^3 (2,655 to 2,715 ft^3) and one smaller 1.7-m^3 (60-ft^3) chamber; this facility uses 89 Mg/yr (197,000 lb/yr) of EO.[2] The third facility has one 11-m^3 (400-ft^3) chamber and uses 25 Mg/yr (54,000 lb/yr) of EO.[5] Because of difficulties with sustaining combustion, commercially available flares are not applicable for facilities emitting only small amounts of EO.

A manufacturer of flare burners for the control of EO emissions claims greater than 99-percent control efficiency for pure EO, but no data were provided to substantiate this claim.[24] The EPA's position is that flares operated within specified

conditions of waste gas heat content and flare exit velocity will achieve at least 98-percent destruction efficiency.[25]

Flares can also be used with EO/CO_2 sterilant gas mixtures (e.g., 10/90) but are not designed for use with EO/CFC-12 mixtures (e.g., 12/88).[24,26] The EPA has not in the past and does not now recommend the use of flares to control emission streams containing halogenated compounds (e.g., CFC-12) because corrosive or toxic byproducts may form. As shown below, thermal oxidation of CFC-12 may produce the following corrosive or toxic byproducts at the high temperatures (400° to 800°C [800° to 1500°F]) associated with the use of flares:

$$CF_2Cl_2 + O_2 \xrightarrow{\text{thermal oxidation}} \begin{array}{ll} COCl_2 & \text{Phosgene} \\ COF_2 & \text{Carbonyl fluoride} \\ HCl & \text{Hydrogen chloride} \\ HF & \text{Hydrogen fluoride} \\ CF_4 & \text{Carbon tetrafluoride} \\ Cl_2 & \text{Chlorine} \\ CO & \text{Carbon monoxide} \end{array}$$

CFC-12

4.1.1.2.2 Catalytic oxidation. Catalytic oxidation of EO occurs in the presence of a solid-phase catalyst as follows:

$$2\ C_2H_4O + 5\ O_2 \xrightarrow[\text{catalytic oxidation}]{} 4\ CO_2 + 4\ H_2O$$

This control technique is applicable to pure EO, EO/CO_2 mixtures, and EO/CFC-12 mixtures. The CFC-12 does not react at the temperatures (150° to 180°C [300° to 350°F]) that occur during catalytic oxidation, and, therefore, the toxic CFC byproducts that result from the higher temperatures associated with thermal oxidation are not produced. During an EPA-sponsored test of a catalytic oxidation unit, no CFC decomposition byproducts were detected; the detection limit was 200 parts per billion (ppb) for the analyte chloride ion. The maximum operating temperature of the unit during testing was 155°C (311°F).[27]

A schematic of a catalytic oxidizer is shown in Figure 4-3. The spent sterilizer gas is first mixed with a large volume of air to reduce the control device inlet EO concentration to 5,000 parts per million by volume (ppmv) or less. This dilution

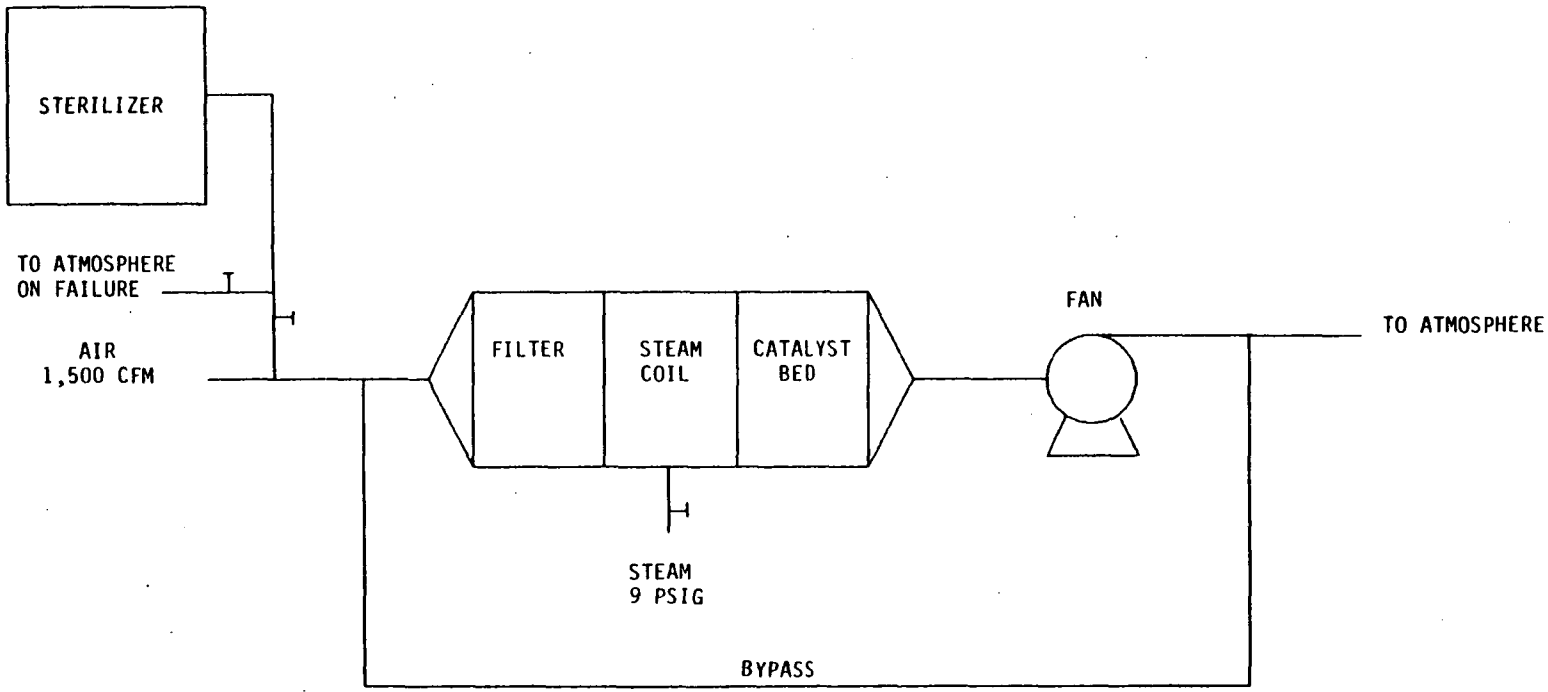

Figure 4-3. Catalytic oxidation system.

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prevents excessive catalyst bed temperatures (which can damage the catalyst) from occurring during the oxidation of EO. The gas stream passes through a filter for dust removal and then is preheated to the reaction temperature with steam or electricity. The gas then enters the catalyst bed(s), where the EO is oxidized. Part of the exiting gas stream may be recycled for heat recovery before being vented to the atmosphere. One manufacturer also sells a catalytic oxidizer that uses excess catalyst, instead of diluent air, to absorb the heat of oxidation.[28] Because of cost considerations, the excess-catalyst system has been used, thus far, only for chambers less than 1 m^3 [40 ft^3]) in volume.[28]

Two of the 188 commercial sterilization facilities represented in the EPA data base reported the use of a catalytic oxidizer to control EO emissions from the chamber vent.[2,4] One facility has one 4-m^3 (130-ft^3) chamber and uses 0.5 Mg/yr (1,000 lb/yr) of EO in an EO/CO_2 sterilant-gas mixture.[2] The other facility has an 18-m^3 (600-ft^3) sterilizer and uses 7 Mg (15,000 lb) of EO annually; the EO concentration to the control unit at this facility is regulated by throttles.[4]

Because catalytic oxidation is applicable to the control of low EO concentrations, facilities can manifold other EO emission sources (e.g., aeration chambers or rooms, sterilizer hood and door vent, and the gas cylinder room) to the control device. In addition, if the catalytic oxidizer requires diluent air, these low-concentration emission sources can provide part or all of the necessary diluent.

Manufacturers of catalytic oxidation units claim EO destruction efficiencies greater than 99.9 percent.[29,30] Third-party testing and an EPA-sponsored test support these claims for small (<0.85 m^3 [<30 ft^3]) sterilizers.[27,29]

4.1.1.3 Condensation/Reclamation Systems. Recovery of sterilant gas mixtures is possible using a reclamation system. The sterilant gas mixtures will condense under conditions of

reduced temperature and increased pressure, but precautions are necessary to avoid explosions.

Figure 4-4 is a schematic of a condensation/reclamation system for a 12/88 sterilant-gas mixture. (See Table 3-4 for physical and chemical properties of CFC-12.) After each sterilization cycle, the 12/88 gas is withdrawn and passed through one of the two desiccant beds next to the chamber. (One of the desiccant beds is regenerated while the other is in use.) The dried 12/88 gas then passes to a compressor where it is compressed to 345 kilopascals (65 psia) to improve condensation efficiency.[31] The compressed gas is piped to a separate explosion-proof room, where it passes through a pressurized condenser that is chilled by ethylene glycol to about -18°C (0°F).[31] The liquid 12/88 mixture is collected in a pressurized, chilled holding tank. The noncondensed gas is recirculated to the chamber and back through the condenser. The liquid collected in the holding tank is transferred to a pressurized reblending tank where the liquid is mixed and its composition determined by infrared analysis. The liquid is then adjusted to the 12/88 (weight percent) ratio by adding the necessary amount of EO or CFC-12. When the correct ratio is obtained, the liquid is transferred to a pressurized storage tank in the chamber room.[31]

Although the reclamation cycle could be continued indefinitely, the amount of EO recovered declines to the point where it is not cost effective to continue the reclamation cycle after about three passes through the system (i.e., typically 60 to 90 minutes). The majority of the EO (80 to 85 percent) is recovered during this time. Also, increasing the reclamation time would require that products spend additional time in the sterilizer and could affect the plant's operating schedule. However, even if the reclamation time was increased, this system is not designed for low EO concentrations. Therefore, if this type of control system is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete.

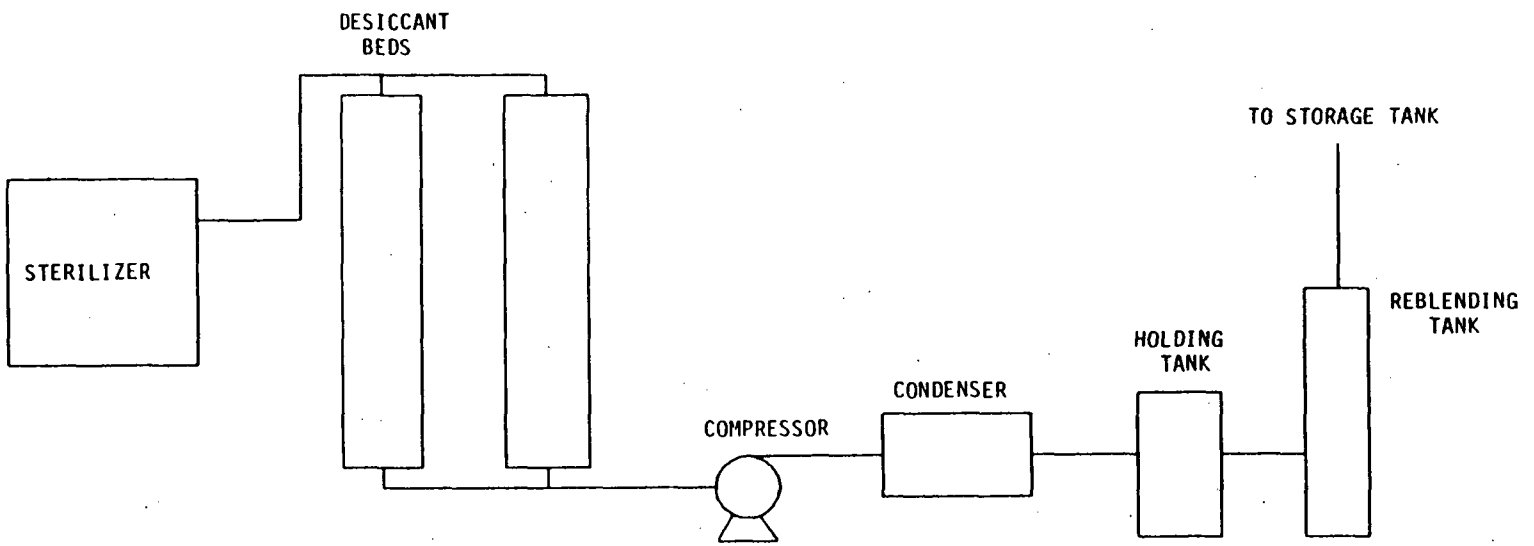

Figure 4-4. Condensation/reclamation system.

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Six of the 188 commercial sterilization facilities represented in the EPA data base reported the use of condensation/reclamation systems; one of these facilities reported an 83-percent EO recovery efficiency, four reported 80 percent, and one reported 50 percent.[2,3,5] These six facilities recover EO/CO_2 and EO/CFC-12 sterilant gases. Five of these facilities use over 23 Mg/yr (50,000 lb/yr) of EO.[2,3,5] The sixth facility uses just over 6.8 Mg/yr (15,000 lb/yr).[2,3] The chamber sizes range from 5 to 45 m^3 (190 to 1,580 ft^3) at these six facilities.[2,3,5]

The condensation/reclamation systems currently available are designed for the high volumetric flow rates of larger, industrial-sized chambers. The systems are not technically or economically feasible for use with smaller chambers or at facilities that use small amounts of EO.

4.1.1.4 Gas/Solid Reactor. A fourth control technique to control vent emissions is a dry, solid-phase system that chemically converts EO and then binds the product to the solid packing.[1] This system is generally paired with an acid water scrubber. The system operates at room temperature. There are no liquid waste streams produced; the solid waste is returned to the vendor for recycling.[32,33] Although the gas/solid reactor can handle high EO concentrations (i.e., >100,000 ppmv) for brief periods of time, it is designed for low concentrations such as the exhaust from an acid-water scrubber. The manufacturer of this device markets a two-stage control system, which consists of an acid-water scrubber and the gas/solid reactor. (The company also sells the stages separately.) The majority of the EO is removed by the scrubber, which is specifically designed for small sterilizers (<2 m^3 [70 ft^3]). The gas/solid reactor removes the residual EO exiting the scrubber and, because it is designed for low EO concentrations, can also be manifolded to other emission sources (e.g., aeration chambers, sterilizer hood and door, and gas cylinder storage room).

The manufacturer of this system claims greater than 99.9 percent efficiency for the gas/solid reactor.[1] However,

this efficiency is based on a test performed with an inlet EO concentration of 140,000 ppmv, which is much higher than the concentration of the scrubber outlet stream. In another test, no EO was detected (with a lower detection limit of 0.1 ppmv) in the gas/solid reactor outlet stream when the inlet stream (i.e., scrubber outlet stream) was 2 ppmv EO.[32] Because of the inherent problems associated with measuring low EO concentrations, the actual efficiency of the system under normal operating conditions presently cannot be determined. (See Section 4.1.3 for a more detailed discussion of measuring low EO concentrations.) However, the maximum removal efficiency that the gas/solid reactor can achieve on a continuous basis is assumed to be 99.0 percent.

4.1.2 Sterilization Chamber Vacuum Pump Drain Emissions

Ethylene oxide drain emissions result from the use of vacuum pumps that use once-through water as the working fluid. Ethylene oxide is infinitely soluble in water, and, therefore, a portion of the EO evacuated from the chamber enters the drain with the vacuum pump water (see Figure 4-5a). The EO that enters the drain with the vacuum pump water is subsequently released uncontrolled from the air break in the drain line, sewer lines, or the waste water treatment plant.[6-8]

The EO drain emissions can be eliminated by replacing the existing once-through vacuum pump with a closed-loop (recirculating-fluid) vacuum pump. The recirculating fluid (sealant) can be water, oil, or ethylene glycol.[34] In this closed-loop system, the water or liquid from the liquid-gas separator is cooled in a heat exchanger and recirculated through the vacuum pump (see Figure 4-5b). Because ethylene oxide is not soluble in oil or ethylene glycol and will off-gas from water as it is recirculated, nearly all of the EO will be emitted through the liquid-gas separator (chamber) vent. (Techniques for control of chamber vent emissions are discussed above.) In addition, mechanical seals are used to eliminate leakage (and, thus, any EO emissions) from the pump.[35]

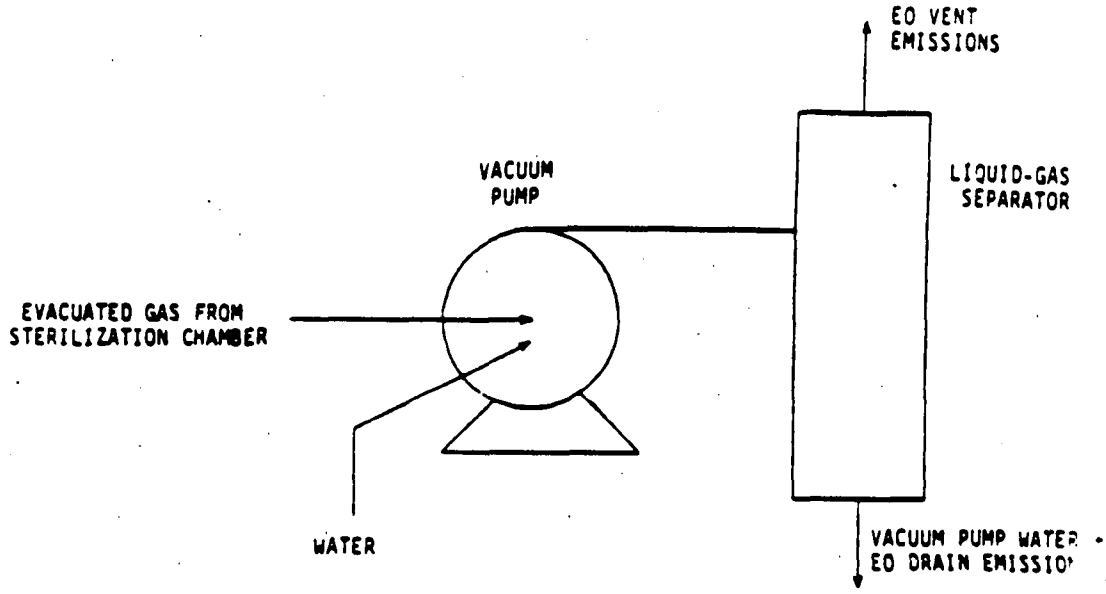

Figure 4-5a. Once-through liquid-ring vacuum pump.

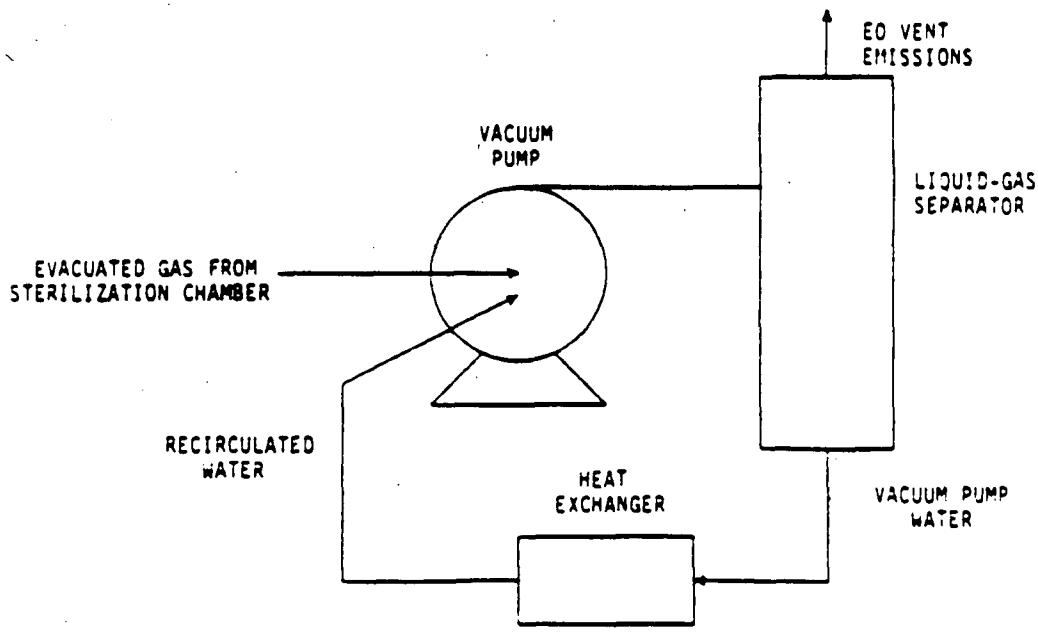

Figure 4-5b. Recirculating liquid-ring vacuum pump.

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Because the sterilization cycle operates under humid conditions, some water will be condensed in the liquid-gas separator and, thus, mix with the liquid sealant in the pump. An overflow collection tank is used to maintain a constant amount of sealant recirculating in the pump.[35] If ethylene glycol is used as the sealant, the contaminated glycol will eventually need to be disposed and replaced with a fresh charge.[35] However, if oil is used as the sealant, the condensed water can be drained off the bottom with minimal oil loss because of the immiscibility of oil and water.[34]

4.1.3 Chamber Exhaust Emissions

Some facilities, in an effort to meet the EO permissible worker exposure level set by the Occupational Safety and Health Administration (OSHA) (see Section 3.5), have installed chamber exhaust vents on sterilizers. The purpose of the exhaust is to quickly dilute EO concentrations in the sterilizer chamber void space and thereby prevent exceedances of exposure limits for workers. Other facilities have installed hoods above the chamber door to reduce worker exposure. At present, there are no data on controlled chamber exhaust emissions in the commercial sterilization data base. As with aeration rooms (see Section 4.1.4.1 for a more detailed discussion), the low-concentration, high-flow-rate exhaust streams of chamber exhausts limit the feasibility and efficiency of add-on controls (particularly thermal oxidation and condensation/reclamation), and the lower detection limit of most analytical methods may make it impossible to determine the efficiency of the control devices at the concentrations typical of the chamber exhaust stream. The same control techniques that are applicable to the control of aeration room emissions (i.e., catalytic oxidation units and gas/solid reactors) may also be applicable to chamber exhaust emissions. In addition, acid/water scrubbers may also be feasible.

The typical chamber exhaust provides a flow rate of 84 m^3/min (3,000 ft^3/min), and the EO concentration in the void volume as the sterilizer door is opened is estimated to be 500 to 15,000 ppmv, depending on sterilizer operating parameters. As

the diluent air enters the chamber, the EO concentration rapidly decreases to below the 1 ppmv OSHA limit. Some EO may evolve from the product during the chamber exhaust cycle, but this amount is negligible when compared to the EO concentration in the void volume.

4.1.3.1 Acid-Water Scrubber. As discussed in Section 4.1.1.1, acid-water scrubbers are commonly used to control sterilizer vent emissions, which have low to moderate flow rates (0.7 to 14 m^3/min [25 to 500 ft^3]) and potentially high EO concentrations (400,000 ppm).[20] Under these conditions, acid-water scrubbers can achieve EO removal efficiencies of 99 percent or greater.[6] While it is technically feasible to control the higher-flow-rate, lower-concentration emissions from the chamber exhaust, the EO removal efficiency of the scrubber may be reduced. The potential decrease in efficiency would be due to decreased residence times of EO in the scrubber and because there would be less EO to react in the scrubbing liquor. Because an acid-water scrubber has never been demonstrated to control chamber exhaust emissions, the control efficiency of the unit under these conditions is unknown.

4.1.3.2 Catalytic Oxidation System. As discussed in Section 4.1.1.2.2, the inlet EO concentration for excess-air catalytic oxidizers is typically reduced to 5,000 ppmv or less, which means that use of this control device could be feasible with chamber exhaust streams. Catalytic oxidation units are also commercially available to handle flow rates from chamber exhausts.[37,38] While no catalytic oxidizers are known to have been installed to control chamber exhaust emissions, units have been installed to control aeration room emissions. As discussed in Section 4.1.4.1, the control efficiency of these units has not been adequately demonstrated.

4.1.3.3 Gas/Solid Reactor. Like the catalytic oxidizers, the gas/solid reactor is designed for low concentration (<100 ppm) inlet streams.[33] As discussed in Section 4.1.4.1, gas/solid reactors are being used for flow rates up to 42 m^3/min (1,500 ft^3/min), and systems can be sized to accommodate larger

flow rates.[39] However, the control efficiency of these units with low EO concentrations has not been adequately determined.

4.1.4 Aeration Room Vent Emissions

4.1.4.1 Aeration Rooms. Most commercial sterilization facilities aerate the sterile products in large, warehouse-type aeration rooms that are typically 280 to 2,800 m^3 (10,000 to 100,000 ft^3) in volume but may be larger than 14,000 m^3 (500,000 ft^3).[4] The ventilation rates are, generally, in the range of 112 to 560 m^3/min (4,000 to 20,000 ft^3/min) but may be as high as 1,680 m^3/min (60,000 ft^3/min).[4] These large flow rates are necessary to maintain a low EO concentration in the room to comply with OSHA standards (see Section 3.5). Data from a cross-sectional survey (44 facilities) of the 188 commercial sterilization facilities represented in EPA's data base indicated an average 8-hour, time-weighted average (TWA) EO concentration of 2.5 to 3 ppmv in aeration rooms.[4]

Two issues of concern regarding the control of aeration room emissions are: (1) most EO emission control devices are impracticable for the low-concentration, high-flow-rate exhaust streams from aeration rooms; and (2) the lower detection limit of most analytical methods may make it impossible to determine the true control efficiency of the low EO concentrations (less than 1 ppmv) found in most aeration rooms. Hydrolysis, thermal oxidation, and condensation/reclamation presently have not been demonstrated to be practicable control techniques for low-concentration, high-flow-rate gas streams. However, catalytic oxidation and the gas/solid reactor system have the potential to control aeration room emissions. Catalytic oxidation units are commercially available to handle flow rates from less than 1 m^3/min (40 ft^3/min) to approximately 340 m^3/min (12,000 ft^3/min).[37,38] The catalytic oxidizers are modular, and systems can be designed to handle higher flow rates; however, the increased size of the system for high flow rates can restrict its practical use. Gas/solid reactors are being used for flow rates up to 42 m^3/min (1,500 ft^3/min), and systems can be designed to

handle any flow rate; however, as with catalytic oxidation, the system size can become impractical.[39]

The manufacturers of catalytic oxidizers and gas/solid reactors claim EO destruction efficiencies greater than 99.9 percent and offer the results of third-party tests to support these claims.[32,40,41] However, test data are not available on the efficiencies of the control units operating under conditions that are typical of aeration room exhaust streams (i.e., low concentrations and high flow rates).

Generally, the control units are tested by sending the control device a stream of EO with a much higher concentration (e.g., 100 to 140,000 ppmv) than that associated with normal operating conditions.[32,40,41] The results of these tests are the efficiencies reported by the manufacturers. However, these test results may be misleading because: (1) it has not been demonstrated whether the control units perform at the same efficiencies under normal operating conditions (i.e., very low inlet concentrations) as during test conditions (i.e., controlled flow, high concentration); (2) EPA has not conducted its own emission test program to verify the efficiency of control devices with aeration room emissions; and (3) EPA has not yet developed or approved a test reference method that is applicable to the evaluation of the efficiencies of these control devices with aeration room emissions.

The lower detection limits of most analytical procedures that are used to measure EO concentrations are approximately 0.5 ppmv to 1 ppmv, which is equal to or greater than the EO concentrations in many aeration rooms. Although one testing laboratory reportedly used a method with a detection limit less than 0.1 ppmv, the test data have not been verified by EPA, and it is unknown whether this method can be applied to high flow rates. (The flow rate tested was 14 m^3/min [500 ft^3/min].)[41] Also, because of the reactivity of EO, the validity of detection limits below 1 ppmv, and particularly below 0.5 ppmv, is questionable.[42] Because the detection limits of the analytical methods (in ppmv) are so close to the room concentrations,

testing under normal operating conditions may yield an efficiency that can only be calculated to be equal to 50 percent or less.

Three possible techniques for reducing EO emissions from aeration rooms are to (1) recirculate the air from the aeration room control device to the aeration room, (2) replace the warehouse-type aeration rooms with smaller, heated aeration chambers, or (3) modify the evacuation and air wash phase of the sterilization cycle. The first two techniques increase the EO concentration in the aeration room and lower the flow rate, which makes both control of the emissions and testing of the control efficiency more practical. The third alternative lowers the EO emissions from the aeration room by decreasing the residual EO in the product prior to aeration. These techniques are discussed in more detail below.

The first alternative refers to routing the aeration room air through an emission control device and back to the aeration room. A small amount of makeup air is added to the control device exit stream to regulate the room temperature. This practice increases the room temperature and, therefore, increases the diffusion rate of EO from the product, producing a higher EO concentration in the room. (Worker exposure and compliance with the OSHA standards will need to be considered if frequent worker access to the room is required.) Catalytic oxidation and the gas/solid reactor are more applicable to gas streams having increased EO concentrations and decreased flow rates associated with this process than to typical aeration room emissions. In addition, increasing the room temperature reduces the energy costs of preheating the inlet stream to the catalytic oxidizer. Hydrolysis, thermal oxidation, and condensation/reclamation are not applicable control techniques because the EO concentrations are too low (<20 ppmv) for these techniques to be practicable. Because the room air is recirculated and not vented to the atmosphere, this technique eliminates practically all aeration room emissions; only a small amount of the emissions from the control device are vented to allow fresh makeup air to enter the room. This practice of recirculating the aeration room air is

used by 2 of the 188 commercial sterilization facilities represented in the EPA data base.[3] The aeration rooms at these two commercial sterilization facilities are each approximately 140 m^3 (5,000 ft^3) in volume.[4] These two facilities manufacture synthetic rubber products, which retain a large amount of residual EO and, therefore, require a longer aeration period than the majority of products that are sterilized with EO. The facilities installed the recirculating system to decrease the aeration time and the residual EO concentrations in the products.[41] A catalytic oxidation system is used to control the EO emissions at these facilities and to provide hot air to heat the room.[43]

Another alternative is to replace the large, warehouse-type aeration rooms with smaller (70 m^3 [2,500 ft^3] or less), heated aeration chambers and control the emissions from the chamber. In this process, instead of storing the sterile products in a warehouse and aerating at normal room temperatures, the products are aerated in heated (>43°C [110°F]), insulated chambers. The emissions from these units can be controlled by catalytic oxidation or the gas/solid reactor system. Emissions from the control device can be recirculated to the aeration chamber or vented to the atmosphere. The aeration chambers can be filled approximately 40 to 75 percent full and still allow sufficient air space for off-gassing.[28,44] The aeration chamber is heated with either supplemental heat or hot air from the control device if catalytic oxidation is used. Several commercial sterilization facilities, particularly contract sterilizers, are aerating at least some of the sterile products in heated, aeration chambers.[4,38] Structures used for aeration include insulated shipping containers, modified walk-in coolers (which are heated instead of cooled), and manufactured units designed specifically for the heated aeration process.[45-47] Most of these facilities have installed these chambers to reduce the aeration time or the residual EO concentration in the products. The heated aeration chambers are similar to the first technique described above (i.e., the practice of recirculating the aeration room air) in

that the EO concentration in the chamber will increase as a result of EO off-gassing from the product due to elevated temperature.

Another strategy for reducing aeration room emissions is to modify the evacuation/air wash phase of the sterilization cycle. Residual EO in the product can be reduced by performing additional sterilization chamber purges. However, this procedure requires that products be held for additional time in the sterilizer and could affect plant operating schedules. The potential reduction in residual EO with evacuation-phase modifications is product dependent. Results from tests performed at one facility that fumigates spices showed an average reduction in residual EO of 26 percent for four different spices following evacuation-phase modifications.[15] Some facilities aerate in the sterilizer, with and without cycle modifications.[4] Aeration emissions from the sterilizer can be sent to the sterilizer control device. However, the removal efficiencies of the hydrolysis techniques have not been determined for the low inlet concentrations associated with aeration emissions. Also, condensation/reclamation would not be practicable for controlling these low concentrations.

An additional system currently used to control EO emissions from aeration rooms is an acid-impregnated carbon adsorption system. When such a system is used, emissions from an aeration room or aeration cabinet (see Chapter 4.1.4.2) are ducted to the carbon adsorption system which typically consists of approximately 20 acid-treated carbon trays. The carbon in these carbon trays has been treated with a strong acid (e.g., sulfuric acid) and is humidified. The EO in the emissions from the aeration room(s)/cabinet(s) is hydrolyzed to ethylene glycol. Because of its increased affinity for EO, the EO removal efficiency of the acid-impregnated carbon greatly exceeds that of plain carbon. However, the actual removal efficiency for this emissions control device have not yet been determined.[48]

4.1.4.2 Aeration Cabinets. Some commercial sterilization facilities use aeration cabinets instead of aeration rooms.

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These cabinets are similar in appearance and size (<1 m^3 [40 ft^3]) to the sterilization chambers used at hospitals. However, the flow rate from the cabinet is much lower than that from aeration rooms. Therefore, catalytic oxidation and the gas/solid reactor are applicable to the control of EO emissions from aeration cabinets. Several small commercial sterilization facilities use catalytic oxidation or the gas/solid reactor system to control aeration cabinet emissions, and at least one commercial sterilization facility uses an acid-water scrubber to control these emissions.[4,37,49] However, as stated in Section 4.1.3.1, the control efficiencies of these techniques have not been determined for the low concentrations from aeration processes.

4.2 OTHER STERILIZATION PROCESSES

There are no demonstrated EO emission control devices for single-item sterilization processes or for portable fumigation units, including beehive fumigators. The problems associated with controlling EO emissions from these sources are discussed below.

4.2.1 Single-Item Sterilization

Single-item sterilization systems do not use a chamber evacuated with a vacuum pump. (See Section 3.2.2 for a description of single-item sterilization.) Instead, the EO is allowed to diffuse from products while they are inside an aeration room or cabinet. The EO from facilities using single-item sterilization systems is, therefore, emitted from one major source, the aeration room/cabinet vent. Because there is no evacuation phase, the EO concentration in the gas stream from single-item sterilization systems is higher than the concentration of EO in aeration rooms. However, the concentration is sufficiently low such that catalytic oxidation or the gas/solid reactor system may be viable control options.

4.2.2 Fumigation with Portable Units

Because of problems with transporting an emission control device, it is not practical to control EO emissions from the portable units operated by State departments of agriculture to

fumigate beehives. However, one State Department of Agriculture is working on the development of an acid-water scrubber for portable fumigation units.[3]

4.3 ALTERNATIVES TO EO STERILIZATION

In some cases, radiation sterilization can replace EO sterilization. Radiation sterilization is used for about half of the products sterilized in the United States.[50] However, not all products can be sterilized with radiation; plastics can become broken, discolored, or rendered malodorous, and Teflon® and acetyl delrin are damaged by radiation.[50,51] According to industry representatives, most of the commonly used plastics have been or are in the process of being reformulated to withstand radiation.[52,53] Therefore, the potential use of this alternative may increase.

There are several chemical alternatives to EO sterilization (e.g., chlorine dioxide, gas plasma, hydrogen peroxide, and ozone). However, these chemicals do not necessarily offer environmental improvements over EO. Other alternatives include X-ray sterilization (a new, developing technology), deep freezing (museum and spice industry), and increased use of disposable medical items in hospitals. However, none of these alternatives can replace the use of EO for all applications, and they may have adverse environmental impacts as well. For example, the increased use of disposables may conflict with a pollution prevention program. Additionally, there may be significant health effects if these alternatives produce less-effective sterilants.[54]

4.4 RETROFIT CONSIDERATIONS

All of the control devices discussed above can be retrofitted to existing EO bulk sterilization chambers. However, the use of flares in urban areas is prohibited because of safety hazards. There are no retrofit problems associated with the replacement of once-through vacuum pumps with closed-loop recirculating vacuum pumps for control of drain emissions.

4.5 IMPACTS OF CFC REGULATION ON EO EMISSION CONTROLS

Federal regulations for stratospheric ozone-depleting chlorofluorocarbons (CFC's) have been developed under EPA's Stratospheric Ozone Protection Program (SOPP). The use of CFC's in sterilant gases is one of the source categories subject to the CFC regulation. The most popular sterilant gas mixture, 12/88, contains 88 percent by weight CFC-12, which is an ozone-depleting CFC. Seventy-five percent of the 188 commercial sterilization facilities represented in the EPA data base use 12/88 at least part of the time.[2,3,5] The requirements of a CFC regulation would not change the ability of a sterilization facility to control EO emissions. The explosion-proof condensation/reclamation system discussed above recovers CFC-12 emissions in addition to EO emissions. However, if this control device is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete. Also, a dedicated CFC-12 condensation/reclamation system that follows the acid-water scrubbing of EO to ethylene glycol would not have to be explosion-proof.[55] Some facilities may switch to sterilant gases that do not contain CFC-12 (such as 10/90 and pure EO), in which case the EO control techniques discussed above would still be applicable.

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5.0 REGULATORY ALTERNATIVES

5.1 INTRODUCTION

The purpose of this chapter is to present the regulatory alternatives developed by EPA. These regulatory alternatives represent the various courses of action that EPA could take in controlling ethylene oxide emissions from commercial sterilization facilities. The environmental, cost, and economic impacts associated with the application of these alternatives to this source category are presented in subsequent chapters. The EPA has developed a facility-specific data base for this source category; the impacts of the regulatory alternatives are based on actual facility data.

Data in the EPA commercial sterilization (CS) data base include facility-specific information from 196 facilities. This information was obtained through a November 1985 Health Industry Manufacturers' Association (HIMA) survey of medical equipment suppliers and a July 1986 Section 114 information collection request submitted to miscellaneous sterilizers and fumigators. Additional information that was used to update the 1986 EPA CS data base was obtained from two subsequent Section 114 information requests (July 1988 and July 1989). Facilities using single-item sterilization (Sterijet®) units and beehive fumigators used by State agriculture departments were not included in the regulatory analyses because there are no demonstrated control technologies for facilities using these sterilization processes (see Section 4.2). Therefore, 188 facilities that operate a total of 404 sterilization chambers are included in the regulatory alternatives analyses. These

facilities are grouped by Standard Industrial Classification (SIC) code into the following categories:

1. Medical equipment suppliers;
2. Pharmaceuticals;
3. Other health-related industries;
4. Spice manufacturers;
5. Contract sterilizers;
6. Libraries, museums, and archives; and
7. Laboratories (research, testing, and animal breeding).

The data base includes information on the number of chambers, chamber size, sterilant gas type, total annual sterilant gas throughput, annual EO use, and levels of emission control.

5.2 REGULATORY ALTERNATIVES

Table 5-1 presents the regulatory alternatives EPA developed to evaluate the environmental and cost impacts of potential emissions controls on commercial sterilization facilities. The regulatory alternatives represent incremental increases in the use of control devices and decreases in the EO use cutoffs that are applicable to the emissions sources. The control devices examined exhibited control efficiencies consistent with those comprising the (MACT) floor. In other words, these devices provide an emission reduction that is at least as stringent as the average emission limitation achieved by the best performing 12 percent of the existing sources. The cutoff levels are based on a facility's total annual EO use. Any facility with an annual EO use rate greater than or equal to the particular cutoff level would be subject to regulation. The analysis of emissions control versus the impacts of control yielded a nonclustered, continuous curve from which clear regulatory cutoffs were not readily determined. However, the trend of the data indicates that lower ethylene oxide annual use rates resulted in higher costs. The cutoff levels presented in Table 5-1 reflect this trend. Sterilization chamber size was also considered as a basis for regulatory alternatives. However, although the sterilization

TABLE 5-1. REGULATORY ALTERNATIVES

Regulatory Alternative	Emission source						Total nationwide emission reduction
	Sterilizer vent		Aeration room		Chamber exhaust		
	Cutoff, kg/yr (lb/yr)	Control device efficiency, percent	Cutoff, kg/yr (lb/yr)	Efficiency of control device, percent	Cutoff, kg Mg/yr (lb/yr)	Efficiency of control device, percent	
A	11 (25)	99	11 (25)	99	11 (25)	98	99
B	270 (600)	99	18,160 (40,000)	99	270 (600)	98	97
C	270 (600)	99	18,160 (40,000)	99	Status quo[a]	N/A[b]	94
D	270 (600)	99	No controls	N/A[b]	Status quo[a]	N/A[b]	91
E	900 (2,000)	99	No controls	N/A[b]	Status quo[a]	N/A[b]	90

[a]Status quo means that baseline chamber exhaust emissions are not exceeded.
[b]N/A = Not applicable.

chamber size is related to the quantity of EO used, actual EO use is a more direct measure of emissions.

Regarding the 900 kilograms per year (kg/yr) (2,000 pounds per year [lb/yr]) EO use cutoff for sterilizer vent and chamber exhaust emissions controls, no plants in the CS data base using less than 900 kg/yr (2,000 lb/yr) of EO have controlled emissions from sterilizer vents or chamber exhausts. Regarding the 18,160 kg/yr (40,000 lb/yr) EO use cutoff for aeration room emissions control, none of the existing sources presently control emissions from facilities using less than 18,160 kg/yr (40,000 lb/yr) of EO. Additionally, risk modeling data indicated that emissions from sources above these cutoffs would pose a more significant threat to human health and the environment. Also, cost estimates show that the cost impacts would be unreasonably high for sources below these cutoffs.

Estimates for emission rates and the cost of regulatory compliance are based on the following control technologies: EO emissions from the sterilizer vent would be controlled by an acid-water scrubber, and vacuum-pump drain emissions would be controlled by replacing the once-through, water-sealed, vacuum pump with a vacuum pump that has a closed-loop recirculation system. All EO entering the vacuum pump would be routed to the control device through the sterilizer vent rather than being split between the vent and drain, thus eliminating EO emissions from the drain. Aeration room emissions would be controlled by either a catalytic oxidizer or solid-bed reactor. The same controls as the aeration room would apply to chamber exhaust emissions.

The alternatives are presented in decreasing order of stringency. Regulatory Alternative A represents the maximum nationwide level of control. At this level, an estimated 99 percent of ethylene oxide emissions from commercial sterilization operations would be captured and controlled. All facilities in the data base would be subject to the control requirements because there are no facilities in the EPA data base that use less than 11 kg (25 lb) of EO per year. Regulatory

Alternative B has less stringent maximum EO use cutoffs. Under Regulatory Alternative C, a cap on chamber exhaust emissions limiting emissions to baseline emission levels would be required; additional controls are assumed necessary to maintain the baseline level. Under Regulatory Alternatives D and E, the only emission source to be controlled is the main sterilizer vent. Regulatory Alternative E represents the MACT floor for existing sources; at least 12 percent of the best performing existing sources already apply a 99-percent efficient control device to control sterilizer vent emissions.

It is important to note that while the efficiency of acid-water scrubbers (at least 99-percent) is widely accepted, the efficiencies assumed for the controls for aeration rooms and chamber exhaust vents are not well supported. For purposes of the analyses in this document, 99 and 98 percent were selected for the aeration room and chamber exhaust vent control device efficiencies, respectively. However, actual control efficiencies may be lower given the high-flow, low concentration emissions streams that are typical of these emissions sources.

6.0 ENVIRONMENTAL IMPACTS

This chapter presents estimated primary and secondary impacts on air, water, solid waste, and energy for each of the regulatory alternatives discussed in Chapter 5. Both beneficial and adverse impacts, as well as potential emission reductions, are assessed for the 188 facilities represented in EPA's 1989 commercial sterilization (CS) data base. Because no significant growth is expected for this industry, the 5-year impacts are the same as current impacts, and, therefore, only current impacts are presented in this section.[1,2]

6.1 AIR POLLUTION IMPACTS

6.1.1 Baseline Emissions and Emission Reduction

Based on facility-specific data in the EPA 1989 CS data base, baseline EO emissions and potential emission reductions were calculated for each of the regulatory alternatives described in Section 5.2. The control devices (and their efficiencies) at each emission point considered were respectively: (1) acid-water scrubber for sterilizer vent (99 percent); (2) recirculating-fluid vacuum pump for sterilizer vent drain (100 percent); (3) acid-water scrubber for chamber exhaust (assumed to be 98 percent), and (4) a gas/solid reactor for aeration room vent (99 percent).

The total nationwide estimated potential emission reductions and residual emissions for each of the five regulatory alternatives are presented in Table 6-1.

6.1.2 Secondary Impacts

Secondary air pollutants are those emissions that are not usually associated with an uncontrolled facility but result from the use of pollution control equipment (i.e., the control of one

TABLE 6-1. NATIONWIDE AIR IMPACTS

Regulatory Alternative	Nationwide emission reduction, %	EO emission reduction, Mg/yr (tons/yr)	EO residual emissions, Mg/yr (tons/yr)
A	99	1,061 (1,170)	11 (12)
B	97	1,042 (1,148)	30 (33)
C	94	1,004 (1,107)	68 (75)
D	90	963 (1,062)	109 (120)
E	89	952 (1,049)	120 (132)

Source: U. S. EPA Ethylene Oxide Commercial Sterilization Data Base, 1986, 1988.

pollutant results in the production of another pollutant). Secondary air pollutants are not associated with the use of acid-water scrubbers, recirculating-fluid vacuum pumps, or gas/solid reactors.

6.2 WATER QUALITY IMPACTS

If an acid-water scrubber is used to control EO emissions, there may be water quality impacts, depending on how the spent scrubber solution (predominately ethylene glycol) is disposed. Ethylene glycol is generated when the EO exhaust stream contacts and then reacts with the acid-water solution in the scrubber. When this solution is spent, the scrubber tank must be emptied and a fresh acid-water solution added. Each tank initially holds about 220 gallons (833 liters) of a 10 percent (by volume) aqueous sulfuric acid (H_2SO_4) solution, which is neutralized with 50 percent (by weight) caustic (NaOH) before the tank is drained.[3] (See Appendix E Section E.2 [sample calculations for acid-water scrubbers, assumption 3] for a sample calculation of the amount of ethylene glycol solution produced per pound of EO entering the scrubber.) The amount of ethylene glycol solution produced was calculated based on the assumption that the scrubber would be drained after 907 kilograms (kg) (2,000 pounds [lb]) of EO were treated, resulting in a 64 percent (by weight) aqueous solution of ethylene glycol.

Several methods for the final disposal of the ethylene glycol were examined. The ethylene glycol produced by the scrubber can be removed by a waste disposal company, sent to a municipal wastewater treatment plant, or shipped to a recovery plant. Removal of the ethylene glycol by a waste disposal company may not be economically practical for all of the facilities; this disposal method could account for a high percentage of the annual operating costs.[3] Sending the ethylene glycol solution to a municipal wastewater treatment plant also would not be feasible for all sterilization facilities. Some municipal treatment facilities restrict the concentration level and amount of ethylene glycol allowed in the discharge to the wastewater treatment plant.[3]

The final disposal method examined was shipping the ethylene glycol solution to a recovery company. At least three companies accept the ethylene glycol solutions for recovery on a no-credit, no-cost (except for shipping) basis.[4-6] Shipment of the ethylene glycol solution to a recovery company is a disposal method that would be applicable to all EO users and would not result in any wastewater impacts. Therefore, the nationwide wastewater impacts calculated for this control device shown in Table 6-2 represent the maximum potential wastewater impacts. Because of ethylene glycol recycling, the actual impacts are expected to be lower.

6.3 SOLID WASTE IMPACTS

Solid waste impacts could occur if the owners or operators of EO sterilization facilities choose to landfill spent reactant from the gas/solid reactor used to control aeration room emissions. However, the reactant replacement costs were developed based on spent reactant being returned to the vendor for recycling because this alternative was more cost-effective. Therefore, the nationwide solid waste impacts calculated for this control device shown in Table 6-2 represent the maximum potential solid waste impacts. Because of spent reactant recycling, the actual impacts are expected to be lower.

Additionally, if an owner or operator of an EO sterilization facility chooses to control emissions with a catalytic oxidizer, solid waste impacts may occur if the spent catalyst is landfilled.

6.4 ENERGY IMPACTS

The energy requirements for acid-water scrubbers are considerably less than those of the gas/solid reactor fan. Energy requirements for each of the regulatory alternatives are also presented in Table 6-2. If a catalytic oxidizer is used at a facility to control emissions, energy impacts will be considerably higher.

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TABLE 6-2. POTENTIAL NATIONWIDE WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS

Regulatory Alternative	Total annual wastewater production, m^3 (gal)[a b]	Total annual solid waste production, Mg/(tons)[c d]	Total annual electricity consumption, Kw/hr (000's)
A	2,150 (569,000)	190 (209)	4,600
B	2,140 (566,000)	137 (151)	2,700
C	2,140 (566,000)	137 (151)	2,700
D	2,140 (566,000)	0	0
E	2,120 (561,000)	0	0

[a]Actual impacts anticipated to be zero because of recycling of ethylene glycol.
[b]Approximately 60 percent (by volume) of wastewater is composed of ethylene glycol.
[c]Actual impacts anticipated to be zero because of recycling of reactant.
[d]Based on the use of gas/solid reactor.

Source: U. S. EPA Ethylene Oxide Commercial Sterlization Data Base, 1986, 1988.

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6.5 OTHER ENVIRONMENTAL CONCERNS

6.5.1 Irreversible and Irretrievable Commitment of Resources

Regulatory compliance would not preclude the development of future control options nor would such compliance curtail any beneficial use of the environment. No long-term environmental losses would result from regulatory compliance by commercial sterilization facilities.

6.5.2 Environmental Impact of Delayed Standards

Delaying the standards would result in possible solid waste impact reductions, but the reductions would be minimal compared with the air quality benefits attributable to promulgation of the standards. There do not appear to be any emerging emission control technologies that achieve greater emissions reductions or have significantly lower costs than the control devices considered here. Consequently, there are no benefits or advantages to delaying the proposed standards.

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7.0 EMISSION CONTROL COSTS

This chapter presents a summary of the methodology used to develop emission control cost estimates for 188 of the 196 facilities (8 State department of agriculture mobile beehive fumigation units were not included in this cost analysis) in the 1989 EPA commercial sterilization (CS) data base. These 188 CS facilities operate a total of 404 sterilization chambers. A method for estimating EO emission control costs for sterilizer vents at CS facilities is presented in Section 7.1. Cost information for chamber exhaust and aeration room controls is discussed in Sections 7.2 and 7.3, respectively. The results of the cost analyses are presented in Section 7.4, and Section 7.5 presents other cost considerations.

Costs are further explained in Appendix E. Appendix E includes: (1) costs for acid-water scrubbers (Section E.1); (2) sample calculations of the equations used to develop capital and annual costs for acid-water scrubbers (Section E.2); (3) aeration room cost analysis (Section E.3); (4) capital and annual control costs for the sterilizer chamber, chamber exhaust, and aeration room vent(s) at an example facility (Section E.4); (5) a breakdown of manifolding costs for these three vents (Section E.5); and (6) the cost indices and conversion factors used to convert costs to fourth quarter 1987 dollars (Section E.6).

Costs presented in this chapter are in fourth quarter 1987 dollars and are for existing facilities only. No new facilities are anticipated.

7.1 STERILIZER VENT CONTROL COSTS

This section describes a method for estimating emission control costs for sterilizer vent(s) and vacuum pump drains at commercial sterilization facilities. Acid hydrolysis (i.e., acid-water scrubbing) was chosen as the basis for the costing procedure because this control technique currently is known to be used at 28 commercial sterilization facilities, representing a variety of industries and a wide range of sterilizer chamber sizes (7 to 274 cubic meters [m^3] [264 to 9,800 cubic feet {ft^3}]).[1,2] This control technique is also the most cost effective of the technologies in use.[3] A detailed review of the available test data indicated that 99.0 percent is the maximum EO removal efficiency that acid hydrolysis techniques can achieve on a continuous basis.[4] Therefore, 99.0 percent was used to calculate the emission reductions.

The costing procedure presented in this section has been used to develop emission control costs for the 188 commercial sterilization facilities represented in the 1989 EPA CS data base.[5] (See Chapter 3 for a description of how the data base was developed.) Detailed example calculations for a typical commercial sterilization facility are given in Appendix E, Section E.4. Because these costs depend on sterilizer volume, the number of sterilizers, and annual EO use, example cost calculations for the sterilizer vent and chamber exhaust controls were provided for only one facility. However, the methodology for determining example costs for sterilizer vent and chamber exhaust emission controls was applied to all plants represented in the CS database. Therefore, the example costs provided in Appendix E, Section E.4, apply to all commercial sterilization facilities. However, because the methodology used to develop control costs for the aeration room is more complex, facility-specific costs are included in Appendix E, Section E.3, to supplement Tables E-12 and E-13 in Section E.4.

7.1.1 Description of Components Costed

The following components were costed: (1) an acid-water scrubber, (2) water-sealed vacuum pump(s) with closed-loop recirculation, (3) piping for manifolding the chambers to the existing control device or to a scrubber, (4) operating materials (i.e., chemicals and chlorine filters), (5) scrubber effluent disposal, and (6) labor.

Scrubber prices (freight-on-board [F.O.B.]) are listed in Table E-1. The capital costs associated with the scrubber and the piping system (for manifolding) are presented in Appendix E, Sections E.2 and E.5, respectively. The costs of operating materials, as well as the shipping charges used for computing disposal costs for the spent scrubber solution, are also presented in Appendix E, Section E.2.

7.1.2 General Assumptions

Scrubbers were not costed for facilities that had existing sterilizer vent control devices with efficiencies greater than or equal to 98-percent. Because of the chemical/physical characteristics of ethylene oxide as explained in Section 3.4.1, control devices operating at 98-percent efficiency (e.g., flares) may be assumed to operate at 99-percent efficiency. If a facility had a control device with an efficiency below 98 percent, a scrubber to remove 99.0 percent of the remaining emissions was costed. If a facility had an existing control but had uncontrolled chambers, it was assumed that the uncontrolled chambers were manifolded to the control device and that the existing control device had the capacity to control the additional emissions from the uncontrolled chambers.

Chamber volume was used as the basis for scrubber sizing. The relationship of chamber volume to a typical scrubber size is presented in Table E-1.

If a facility had three or more sterilization chambers, the scrubber costed was chosen based on the sum of the volumes of the two largest chambers at that facility. This methodology simulates the cost of controlling emissions from a facility if two chambers at that facility were to be evacuated

simultaneously. If a facility had two chambers, the scrubber was selected based on the volume of the larger chamber. For facilities with only two chambers, it was assumed that the sterilization cycles could be staggered so that the chambers would not be evacuated simultaneously.[5]

Costs were developed for recirculating-fluid vacuum pumps to control drain emissions normally associated with once-through, water-sealed vacuum pumps. Each sterilization chamber at a facility was costed for a recirculating-fluid vacuum pump unless the chamber had a control device that utilized a recirculating-fluid vacuum pump or a recirculating-fluid vacuum pump was already in place.

Piping costs for existing low-efficiency control devices were calculated based on the assumption that all sterilizers at a facility could be manifolded to the existing control device. An acid-water scrubber could then be manifolded to the existing control device to handle the remaining emissions. For facilities that had existing high-efficiency control devices, piping was costed to manifold any uncontrolled chambers to the existing control device. Otherwise, piping was costed to manifold all sterilizer chambers to an acid-water scrubber.

The disposal cost for the aqueous ethylene glycol solution produced by the acid-water scrubbers was computed as the cost to ship the solution, either in 55-gallon drums or in a tank truck, depending on quantity, to a recovery facility. Three recovery facilities that will accept the ethylene glycol on a no cost/no payment agreement were identified.[6-8] Transportation costs were calculated by assuming that most CS facilities (except those in Puerto Rico) are located within 1,000 miles of one of the three known recovery facilities.[5] This method of disposal was chosen because an earlier investigation of alternative disposal methods indicated that (1) discharging ethylene glycol to municipal wastewater treatment plants is a disposal method that may not be available to all sterilization facilities and (2) hauling by a waste disposal company would be costly for most sterilization facilities.

7.2 CHAMBER EXHAUST CONTROL COSTS

This section describes a method for estimating control costs for chamber exhausts. Although three types of control devices (i.e., catalytic oxidizers, gas/solid reactors, and acid-water scrubbers) are theoretically applicable to chamber exhaust emissions, none are currently in operation controlling chamber exhaust emissions. The costs of all three control devices were estimated. However, only the costs of the least expensive option, acid-water scrubbers, are presented here. Normally, an efficiency of 99.0 percent is used for an acid-water scrubber controlling sterilizer vent emissions. However, due to the differences in emission stream characteristics between the sterilizer vent and the chamber exhaust, an efficiency of 98 percent was used as a best-case estimate for an acid-water scrubber controlling the chamber exhaust.

Because both the sterilizer chamber and chamber exhaust vent use acid-water scrubbers to control EO emissions, the calculations used to determine annual operating costs (in Appendix E, Section E.2) for chamber exhaust controls are similar to those for the sterilizer vent. The main difference is that the acid-water scrubber for the chamber exhaust controls only 2 percent of the total facility EO use at an efficiency of 98 percent, whereas the sterilizer vent scrubber controls 95 percent of the total facility EO use at an efficiency of 99 percent. Capital costs for the chamber exhaust are based on a scrubber sized to control a flow rate of either 84 or 168 m^3/min (3,000 or 6,000 ft^3/min) (shown in Table E-1), ductwork for manifolding the chamber exhaust(s) to a common control (Table E-15), and associated installation costs. A breakdown of control costs for the chamber exhaust is included in Table E-11.

7.2.1 Description of Components Costed

The following components were costed: (1) an acid-water scrubber, (2) ductwork for manifolding vents, (3) operating materials, (4) scrubber effluent disposal, and (5) labor. Because of the extreme differences in ethylene oxide concentrations and the flow rates emitted from the emission

vents, manifolding was only costed between multiple emissions sources of the same type (e.g., manifolding multiple sterilizer vents or chamber exhaust vents or aeration room vents).

7.2.2 General Assumptions

In November 1989, the Health Industry Manufacturer's Association (HIMA) conducted a survey of 14 companies (23 facilities) to determine the prevalence of chamber exhaust use. Although these facilities represent only 12 percent of the facilities in the EPA CS data base, they represent 40 percent of the annual EO use. Of the 156 chambers these companies operate, 35 chambers (22 percent) do not have chamber exhausts.[9] Typically, these chambers are small in size, i.e., less than 7 m^3 (250 ft^3). Therefore, based on this HIMA survey, sterilizer chambers that were smaller than 7 m^3 (250 ft^3) were not assumed to have chamber exhaust and were not costed for control devices. It was assumed that these facilities can perform more air washes to reduce worker exposure to EO, which is the purpose of the chamber exhaust.

A flow rate of 84 m^3/min (3,000 ft^3/min) was assumed for chamber exhaust emissions and served as the basis for sizing an acid-water scrubber to control chamber exhausts. For this cost analysis, if a facility has more than two sterilizers, the total emission flow rate to the control is assumed to be 168 m^3/min (6,000 ft^3/min). This methodology simulates the control cost if two sterilizers were to vent to the chamber exhaust simultaneously. If a facility has one or two sterilizers, the emission flow rate is assumed to be 84 m^3/min (3,000 ft^3/min). This methodology is based on the assumption that a facility with only two sterilizers will rarely need to vent the chamber exhausts simultaneously and is consistent with the methodology used to develop sterilizer vent costs.[5]

The scrubber effluent disposal costs for the chamber exhaust scrubber are the same as those for the sterilizer vent control.

7.3 AERATION ROOM CONTROL COSTS

This section describes a method for estimating emission control costs for aeration rooms at CS facilities.

Initially, costs were developed for gas/solid reactors and catalytic oxidizers to control aeration room emissions. Because the gas/solid reactor was the most cost-effective of the controls considered, it was selected as the basis for the cost estimating procedure. However, catalytic oxidizers are equally viable and effective control devices; therefore, cost estimating tables for catalytic oxidizers, similar to those developed for gas/solid reactors, are included in Appendix E (Tables E-9 and E-13). For both of these control devices, facilities and test reports reported a 99-percent efficiency; therefore, 99 percent was used as a best-case estimate of control device efficiency.

A gas/solid reactor was costed for 185 of the 188 CS facilities. Three facilities already controlled aeration room emissions with catalytic oxidizers and were, therefore, not included in the cost analysis. A breakdown of the costs of controlling aeration emissions with gas/solid reactors is included in Table E-8. A breakdown of the manifolding costs is shown in Table E-16.

7.3.1 Description of Components Costed

The following components were costed: (1) gas/solid reactor(s), (2) insulated shipping containers (aeration chambers) to take the place of aeration rooms, (3) ductwork to manifold the aeration chambers to a common control device, (4) operating materials (including utilities), and (5) labor.

7.3.2 General Assumptions

Aeration chambers were costed to replace existing aeration rooms because emission flow rates from aeration rooms are typically high (greater than 280 m^3/min [10,000 ft^3/min]) with very low (less than 2 parts per million [ppm]) EO concentrations. By reducing the aeration room size, the emissions can be more easily controlled because the flow rate is decreased, and the EO concentration is increased. Therefore, it was assumed that aeration chambers could be used to replace all existing aeration processes. The aeration chambers were assumed to be unheated and, consequently, at ambient temperature. No decrease in aeration time was attributed to temperature for this cost analysis.

A regression analysis was performed on aeration room data received from 35 facilities.[10] This analysis was used to correlate the number of model aeration chambers (necessary to replace existing aeration processes) to a facility's EO use so that aeration chambers could be assigned to facilities to replace existing aeration rooms.

The result of the correlation is that facilities that use 2.27 Mg/yr (5,000 lb/yr) or less of EO were assigned one aeration chamber; however, no cost was attributed to this unit because facilities that use this amount of EO typically have aeration rooms smaller than the aeration chamber. Facilities that use 2.27 to 4.54 Mg/yr (5,000 to 10,000 lb/yr) EO were costed for one aeration chamber. Facilities that use between 4.54 and 36.3 Mg/yr (10,000 and 80,000 lb/yr) EO were costed for aeration chambers based on the equation $Y = 1.35 \times (10^{-4})X$. Facilities that use more than 36.3 Mg/yr (80,000 lb/yr) were costed for aeration chambers based on the equation $Y = 2.9\ (10^{-5})X + 8.6$ (where Y = number of aeration chambers and X = annual EO use, lb/yr, for both equations).

Cost estimates for a 28 m^3/min (1,000 ft^3/min) gas/solid reactor were obtained from a vendor. This gas/solid reactor is capable of handling EO emission concentrations up to 100 ppm.[11] Costs were extrapolated using an equation provided by the vendor to determine the cost of an 84 m^3/min (3,000 ft^3/min) gas/solid reactor. It was assumed that a maximum of 12 aeration chambers (2 parallel sets of 6 in series) could be vented to a control unit. The emission flow rate from each of these aeration chambers was assumed to be 7 m^3/min (250 ft^3/min), and the number of control units was selected so as to minimize capital costs.[11]

Disposal costs for the spent gas/solid reactant were calculated for a transportation distance of 1,500 miles. This cost was based on the assumption that the reactant could be returned to the vendor for recycling on a no-charge, no-credit basis. A distance of 1,500 miles was used because most facilities (except those in Puerto Rico) are located within 1,500 miles of the manufacturer of the reactant.[11]

7.4 RESULTS OF COST ANALYSIS

The nationwide cost impacts associated with each of the regulatory alternatives are shown in Table 7-1. Table 7-2, shows the cost impacts on three representative facilities. A "facility" in this case includes the sterilization vent, chamber exhaust vent, and aeration room vent emissions. These facilities were selected to represent the median facility (with regard to annual EO use and cumulative sterilizer chamber volume) in each of the following annual EO use ranges: <272, 272 to 18,150, and >18,150 kg/yr (<600, 600 to 40,000, and >40,000 lb/yr). A representative facility was not selected for facilities that use less than 11 kg/yr (25 lb/yr) EO because such a facility does not exist. The facilities that were selected represent small, medium, and large facilities that use 228, 3,963, and 67,604 kg/yr (504, 8,736, and 149,000 lb/yr) of EO; and have cumulative sterilizer volumes of 5.7, 28, and 112 m^3 (204, 1,000, and 4,002 ft^3), respectively.

7.5 OTHER COST CONSIDERATIONS

In addition to the costs described above, costs to comply with other Federal rules or regulations may be incurred by commercial sterilization facilities. These costs are described in the following section.

At CS facilities where workers handle or are near product during the sterilization process, measures must be taken to reduce EO worker exposure to less than 1 ppm per 8-hour time-weighted average concentration. In most facilities with cumulative sterilizer volumes less than 7 m^3 (250 ft^3) worker exposure is minimized using the chamber exhaust, which evacuates EO-laden air from the chamber while workers are loading/unloading the sterilizer chamber. Two of the regulatory alternatives require add-on controls for the chamber exhaust. If a facility were to elect to disable the chamber exhaust in lieu of the add-on control there would be additional costs to ensure continued OSHA compliance.

TABLE 7-1. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS

Regulatory Alternative	Emission reduction, %	EO use cutoff			Total annual costs, $/MM	Emission reduction, Mg/yr (tons/yr)	Cost effectiveness $/Mg ($/ton)	Incremental cost effectiveness, $/Mg ($/ton)
		Sterilizer vent, kg/yr (lb/yr)	Aeration room, kg/yr (lb/yr)	Chamber exhaust				
A	99	11 (25)	11 (25)	Add-on controls[a]	12	1,061 (1,170)	11,300 (10,300)	47,000 (133,000)
B	97	272 (600)	18,144 (40,000)	Add-on controls[a]	9.2	1,042 (1,149)	8,800 (8,000)	74,000 (67,000)
C	94	272 (600)	18,144 (40,000)	Status quo[b]	6.4	1,004 (1,107)	6,400 (5,800)	51,000 (46,000)
D	90	272 (600)	N/A	Status quo[b]	4.3	963 (1,062)	4,500 (4,050)	45,000 (41,000)
E	89	907 (2,000)	N/A	Status quo[b]	3.8	952 (1,049)	4,000 (3,600)	4,000 (3,600)

[a]Ethylene oxide use cutoff same as for sterilizer vent.
[b]Status quo means that baseline chambers exhaust emissions are not exceeded.

TABLE 7-2. REPRESENTATIVE FACILITY COST IMPACTS

Regulatory Alternative	Facility EO use, kg/yr (lb/yr)	Sterilizer control costs, $1,000		Chamber exhaust control costs, $1,000		Aeration room control costs, $1,000		Total emission reduction Mg (ton)	Total cost effectiveness, $/Mg ($/ton)
		Capital	Annual	Capital	Annual	Capital	Annual		
A	228 (504)	82.4	22.1	a	a	27.5	9.3	0.226 (0.249)	139,000
	3,963 (8,736)	175	43.7	66.8	18.8	45.9	13	3.92 (4.32)	(126,000)
	67,604 (149,000)	309	103	118	30.6	274	73.4	66.9 (73.7)	19,300 (17,500)
									3,090 (2,810)
B	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	66.8	18.8	N/A	N/A	3.8 (4.19)	16,500 (14,900)
	67,604 (149,000)	309	103	118	30.6	274	73.4	66.9 (73.7)	3,090 (2,810)
C	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	274	73.4	65.6 (72.3)	2,690 (2,440)
D	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	N/A	N/A	63.6 (70.1)	1,620 (1,470)
E	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	N/A	N/A	63.6 (70.1)	1,620 (1,470)

7.6 REFERENCES FOR CHAPTER 7

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3. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Baseline Cost of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. November 15, 1990.

4. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Examination of Ethylene Oxide Control Efficiencies. October 5, 1988.

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9. Letter and confidential attachments from Jorkasky J., Health Industry Manufacturers' Association, to S. Srebro, MRI. December 1989. Information on use of rear chamber exhaust at medical equipment suppliers.

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8.0 THE ECONOMIC IMPACTS OF THE CANDIDATE NESHAP CONTROLS

8.1 INTRODUCTION

Companies performing ethylene oxide (EO) sterilization fall into two general groups: in-house sterilizers and contract sterilizers. In-house sterilizers are companies that produce the goods needing sterilization. As part of their production process, they also sterilize the products. Also included in this group are laboratories, museums, and libraries. These in-house sterilizers do not produce goods needing sterilization, but, like the other in-house sterilizers, sterilization is a small but necessary part of their operations. Museums, for example, specialize in preserving and displaying artworks or artifacts. To be preserved, some of these artifacts must be sterilized or fumigated. Sterilization is only a very small part of the activities carried on by museums; some of them choose to perform it onsite, while others send their artifacts offsite to a contract sterilizer.

Contract sterilizers are companies that specialize in sterilization/fumigation, so sterilization is a major part of their business. They do not, in general, produce any of the goods being sterilized; rather, they offer the service of sterilization to other producers.

This chapter identifies the industries affected by this regulation and evaluates the economic impacts of three possible control options. First, the industries that perform EO sterilization are described; then the industries producing

products requiring sterilization are profiled. Finally, the effects of the control options on these industries are assessed.

8.2 ETHYLENE OXIDE STERILIZATION

8.2.1 Process Inputs

The major capital equipment requirement for sterilization is the sterilization chamber. The 188 facilities covered in this profile operate 404 chambers, an average of 2.2 chambers per facility. The number of chambers per facility ranges from one to nine. Chamber sizes range from 0.01 cubic meters (m^3) (0.35 cubic feet [ft^3]) to 177 m^3 (6,250 ft^3) and average about 16 m^3 (565 ft^3).[1] A typical chamber has a useful life of approximately 10 years; at the end of that time, the salvage value of the chamber is less than 1 percent of the initial capital investment.[2]

Certain design characteristics of the sterilization chamber are determined by the gas to be used for sterilization. These design characteristics limit the possibility of switching gases in the short run. When pure EO is used, the chamber instrumentation and room must be explosion-proof.[3] Pure EO chambers must also operate with a deep vacuum to rid the chamber of oxygen. Chambers that use an EO/CO_2 mixture, which requires a substantially higher operating pressure than other gases, have to meet higher standards of construction to withstand the pressure.[4]

The various chamber specifications are not mutually exclusive. For example, a chamber designed to withstand the high operating pressure associated with the EO/CO_2 mixture can also accommodate the lower pressures required by other sterilant gases. Therefore, some facilities can have chambers with the characteristics necessary for use with more than one type of sterilant gas. Consequently, these facilities can alternate between gases to achieve optimal combinations of product and sterilant gas for each sterilization cycle. Facilities involved in testing and research and those that sterilize a wide variety of products are more likely to operate chambers in this manner.

Other equipment required for the sterilization process includes:

1. A pump to create a vacuum in the chamber; and
2. A pump to force sterilant gas or air into the chamber.

Some facilities also have a separate room for the aeration step of the process, although aeration at some facilities can be accomplished in the sterilization chamber so that products do not have to be moved.

Labor requirements for EO sterilization are usually higher than for other types of sterilization (e.g., thermal or radiation). Each sterilization cycle must be closely monitored because several critical process variables require careful attention.[5] In addition, sterilization with pure EO requires strict safety precautions and extensive monitoring by facility personnel because pure EO is flammable.

8.3 SUBSTITUTION POSSIBILITIES AND THE PRICE ELASTICITY OF DEMAND

The extent of substitution between the EO-based gases is limited by the characteristics of the sterilization chamber and the compatibility of the sterilizing medium with the products being sterilized. As noted earlier, both pure EO and the EO/CO_2 mixtures may require specially designed sterilization chambers. Chambers may be modified to use pure EO, but industry standards prohibit modifying chambers for use with the EO/CO_2 mixture. However, the different pressures under which sterilization is performed for each sterilant gas can damage some products or packaging. Consequently, substituting with sterilant gases that require extremely high or low operating pressures is limited by the characteristics of the products being sterilized.

Gamma radiation sterilization can substitute for EO sterilization for many products. Unlike EO, radiation can sterilize liquids and products in vapor-tight packages; however, it discolors plastics and damages Teflon and acetyl delrin.[4,5] Gamma radiation cannot be used to sterilize pharmaceuticals because the radiation may alter the chemical structure of the drugs. Gamma radiation is expected to make some additional inroads into the EO market for sterilization.[2] Although gamma radiation is a likely substitute for EO sterilization, safety

concerns regarding transportation and disposal of the radiation source and the cost of the radioactive cobalt used as a radiation source will probably limit any increase in the percentage of the products sterilized by radiation. [Several other chemical substitutes for EO exist, but their use is more limited than gamma radiation; the substitution possibilities for these chemicals are discussed in later sections in conjunction with the appropriate end products.]

The importance of the sterilization procedure in the overall production process of many products presumably has a profound effect on its demand elasticity (i.e., the responsiveness of quantity demanded to a change in the price of sterilization services). Four main issues influence the elasticity of demand for a factor within an industry.[6] Specifically, the elasticity of demand should vary directly with the elasticity of demand for the final product, the factor's share of the costs of production, the elasticity of supply of other factors, and the elasticity of substitution between the factors.

These influences suggest that the demand for sterilization within the relevant industries is relatively inelastic. This conclusion is based in part on the low ratio between the cost of sterilization and the total cost of production.[7] Additionally, the elasticity of substitution between factors of production within the industries is relatively low; precautions taken to minimize contamination during production do not necessarily lessen the need for sterilization but enhance the effectiveness of the process. Generalizations regarding the elasticity of demand for the final product and the elasticity of supply of other factors are not possible due to variations from industry to industry.

8.4 SUPPLY OF EO STERILIZATION SERVICES

This section profiles the facilities that sterilize/fumigate medical devices and other miscellaneous products with EO, excluding sterilization activities in hospitals. For simplicity, we refer to this process simply as sterilization. For a variety of reasons discussed later in this section,

sterilization does not form a cohesive industry but is instead a part of the production process in several industries. Therefore, this profile will be limited in the scope of its analysis. The most important limiting factor is the lack of data on sterilization as a separate step in the production process. Consequently, commercial sterilizers are grouped here by industry; sterilization is then analyzed within the context of that industry.

8.4.1 National Summary of Ethylene Oxide Sterilization

The economic analysis presented in this chapter covers 188 sterilization facilities for which data are available. About half of the 188 facilities are suppliers of medical devices or other health-related items; the other facilities engage in several miscellaneous sterilization and fumigation operations (discussed later).

In 1988, approximately 1,913 megagrams (Mg) (4.22 million pounds [lb]) of EO was used for sterilization purposes by the 188 facilities covered in this analysis. [The EPA commercial sterilization database contains 1988 data for 32 facilities, the remainder are 1985 or 1986 values; for simplicity, 1988 will be referred to as the base year.] Table 8-1 presents some summary statistics on the use of the sterilant gases at the 188 facilities, separated into two categories--EO use and total gas use. The tremendously wide range in the use of sterilant gas per facility is noteworthy.

As mentioned above, several characteristics of the sterilization process make it difficult to profile the process as a discrete industry. The most important characteristic stems from the role of sterilization in the overall production process. Except for contract sterilizers, the sterilization process is an intermediate step in the production process. Therefore, separating sterilization from the production of the sterilized products is difficult. Another difficulty is the absence of a Standard Industrial Classification (SIC) code listing for sterilization either separately or within the classifications for the industries that employ this process. Furthermore, EO

TABLE 8-1. SUMMARY STATISTICS ON THE USE OF STERILANT GAS AT 188 COMMERCIAL STERILIZATION FACILITIES, 1988

		Ethylene oxide	Total gas
Total use	Mg/yr (tons/yr)	1,913 (1,883)	6,560 (6,456)
Use per facility			
Average	kg/yr (lb/yr)	10,179 (22,441)	34,897 (76,935)
Range	kg/yr (lb/yr)	1-129,090 (2-284,594)	6-359,400 (13-792,341)
Use per chamber			
Average	kg/yr (lb/yr)	4,737 (10,443)	16,239 (35,801)
Range	kg/yr (lb/yr)	0.1-62,045 (0.2-136,786)	0.1-168,000 (0.2-370,382)

sterilization accounts for only 50 to 60 percent of all sterilization activities.[4] Finally, the diversity and specialization of the industries that sterilize products limit the amount of data available for this profile.

8.4.2 Industry Groups Supplying EO Sterilization Services

Several main categories of facilities sterilize some portion of their output:

1. Medical device suppliers;
2. Other health-related suppliers;
3. Pharmaceutical manufacturers and other drug-related manufacturers;
4. Spice manufacturers and other food-related manufacturers;
5. Museums and libraries;
6. Laboratories (research, testing, and animal breeding); and
7. Contract sterilizers.

Table 8-2 summarizes the specific SIC codes associated with these industry categories and the number of facilities in each. As might be expected from the large number of SIC codes, the 188 sterilization facilities sterilize a wide variety of products. These products include surgical gloves and hypodermic needles sterilized by medical device suppliers, books fumigated by libraries and museums, and spices fumigated by spice manufacturers.

The sterilization processes used by the above industries have several similarities. However, a distinction can be made between in-house sterilization and contract sterilization. A majority of the facilities covered in this profile operate a sterilization chamber at the same location as the remainder of the production process. The exception to this rule is the subset of commercial sterilizers that sterilize products for other companies on a contract basis. Not only do contract sterilizers accept a variety of products for sterilization, but they may also supervise the final distribution of the products. It should be noted that the distinction between these two types of

TABLE 8-2. STANDARD INDUSTRIAL CLASSIFICATION CODES FOR 188 COMMERCIAL STERILIZATION FACILITIES, 1988

SIC Code	No. of facilities	Description of category
Medical device suppliers = 62		
3841	44	Surgical and medical instruments and apparatus
3842	18	Orthopedic, prosthetic, and surgical appliances and supplies
Other health-related suppliers = 24		
3079	7	Miscellaneous plastic products
3693	5	Radiographic X-ray, fluoroscopic X-ray, therapeutic X-ray, and other X-ray apparatus and tubes; electrochemical and electrotherapeutic apparatus
5086	4	Professional equipment and supplies
2211	1	Broad woven fabric mills, cotton
2821	2	Plastics materials, synthetic resins, and nonvulcanizable elastomers
2879	1	Pesticides and agricultural chemicals, NEC
3069	1	General industrial machinery and equipment NEC
3569	1	Electronic coils, transformers, and other inductors
3677	1	Electronic coils, transformers and other inductors
3999	1	Manufacturing industries, NEC
Pharmaceutical manufacturers = 39		
2834	34	Pharmaceutical preparations
5122	2	Drugs, drug proprietaries, and druggist's sundries
2831	2	Biological products
2833	1	Medicinal chemicals and botanical products
Spice manufacturers = 23		
2099	17	Food preparations, NEC
5149	3	Groceries and related products, NEC
2034	1	Dried and dehydrated fruits, vegetables, and soup mixes
2035	1	Pickled fruits and vegetables, vegetable sauces and seasonings, and salad dressings
2046	1	Wet corn milling
Museums and libraries = 13		
8411	11	Museums and art galleries
8231	2	Libraries and information centers
Laboratories = 10		
2790	4	Animal specialties, NEC
7391	2	Research and development labs
8071	1	Medical labs
8922	2	Noncommercial educational, scientific, and research organizations
7397	1	Commercial testing labs
Contract sterilizers = 17		
7399	14	Business services, NEC
7218	1	Industrial launderers
8091	2	Health and allied services, NEC

NEC = Not elsewhere classified.

sterilization is not always well defined. Some facilities, especially those within the medical device suppliers and pharmaceutical industries, sterilize their own products in-house and also accept products on a contract basis from other firms.[8]

8.4.2.1 Medical Device Suppliers. Sterilizers of medical devices (SIC 3841 and 3842) represent the largest single segment of commercial sterilizers covered in this analysis, including 62 of the 188 facilities. The total annual output of medical devices sterilized in the United States is estimated as 15 to 20 billion products, with at least 50 percent of these products sterilized with EO.[1]

Some medical devices must be sterilized to be marketed. Ethylene oxide, especially the 12/88 mixture, is used for medical device sterilization because of its wide range of effectiveness. The FDA has set strict guidelines for medical device sterilizers to ensure that necessary levels of sterility are achieved. These guidelines, called Good Manufacturing Practices (GMP), include requirements for such things as preliminary testing, procedural supervision, quality assurance, and final labeling.[5]

The U.S. medical device supply industry has been changing rapidly because of cost containment measures, increased competition, and changes in the health care system. A trend toward consolidation among both buyers and sellers of medical devices has been evident. Many hospitals have formed buyers' groups or corporate buying arrangements for purchasing supplies. Consolidation has allowed suppliers to increase their efficiency and broaden their product and distribution bases. Declining hospital occupancy and shorter visits have decreased the demand for medical devices from hospitals. At the same time, demand for medical devices from outpatient facilities has experienced strong growth. The number of surgical procedures being performed has been growing, but a larger share of these procedures is being done on an outpatient basis.

Product quality is becoming a major issue in the medical device industry. Under pressure from the FDA and increasing competition, suppliers are striving to improve their

manufacturing processes and products. The surgical and medical instruments industry (SIC 3841) is expected to grow about 7 percent per year (in 1982 dollars) between 1989 and 1993. The surgical appliances and supplies industry (SIC 3842) is projected to grow at an annual rate of 8.5 percent during this time. According to the Census of Manufactures, there were 2,600 establishments in the surgical and medical instruments and surgical appliances and supplies industries (SIC 3841 and 3842) in 1987. Table 8-3 summarizes various statistics for these industries. Product data were collected for all products classified in either SIC 3841 or 3842 that are produced by all industries; industry data represent all facilities classified in either SIC 3841 or 3842, including their output of nonmedical products.[9,10]

The data presented in Table 8-3 reveal several trends within the industry. The total value of shipments for medical device suppliers is given in current dollars and in 1982 dollars. Throughout the 1980's, the industry has shown strong, steady growth. Total employment has risen steadily since 1972, while the proportion of production workers has fallen slightly. In 1988, production workers made up 63 percent of the total work force, as compared with 69 percent in 1972. Growth in foreign markets, along with a lower value of the U.S. dollar relative to other currencies, has allowed U.S. manufacturers to increase exports of medical devices. Manufacturers of surgical and medical instruments (SIC 3841) increased exports by 17 percent between 1987 and 1988. Imports of these products also increased but at a slower rate (13.8 percent), allowing the trade surplus to grow by 29 percent. Exports of surgical appliances and supplies (SIC 3842) grew 25 percent during this time, while imports grew only 5.7 percent. Exports of medical devices are expected to remain high if the U.S. dollar does not appreciate substantially. Although the U.S. has consistently had an overall trade surplus in the medical device industry, it continues to have trade deficits with West Germany and Japan.[9]

TABLE 8-3. RECENT PERFORMANCE AND FORECAST DATA FOR MEDICAL DEVICE SUPPLIERS (SIC 3841 AND 3842)[a-c]

		1972	1975	1980	1985	1986	1987	1988	1989[d]
Product data[e]									
Value of shipments	(10^6 \$)	2,126	3,302	6,185	11,863	12,447	13,383	14,858	NA
Value of shipments	(10^6 1982 \$)	4,435	5,243	6,892	10,828	11,077	12,165	13,213	14,402
Industry data[f]									
Total employment	(10^3 people)	78.4	94.4	113.1	137.7	140.3	139.4	147	NA
Production workers	(10^3 people)	54.1	64.1	75.8	88.5	88	86.5	92.7	NA
Capital expenditures	(10^6 \$)	89.5	157.6	281.0	551.2[h]	471.7[h]	552.7[h]	NA	NA
Value added	(10 \$)[9]	1,559.0[g]	2,240.9[g]	4,077.3[g]	8,503.2[h]	8,954.8[h]	10,619.8[h]	NA	NA
Trade data									
Value of imports[i]	(10^6 \$)	44.2	106.4	268.4	581	785	959	1,069	1,160
Value of exports[i]	(10^6 \$)	217.6	432.0	698.0	1,124	1,275	1,486	1,790	2,060

NA = not available.
[a]Numbers represent the sum of the values of the two industry groups.
[b]Source: Years 1972, 1975, and 1985 are Reference 11 unless otherwise noted.
[c]Source: Years 1985 through 1989 are Reference 12 unless otherwise noted.
[d]Forecast.
[e]Represents products classified in SIC codes 3841 and 3842 produced by all industries.
[f]Represents all facilities classified as SIC 3841 and 3842.
[g]Source: 13.
[h]Source: 10.
[i]Developed by International Trade Administration.

Although a wide range of products is included under the broad category of medical devices, generalizing about the importance of the products is still possible. Medical equipment is a basic part of health care service, which is a necessary service. Therefore, the elasticity of demand for medical devices should be highly inelastic. However, the trends mentioned above (increased price competition among health care facilities and increased use of alternatives to hospitals) may indicate that the demand for medical devices is becoming more elastic. The availability of imports may also increase the elasticity of demand for domestically produced medical devices.

Table 8-4 shows some summary statistics on the sterilization chambers and sterilant gases used by the 62 medical device suppliers included in this study. These 62 facilities operated a total of 145 EO sterilization chambers in 1988, an average of 2.3 per facility. The number of chambers per facility varied from one to eight. Average chamber volume per facility was 40.1 m^3 (1,416.0 ft^3) but covered a wide range from 0.03 m^3 (1.06 ft^3) to 232 m^3 (8,193 ft^3). In 1988, these 62 facilities used 665 Mg (654 tons) of EO, slightly under 11 Mg (10 tons) per facility. Like chamber volume per facility, EO use varied widely from 0.01 Mg (0.01 tons) to 109 Mg (107 tons). Total gas use, which averaged 42 Mg (41 tons) per facility, also covered a wide range; the smallest user reported 0.05 Mg (0.06 tons) and the largest reported 511 Mg (503 tons).[1]

By subtracting EO use from the total gas use, and then dividing by EO use, an inert-gas ratio is obtained. This ratio indicates the extent of reliance on pure EO versus mixed sterilant gases. In particular, a ratio near zero would suggest extensive reliance on pure EO (because EO use and total gas use would be almost identical), but a much higher ratio would indicate greater use of sterilant mixtures, such as 12/88. During 1988, the inert-gas ratio for the 62 medical device suppliers was 2.88.

8.4.2.2 <u>Other Health-Related Suppliers</u>. Twenty-four facilities were included in this study that produce some type of

TABLE 8-4. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 62 MEDICAL DEVICE SUPPLIERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 145			
Number per facility	2.3	1.6	1 - 7
Chamber volume per facility, m^3 (ft^3)	40.1 (1,416.1)	37.9 (1,338.4)	0.03 - 232 (1.06 - 8,193)
Ethylene oxide use = 665.6, Mg/yr (655.1 tons)			
Use per facility, Mg/yr (tons)	10.7 (10.5)	6.9 (6.8)	<0.05 - 109.1 (<0.05 - 107.3)
Total gas use = 2,576.7 Mg/yr (2,536.0 tons)			
Use per facility, Mg/yr (tons)	41.6 (40.9)	76.2 (75.0)	0.05 - 511.2 (0.5 - 503)

health-related supplies but are classified under a more general SIC code (see Table 8-2). For example, five facilities have a primary SIC code that involves the manufacturing of X-ray equipment and nine facilities manufacture various plastic products. The large number of SIC codes illustrates the diversity of industries that sterilize health-related equipment with EO. For this reason, the value of shipments in Table 8-3 was presented on a product basis rather than on an industry basis. No other data specific to the relevant SIC codes will be presented.

Table 8-5 provides some summary statistics on the sterilization chambers and sterilant gas used by the 24 other health-related suppliers included in this study. These 24 facilities operated a total of 53 sterilization chambers in 1988, an average of 2.2 per facility. This is slightly lower than the medical device suppliers group, which averaged 2.3 chambers per facility.

The other health-related suppliers used 276 Mg (271 tons) of EO in 1988. They averaged 11.5 Mg (11.3 tons) of EO per facility, covering a range of 0.002 Mg (0.0022 tons) to 129.0 Mg (127.0 tons). Overall, these facilities used less EO than did the medical device suppliers. However, their EO use per facility and their total gas use per facility are slightly higher than those of medical device suppliers. The inert gas ratio for other health-related suppliers was 2.46.

8.4.2.3 Pharmaceutical Manufacturers. The broad category of pharmaceutical manufacturers includes those facilities whose SIC code was 2831, 2832, 2834, or 5122. These facilities are all connected with pharmaceutical preparations or other medicinal or biological products as manufacturers or, in some cases, as wholesalers. However, a vast majority of the facilities are classified as SIC 2834. Therefore, the profile of pharmaceutical manufacturers is focused on that industry group. Sterilization has a variety of uses in this industry, but it is as closely tied to the ultimate safety and effectiveness of the products as is the medical device industry.

TABLE 8-5. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 24 OTHER HEALTH-RELATED SUPPLIERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 53			
Number per facility	2.2	1.5	1 - 6
Chamber volume per facility, m^3 (ft^3)	41.3 (1,458.5)	58.4 (2,062.4)	0.4 - 207.2 (14.1 - 7,317.2)
Ethylene oxide use = 275.5 Mg/yr (271.2 tons)			
Use per facility, Mg/yr (tons)	11.5 (11.3)	7.07 (6.96)	<0.05 - 129.1 (<0.05 - 127.1)
Total gas use = 952.5 Mg/yr, (937.5 tons)			
Use per facility, Mg/yr (tons))	39.7 (39.1)	51.1 (50.3)	0.05 - 152.2 (0.05-149.8)

The pharmaceutical industry shows several interesting trends. Pharmaceutical companies continue to spend increasing amounts on research and development: they spent $5.4 billion in 1987 and a record $6 billion in 1988. Experts expect that the high cost of research and development will lead to consolidation, especially among small specialty manufacturers. Patent piracy remains a problem for this industry. Manufacturers lost an estimated $2 billion to patent pirates in 1988. Sales of generic drugs will continue to grow as patents on existing drugs expire. Generic drugs currently make up about 12 percent of the prescription market and will probably account for 30 percent by 1993. The pharmaceutical industry also expects strong growth in the market for over-the-counter drugs as more drugs are made available for purchase without a prescription.[9]

The value of pharmaceutical product shipments rose an estimated 2.7 percent (in constant dollars) between 1987 and 1988. The U.S. Department of Commerce predicts that the industry will grow between 2 and 3 percent a year between 1989 and 1993. Factors contributing to this growth will include an increasing demand for drugs by an aging population, greater exports to developing countries, and improved productivity through computerization.[9]

According to the Census Bureau, a total of 718 facilities were classified under SIC code 2834 in 1987. Only 34 have been identified as commercial sterilizers.[10] The pharmaceuticals group, as defined in this chapter, includes five additional facilities from SIC codes 5122, 2831, and 2833. Table 9-6 reports recent performance and forecast data for all pharmaceutical manufacturers classified under SIC code 2834. The data are presented in much the same manner as in Table 8-3, with a distinction between industry and product data.

As shown in Table 8-6, the value of pharmaceutical shipments has increased steadily through the 1980's in both nominal and real terms. Industry employment, after falling in the early 1980's, has shown an upward trend since 1985. Capital expenditures decreased somewhat between 1985 and 1986 but

TABLE 8-6. RECENT PERFORMANCE AND FORECAST DATA FOR PHARMACEUTICAL MANUFACTURERS (SIC 2834)[12]

	1972	1975	1980	1985	1986	1987	1988	1989
Product data								
Value of shipments (10^6 \$)	6,295	8,247	13,012	22,318	24,280	26,898	29,820	NA
Value of shipments (10^6 1982 \$)	12,422	14,202	15,974	17,283	18,836	19,213	19,735	20,290
Industry data								
Total employment (10^3 people)	112.0	123.0	135.0	123.0	124.0	128.0	128.0	129.0
Production workers (10^3 people)	57.0	60.2	68.4	58.4	58.7	59.4	60.7	61.3
Capital expenditures (10^6 \$)	167.0	321.0	675.0	1,171.1[a]	1,057.8[a]	1,470.4[a]	NA	NA
Value added (10^6 \$)	5,640[b]	6,923[b]	11,048[b]	19,095[a]	20,598[a]	23,868[a]	NA	NA
Trade data								
Value of imports[c] (10^6 \$)	14.5	33.9	61.6	216	157	164	202	245
Value of exports[c] (10^6 \$)	182.0	270.0	421.0	691	648	675	840	1,050

NA = Not available.
[a]Source: 10.
[b]Source: 13.
[c]Developed by International Trade Administration.

increased in 1987. In recent years, both imports and exports of pharmaceuticals have been increasing.

Table 8-7 contains some summary statistics on the sterilization chambers and sterilant gas used by the 39 pharmaceutical manufacturers included in this study.[1] These 39 facilities operated a total of 82 sterilization chambers in 1988, averaging 2.1 per facility. The average chamber volume per facility for pharmaceutical manufacturers is 29.2 m^3 (1,031.2 ft^3), with chamber volume ranging from 0.1 m^3 to 147 m^3 (3.5 ft^3 to 5,191 ft^3. Although the number of chambers per facility in the pharmaceuticals group roughly equals the number for the medical device suppliers group, the average chamber volume per facility for pharmaceutical manufacturers is about 70 percent of the average for medical device suppliers.

The pharmaceutical manufacturers used 416 Mg (409 tons) of EO in 1986, averaging 10.7 Mg (10.5 tons) per facility and varying from 0.01 Mg (0.01 tons) per facility to 84 Mg (82.7 tons) per facility. They also used 830 Mg (818.9 tons) of total gas, with an average of 21.3 Mg (21.0 tons) per facility and a range of 0.06 Mg to 92 Mg (0.06 to 90.5 tons) per facility. The ranges of both EO use and total gas use are much narrower for pharmaceutical manufacturers than they are for medical device suppliers. Finally, the inert-gas ratio for pharmaceuticals is 1.00, compared to a 2.88 ratio for the medical device suppliers.

8.4.2.4 Spice Manufacturers. Twenty-three of the 188 facilities in this study have been categorized as spice manufacturers. These firms fall into five SIC codes: 2099, 5149, 2034, 2035, and 2046. However, as shown in Table 8-2, about two-thirds of these firms are in SIC code 2099. Consequently, the discussion below focuses on this industry group.

About one-quarter of all spices manufactured in the United States are treated with EO to control fungi, molds, bacteria, and insect eggs.[14] Ethylene oxide pasteurization increases shelf life and decreases health risks.[14] An industry magazine reports that "since the spice processor cannot preclude or remove

TABLE 8-7. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 39 PHARMACEUTICAL MANUFACTURERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 82			
Number per facility	2.1	1.4	1 - 6
Chamber volume per facility, m^3 (ft^3)	29.2 (1,031.2)	20.0 (706.3)	0.1 - 147.3 (3.5-5,201.9)
Ethylene oxide use = 416.1 Mg/yr (409.6 tons)			
Use per facility, Mg/yr (tons)	10.7 (10.5)	3.12 (3.07)	<0.05 -129.1 (<0.05-127.1)
Total gas use = 830.4 Mg/yr (817.3 tons)			
Use per facility, Mg/yr (tons)	21.3 (21.0)	28.1 (27.7)	0.06 - 92.2 (0.06 - 90.7)

microorganisms from spices, the only means to control microorganisms are: (1) to maintain low moisture content to hinder growth and activity and (2) to treat spices with EO."[15]

Several substitutes within the spice industry are available for EO, each of which has disadvantages. Heat sterilization is useful on only a small number of spices, because it lightens or darkens spice color and can cause a 15-percent loss in spice strength by volatizing spice oils. Neither ionizing radiation nor ethylene imine are approved by the FDA, and their effectiveness is not known. The use of propylene oxide is restricted by the FDA to starches, gums, processed spices, cocoa, and processed nut meats.[14] However, propylene oxide must be heated to be as effective as EO. Using heat restricts its use to a small number of spices because heat volatizes oils in spices, affecting their quality. Without heat, propylene oxide has one-tenth the microbial killing activity of EO. Finally, propylene oxide requires 16 to 48 hours of exposure time, compared to 6 to 8 hours for EO.

According to an industry source, radiation treatment is a promising alternative to EO fumigation, having several advantages over EO.[16] First, although EO kills a high percentage of bacteria, radiation kills all bacteria. Second, EO requires high humidity and a vacuum, while radiation treatment can be done under ambient conditions. Third, EO leaves a residue in all foods that have been treated, but radiation leaves no residues of any kind.

According to the Census Bureau, SIC 2099 had 1,976 firms in 1982.[17] As shown in Table 8-8, the value of shipments for SIC 2099 increased steadily from $3.6 billion in 1972 to $11.0 billion in 1982, a nominal growth of 201 percent over the 10-year period. Value added also increased steadily over the same period rising from $1.8 billion in 1972 to $5.7 billion in 1982. Employment experienced two low periods, one in the mid-1970's and another in the early 1980's. The number of production workers declined in 1975 and again in 1979 and 1980, while total employment declined in 1979 and 1981. Both employment measures

TABLE 8-8. RECENT PERFORMANCE DATA FOR SPICE MANUFACTURERS (SIC 2099)

		1972	1975	1977	1978	1979	1980	1981	1982
Product data									
Value of shipments	(10^6 $)	3,647.9	5,583.8	6,531.0	7,360.6	7,568.9	8,536.5	9,598.9	10,979.3
Industry data									
Total employment	(10^3 people)	66.2	64.3	71.5	76.8	71.8	73.4	72.8	81.4
Production workers	(10^3 people)	44.7	44.2	50.9	55.8	52.3	51.7	52.3	57.9
Capital expenditures	(10^6 $)	91.8	171.3	166.2	199.6	236.0	285.0	208.0	295.4
Value added	10^6 $)	1,805.2	2,431.3	3,028.1	3,487.8	3,493.8	4,038.0	4,569.6	5,663.3

increased from 1981 to 1982. Capital expenditures increased from $91.8 million in 1972 to $295.4 million in 1982 with declining years in 1977 and 1981.

In 1987, the industry definition of SIC 2099 changed. Although spice manufacturers are still included under the new definition, industry figures for 1987 cannot be compared with previous years. Table 8-9 presents the 1987 data for SIC 2099.

The spice and seasoning industry relies heavily on foreign trade. According to one estimate, two-thirds of the spices consumed in the United States are imported.[18] This estimate includes some dehydrated vegetables that are used as seasonings but are not included in the FDA definition of spices.

The 23 firms in the spice manufacturers group that use EO sterilization are distributed evenly across the country, except for a large concentration of seven firms in California.[10,13] Table 8-10 shows some summary statistics on the sterilization chambers and sterilant gas used by these manufacturers.[1] The 23 facilities operated a total of 27 sterilization chambers in 1986, an average of only 1.2 per facility. The number of chambers per facility ranged from one to four. Average chamber volume per facility was 33.1 m^3 (1,168.9 ft^3), which is considerably lower than the average for medical device suppliers of 40.1 m^3 (1,416.1 ft^3). In addition, the range of chamber volumes per facility, 0.1 m^3 to 177 m^3 (3.5 ft^3 to 6,250 ft^3), was narrower for the spice manufacturers. Both average chamber volume per facility and the range of chamber volumes per facility for the spices group were roughly equal to the average range for the pharmaceuticals group. Table 8-10 presents the 1987 data for SIC 2099.

The spice manufacturers used 124 Mg (122 tons) of EO and 287 Mg (282 tons) of total gas during 1986. Annual EO use per facility averaged 5.4 Mg (5.3 tons), while total gas use per facility averaged 12.5 Mg (12.3 tons). Average total gas use per facility is roughly equal to average total gas use for the pharmaceuticals group, but average EO use per facility is about half the average for pharmaceutical manufacturers. The inert-gas

TABLE 8-9. 1987 PERFORMANCE DATA FOR SPICE MANUFACTURES (SIC 2099)

Product data	1987
Value of shipments (10^6 $)	9,815.8
Industry data	
Total employment (10^3 people)	58.1
Production workers (10^3 people)	40.9
Capital expenditures (10^6 $)	248.0
Value added (10^6 $)	5,201.1

TABLE 8-10. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 23 SPICE MANUFACTURERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 27			
Number per facility	1.2	0.6	1 - 4
Chamber volume per facility, m^3 (ft^3)	33.1 (1,168.9)	14.3 (499.4)	0.1 - 177.0 (3.5 - 6,250.7)
Ethylene oxide use = 124.0 Mg/yr (122.0 tons)			
Use per facility, Mg/yr (tons)	5.4 (5.3)	11.2 (11.0)	<0.05 - 40.0 (<0.05-39.4)
Total gas use = 286.6 Mg/yr (282.1 tons)			
Use per facility, Mg/yr (tons)	12.5 (12.0)	14.0 (13.8)	<0.05 - 56.3 (<0.05 - 55.4)

ratio for the spice manufacturers is 1.31, which is comparable to the 2.88 ratio for the medical device suppliers.

8.4.2.5 Museums and Libraries. According to the 1982 Census of Services, the United States has 1,909 non-commercial museums and art galleries (SIC 8411).[17] In addition, the country had 31,524 public and private libraries in 1987. The sterilization data base contains data for 11 museums and 2 libraries. Interestingly, 4 of the 13 are in Massachusetts and none are in the Southeast or Northwest.

Museums and libraries fumigate books, documents, and other artifacts with EO chiefly to control insect pests and mold. Museum experts report that EO is "especially valuable for treatment of books and archival documents, furs, textiles, and furniture."[19] However, EO has one significant drawback as an artifact fumigant: it settles in rubber, leather, wood, and other organic materials, making it necessary for EO-fumigated artifacts to be aerated for up to a month before they are safe to handle.[19,20]

It is recommended that all organic materials be fumigated before they are introduced into a museum or library collection.[19] However, telephone conversations with museum and library conservators who use EO revealed a range of fumigation criteria. Some conservators fumigate all new articles, while others fumigate only those articles that fail a visual inspection or that have suspect backgrounds, such as books that were kept in a damp basement.[21,22]

Ethylene oxide has several substitutes as a fumigant in museum and library use. One possible substitute is sulfuryl fluoride, marketed under the trademark Vikane™. Sulfuryl fluoride is not absorbed by organic materials and dissipates more quickly than EO.[20] Furthermore, the cost of sulfuryl fluoride has generally been comparable to the cost of 12/88, based on retail prices and the recommended doses of each sterilant.[19] Sulfuryl fluoride, however, is toxic at high concentrations. It is also corrosive to metals, making it an unacceptable

alternative for artifacts that contain metal. In particular, it could damage books with staple bindings.[23]

Conversion from EO to sulfuryl fluoride would entail some startup costs. Some EO fumigation chambers would require modifications to use sulfuryl fluoride. Because sulfuryl fluoride is corrosive to metals, the vent pipes from the chamber must be stainless steel; installing these new vent pipes would represent a startup capital cost for museums/libraries converting to sulfuryl fluoride use.[23]

Sulfuryl fluoride is registered with the U.S. Department of Agriculture as a "restricted" pesticide and, therefore, can only be applied by a certified applicator. Certified applicators must pass a test administered by the U.S. Department of Agriculture. Ethylene oxide is not registered as a restricted pesticide and can, therefore, be applied by anyone.[24] The time and effort involved in passing the certified applicator test would represent another startup cost for museums/libraries converting to sulfuryl fluoride. Finally, sulfuryl fluoride is registered for use in fumigation chambers, and presently no regulations control sulfuryl fluoride emissions.[24]

Other alternatives to EO fumigation include deep freezing, CO_2 fumigation, and vacuum treatment. Several European institutions have tested the freezing method and reported that maintaining -18°C (-0.4°F) for 48 hours kills 100 percent of insect life in all stages of the life cycle. Freezers ranging from 0.9 to 1.1 m^3 (31.8 to 40 ft^3) in size are most commonly used.[19] The necessary freezing apparatus costs approximately $3,000 to $4,000.[22] Placing artifacts in a vacuum or fumigating them with carbon dioxide also kills insect life.[21,25] These three methods, however, do not kill mold and fungi; therefore, they are only partial substitutes for EO.

Table 8-11 provides some summary statistics on the sterilization chambers and sterilant gas used by the 11 museums and two libraries included in this study.[1] Each of these 13 facilities operated one sterilization chamber in 1988. These chambers averaged 2.60 m^3 (91.82 ft^3) in volume and ranged from

TABLE 8-11. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 13 MUSEUMS AND LIBRARIES, 1988

	Average	Standard deviation	Range
Sterilization chambers = 13			
Number per facility	1.0	0.0	1 - 1
Chamber volume per facility, m^3 (ft^3)	2.6 (91.8)	3.7 (130.7)	0.5 - 13.7 (17.7 - 483.8)
Ethylene oxide use = 0.20 Mg/yr (0.20 tons/yr)			
Use per facility, Mg/yr (tons))	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 - 0.05 (<0.05 - 0.05)
Total gas use = 1.68 Mg/yr (1.65 tons/yr)			
Use per facility, Mg/yr (tons/yr)	0.1 (0.1)	0.1 (0.1)	<0.05 - 0.4 (<0.05-0.4)

0.5 m^3 to 13.8 m^3 (17.7 ft^3 to 487.3 ft^3). The average chamber volume per facility for this group is roughly one-twentieth the average chamber volume per facility for the medical device suppliers. Additionally, all of the gas use figures are much lower than are the figures for medical device suppliers.[1]

During 1988, the museums and libraries group used a total of 0.20 Mg (0.20 tons) of EO and 1.67 Mg (1.64 tons) of total gas. Medical devices suppliers used over 3,000 times as much EO and over 1,500 times as much total gas as did the museums and libraries group. In addition, gas use per cubic meter of chamber volume was much lower for this group than for any other group. Medical device suppliers used 14 times as much total gas and 22 times as much EO per cubic meter of chamber volume as did the museums and libraries group. Furthermore, this latter group used substantially less EO per cubic meter of chamber volume than any other industry group in this study--12.6 $kg/m^3/yr$ (0.78 $lb/ft^3/yr$), while all other industry groups each used over 200 $kg/m^3/yr$ (12.5 $lb/ft^3/yr$). The inert-gas ratio for the museums and libraries group was 7.40, which suggests that facilities in this group used 12/88 exclusively.

8.4.2.6 Laboratories. Four of the firms being considered for regulation are commercial laboratory rat and mice breeders, which are classified as SIC Code 2790. Animal breeders use EO to sterilize heat-sensitive plastics, heat- and water-sensitive electronic lab equipment, and prepackaged articles required for breeding. These articles include books, phones, optical equipment, meters, microscopes, and face masks.[14]

Some alternatives to EO sterilization for laboratory animal breeding do exist, although each has disadvantages. Pressurized steam damages plastics, electronic equipment, and other heat-/water-sensitive materials. In addition, steam does not permeate prepackaged materials as effectively as EO. Dry heat degrades those heat-sensitive materials that cannot withstand temperatures of 160° to 165°C (320° to 329°F). Another alternative, peracetic acid, is not registered as a pesticide and is considered to be carcinogenic. It is also corrosive to most metals and plastics

and has poor penetrating properties. Glutaraldehyde requires at least 10 hours immersion and cannot be used with prepackaged materials. It poses a recontamination danger from hand manipulations and air and cannot be used for materials that would be damaged by water.[14]

Two noncommercial research organizations, SIC Code 8922, have also been identified as operators of sterilization chambers. These firms use EO in the same manner as the lab animal breeders mentioned above but on a somewhat more limited scale. Ethylene oxide alternatives and disadvantages mentioned for animal breeders also apply here.[14]

The remaining facilities classified as laboratories are two research and development labs (SIC Code 7391), one medical lab (SIC Code 8071), and one commercial testing lab (SIC Code 7397). These firms are considered together because their sterilization practices are similar. In particular, these facilities investigate whether medical devices can be effectively sterilized and yet still function within the human body. Alternatives to EO for these facilities are limited; EO must be used for heat- and moisture-sensitive medical devices and drugs.[14]

Table 8-12 reports some summary statistics on the sterilization chambers and sterilant gas used by the 10 laboratories included in this study.[1] These facilities operated 22 EO sterilization chambers during 1988, an average of 2.2 per facility. The number of chambers per facility ranged from one to five. Average chamber volume per facility was 4.15 m^3 (146.56 ft^3) but varied from 0.05 m^3 to 16.1 m^3 (1.77 ft^3 to 568.57 ft^3) per facility. The laboratories group averaged about the same number of chambers per facility as the medical device suppliers group; however, the laboratories group had a lower average chamber volume per facility than did all other groups (except the museums and libraries group). This comparison suggests that the laboratory group operated smaller chambers than did the other groups (except the museums and libraries group).

The laboratory group used 9.55 Mg (9.40 tons) of EO and 78.1 Mg (76.9 tons) of total gas during 1988. The group average

TABLE 8-12. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 10 LABORATORIES, 1988

	Average	Standard deviation	Range
Sterilization chambers = 22			
Number per facility	2.2	1.6	1 - 5
Chamber volume per facility, m^3 (ft^3)	4.15 (146.56)	4.81 (169.86)	0.5 - 16.1 (17.66-568.57)
Ethylene oxide use = 0.20 Mg/yr (0.20 tons)			
Use per facility, Mg/yr (tons/yr)	0.96 (0.91)	2.57 (2.53)	<0.05 - 8.68 (<0.05 - 8.54)
Total gas use = 1.68 Mg/yr (1.658 tons/yr)			
Use per facility, Mg/yr (tons/yr)	7.8 (7.7)	21.5 (21.2)	<0.05 - 72.3 (<0.05 - 71.2)

of 0.96 Mg (0.94 tons) of EO per facility is roughly equal to the spice manufacturer's use per facility but less than all other groups, excluding museums and libraries. The laboratories also used less total gas per facility, 7.8 Mg/yr (7.7 tons/yr), than did all other groups excluding museums and libraries. The inert gas ratio for laboratories was 7.17.

8.4.2.7 Contract Sterilizers. As mentioned earlier, a subset of sterilization facilities sterilize products on a contract basis. These contract facilities are normally classified under SIC Code 7399 (business services, not elsewhere classified). However, depending on the main type of product sterilized, the facility may fall under another related category. For example, one contract sterilizer works with surgical garments and is classified under SIC Code 7218 (industrial launderers). In addition to the facilities whose primary function is contract sterilization, several facilities that sometimes accept contract work are classified under a different category. These are especially prevalent within the medical device industry.

Reports vary as to the number of contract sterilizers in the United States. One official at the FDA estimated that there are 100 to 125 contract sterilizers of all types (i.e., EO, steam, radiation, etc.). Of these, approximately 60 are EO sterilizers.[26] Another source at the FDA estimated that there are 65 contract sterilizers of medical devices, 18 of which do contract work only.[27] Only 17 of the 188 facilities in this study have been identified as contract sterilizers exclusively; however, an undetermined number of the other facilities also accept contract work.

The price for contract sterilization varies with the type of sterilization performed. The prices for EO contract sterilization are calculated based on the time the product remains in the chambers (length of cycle) and the amount of gas used. The pressure chambers contain a limited amount of space, and the cost to the sterilization firm is the same whether the chamber is completely full or not. Thus, the price per cubic

foot of product sterilized also varies depending on how full the chamber is.

Some contract sterilizers said in telephone conversations that the articles they processed tended to be of awkward shapes and sizes, limiting the number of articles in the sterilization chambers. Other firms processed smaller and denser loads. The prices quoted were those for full chambers and averaged about $0.04 per-cubic meter ($1.30 per-cubic foot).[28]

Typically, sterilizing with 12/88 is more expensive than sterilizing with pure EO. The difference in price between sterilizing with pure EO and with 12/88 is due to the increased amount of gas necessary to sterilize with 12/88.[2] In spite of the higher cost, facilities have used the 12/88 formulation because some products or packaging cannot withstand sterilization with pure EO, as was noted previously. In addition, pure EO is explosive, making worker safety a concern. (Note: However, during the early 1990's many facilities are switching to pure EO because of chlorofluorocarbon (CFC) phase-out regulations.)

One expert on sterilization predicted 30 percent growth in the late 1980's and early 1990's for contract sterilizers.[2] Growth would then continue at a rate of 4 to 5 percent annually. Implicit in this projection is the assumption of no additional Federal regulations in the future. Any new regulations would probably augment the positive growth of contract sterilization, because smaller facilities might cease in-house sterilization operations and begin sending products offsite. [See Section 8.2.1 for further discussion of the possible substitution of contract sterilization for in-house sterilization due to the candidate NESHAP controls on EO emissions.] Indeed, this is already occurring because of CFC regulations.

Table 8-13 contains some summary statistics on the sterilization chambers and sterilant gas used by the 17 contract sterilizers included in this study.[1] These 17 facilities operated 62 EO sterilization chambers in 1988--an average of 3.6 per facility, which is more than any other group in the study. The contract sterilizers also had more chamber volume than any

TABLE 8-13. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 17 CONTRACT STERILIZERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 62			
Number per facility	3.6	2.8	1 - 10
Chamber volume per facility, m^3 (ft^3)	87.1 (3,075.9)	72.6 (2,563.8)	13.8 - 277.5 (487.3 - 9,799.8)
Ethylene oxide use = 336.9 Mg/yr (331.6 tons)			
Use per facility, Mg/yr (tons)	19.8 (19.5)	13.0 (12.8)	1.5 - 97.7 (1.5 - 96.2)
Total gas use = 1,567.6 Mg/yr (1,542.9 tons/yr)			
Use per facility, Mg/yr (tons/yr)	92.2 (90.7)	95.8 (94.3)	10.6 - 359.4 (10.4 - 353.7)

other group, averaging 87.1 m^3 (3,083.0 ft^3) per facility. During 1986, the contract sterilizers used 337 Mg (332 tons) of EO and 1,568 Mg (1,543 tons) of total gas--somewhat more than half the amounts used by the medical device suppliers. However, the contract sterilizers used much more EO and total gas than any other group on a per-facility basis. The inert-gas ratio for contract sterilizers was 3.65, indicating that contract sterilizers fall in the middle of the industry groups regarding their reliance on pure EO. This is not surprising because contract sterilizers service diverse industries with varying sterilization requirements.

8.5 DEMAND FOR ETHYLENE OXIDE STERILIZATION SERVICES

The demanders of EO sterilization services are the facilities that produce (or, in the case of museums and libraries, acquire) the goods that require sterilization. The demand for sterilization arises because sterilization is necessary to ensure the ultimate safety and effectiveness of the object sterilized. Specifically, many products cannot be marketed unless they meet FDA sterilization standards. Medical device suppliers sterilize their products because inadequately sterilized products could cause harmful health effects for users of the devices. Similarly, spice manufacturers sterilize their products because they may otherwise be damaged or contaminated by insects, molds, or bacteria.

The demanders can be separated into two groups. One group demands sterilization of the products they produce and also satisfies their own demand by sterilizing the products in-house. These are the facilities profiled in Sections 8.4.2.1 through 8.4.2.6. The other group of facilities demanding EO sterilization satisfies their demand by using the services of contract sterilizers. We assume that these demanders are facilities in the same industry groups as the facilities that perform in-house EO sterilization. Rather than sterilize their own goods in-house, however, they demand the services of a contract sterilizer.

The market for sterilization services may be viewed as being in equilibrium in the absence of an air emission standard. Demanders of sterilization compare the costs of sterilizing products in-house with the costs of sending their products offsite to a contract sterilizer. Likewise, they compare the costs of the various types of sterilization that can be employed with their products. They select the sterilization technique that minimizes the cost of producing their good or service, including the cost of sterilization. Imposing an air emission standard on EO sterilizers will increase the cost of this type of sterilization relative to other types. It will also increase the cost of producing goods requiring sterilization. The following section analyzes the impact of this relative increase in costs.

8.6 ECONOMIC EFFECTS OF CANDIDATE NESHAP CONTROLS UNDER THREE CONTROL OPTIONS

This section analyzes the economic effects that the candidate NESHAP controls will have on sterilization facilities under three control options.[29] As discussed above, EO has been designated a probable human carcinogen, so EPA has developed three possible control options representing increasing levels of stringency. Imposing controls on EO sterilization will increase the cost of performing this type of sterilization. This increase in sterilization costs will, in turn, increase the cost of producing goods and services in the industry groups that demand sterilization.

In the following sections, the provisions of the three control options are summarized. Then, the theoretical framework for analyzing economic impacts that increase production costs are described. Next, the analytical procedure used to evaluate the impacts of the control options is described, and the empirical results of the analysis are presented.

8.6.1 The Three Control Options

The three control options assessed in this analysis represent increasing levels of stringency of control:

1. Option 1 controls only emissions from the chamber vent and the vacuum pump drain;

2. Option 2 controls these two sources of emissions, plus emissions from the aeration room; and

3. Option 3 controls emissions from the main chamber vent, the vacuum pump drain, the aeration room, and the rear chamber exhaust.

8.6.2 Theoretical Framework for Economic Impact Analysis

The ideal procedures for estimating the economic effects of the proposed NESHAP controls use a framework based on the supply and demand for goods or services in the regulated market. [For a detailed description of this framework, see Chapter 2 in Reference 29.] A market demand curve describes the maximum quantity (per period) of a commodity, Q, that individuals or firms are willing to purchase at various prices, ceterus paribus (all else equal). As shown in Figure 8-1, demand curves slope downward, indicating that consumers are willing to buy more of Q at lower prices than at higher prices. This assumes that all other factors that might influence demand--for example, income, prices of related goods, and tastes or preferences--do not change.

If the market process establishes a price of P_1, consumers will purchase Q_1 of the commodity for a total expenditure equal to OP_1BQ_1. Because a demand curve measures maximum willingness to pay for each unit of a commodity, the total willingness to pay for Q_1 is the entire area $OABQ_1$--total expenditures plus the triangle P_1AB. This triangle, which is the difference between what consumers actually pay and the amount they are willing to pay, is known as consumer surplus. It is a good empirical approximation of the dollar value of the well-being consumers receive from consuming a commodity, over and above what they pay for the commodity.

The other principal construct in our conceptual framework is a market supply curve. A supply curve shows the maximum output (per time period) of a commodity that firms are willing to supply at various prices, ceterus paribus. The upward slope of supply curves (as shown in Figure 8-2) indicates that firms are willing to produce more at higher prices than at lower prices, assuming

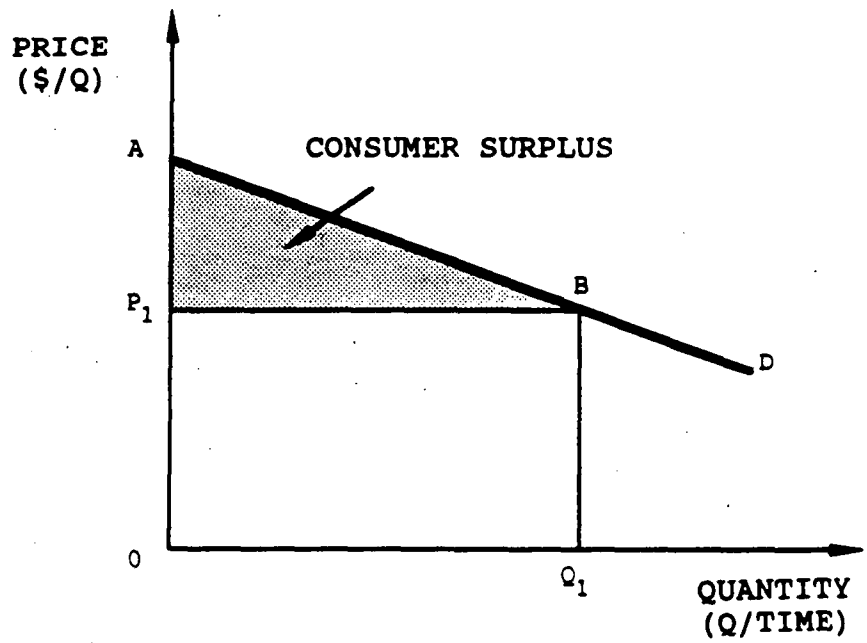

Figure 8-1. Demand curve for Commodity Q.

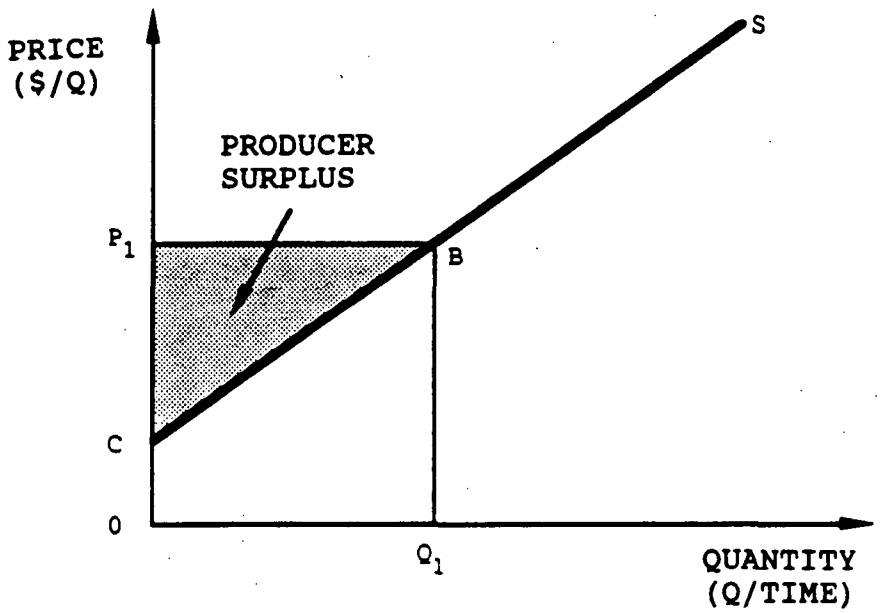

Figure 8-2. Supply curve for Commodity Q.

that other factors influencing the supply curve--prices of inputs (such as labor, energy, and machinery) and production technology--do not change.

If the market process establishes a price of P_1, then suppliers will produce Q_1 units of the commodity, receiving OP_1BQ_1 in total revenues. However, the cost of producing these Q_1 units is represented by the area $OCBQ_1$. The triangle CP_1B, which is known as producer surplus, is the difference between the minimum amount firms would accept for the Q_1 units and the actual amount they receive for these units. Producer surplus is a good empirical approximation of the dollar value of the returns that firms experience from producing a commodity, over and above the costs of production.

Installing and operating controls on EO emissions from sterilization chambers will increase the cost of sterilization. In a demand-supply framework, this additional cost is represented by an upward shift in the supply curve (from S_1 to S_2 in Figure 8-3). This upward shift in the supply curve leads to a higher market price (P_2) and a smaller quantity demanded (Q_2). The changes in price (from P_1 to P_2) and quantity (from Q_1 to Q_2) are market adjustments attributable to the emissions controls.

The cost of this change in market-clearing price and quantity due to the emissions controls is represented by the area CDEB--the area between the two supply curves S_1 and S_2 and under the demand curve. This area, which constitutes the cost that society experiences because of the emissions controls, equals the sum of the additional cost of producing Q_2 units of the commodity (area CDEF) plus the foregone consumer and producer surplus ($Q1 - Q_2$) on the units of the commodity that are no longer produced or consumed (area EFB). Equivalently, the social cost of emissions controls can be determined by aggregating the impact of the controls on the well-being of consumers and producers of affected commodities. In other words, social cost equals the sum of the change in consumer and producer surplus as a result of the price and quantity adjustments.

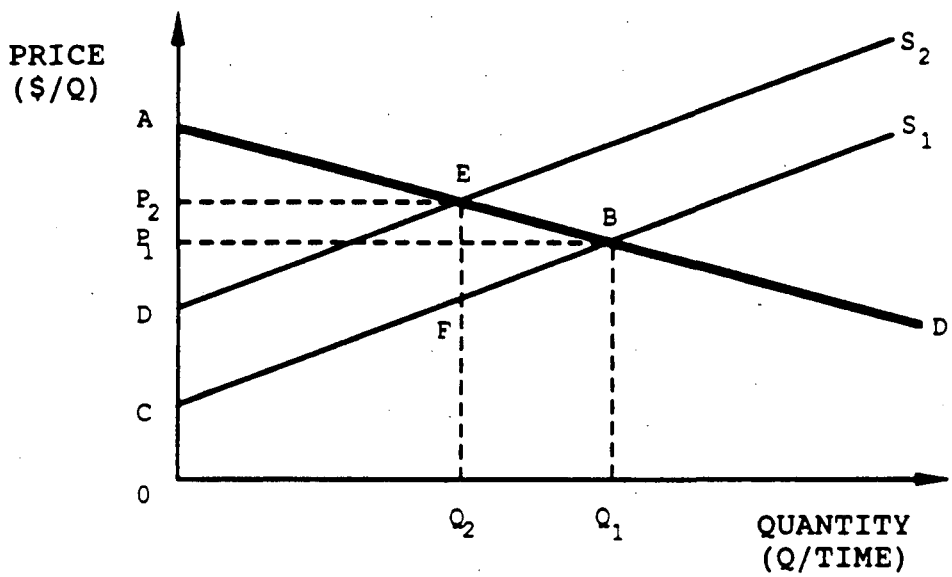

Figure 8-3. Market equilibrium with and without an upward shift in the supply curve due to ethylene oxide emissions controls.

S_1 shows market supply witout EO emissions controls.
S_2 shows market supply with emissions controls.

The simple model in Figure 8-3 ignores two potentially important aspects of the economic impact of the candidate NESHAP control under the three control options. First, the controls will apply both to existing and new plants (when they are constructed) that produce sterilized products. Thus, two supply curves are relevant: a supply curve from existing plants and a supply curve from new plants. The candidate NESHAP controls will shift both of these supply curves upward, although the magnitude of these shifts will probably differ. The potential effects of the candidate NESHAP controls on new facilities are addressed in Section 8.8.2.

Second, this discussion implies that all EO sterilization is offered in a market. In fact, much EO sterilization is performed in-house. In this case, the facility's demand for sterilization services is met by its own supply of sterilization services. These facilities do not generally offer to sterilize products for others on a contract basis, so their services are not part of market supply and have no market price. Only the EO sterilization performed on a contract basis is actually marketed. Therefore, employing the supply and demand framework to analyze the impacts of the regulation is not possible. Rather, because most sterilization takes place in the context of producing some other good or service, the impact of the regulation on the production of those goods and services has been analyzed.

As noted above, imposing air emission controls on EO sterilization increases the cost of sterilization, which in turn increases the cost of producing goods requiring sterilization. The candidate NESHAP controls will probably cause some firms to substitute contract sterilization for in-house sterilization. If the candidate NESHAP controls are promulgated, facilities currently sterilizing in-house using EO will face four possible alternatives:

1. Adopt the candidate controls;
2. Switch to another sterilization process;
3. Discontinue in-house sterilization, switching to contract sterilization; or

4. Discontinue sterilizing or producing the sterilized product.

Undoubtedly, substituting contract sterilization for in-house sterilization (Alternative 3) will be the least-cost alternative for some facilities. Others may choose to switch to another method of sterilization. Finally, some facilities may decide to discontinue sterilization or to stop producing products that require sterilization. Because of a lack of necessary data, no attempts are made to decide which facilities will respond in which way to the candidate NESHAP. [For a detailed explanation of the substitution effect, see Section 8.7.4.]

Contract sterilizers' costs will also be increased by imposing the control options. Their choices of possible responses are limited to three alternatives:

1. Adopt the candidate controls;
2. Switch to another sterilization process; or
3. Discontinue sterilization.

8.6.3 Analytical Procedure

The theoretical framework for analyzing economic impacts involves estimating changes in the market price and quantity sold of a product or service. As noted above, however, in-house sterilization is not marketed. Consequently, using the supply and demand framework to analyze the economic effects of the candidate commercial sterilization NESHAP is not possible. As an alternative, EO sterilization is analyzed within the context of the production of the goods and services requiring sterilization and a more qualitative approach is used that approximates the ideal approach.

This approach has four parts. First, dividing commercial sterilizers into seven industry groups imposes some homogeneity on the facilities. Second, each facility's chamber volume and annual EO use is used as proxies for the quantity of sterilized goods produced. By dividing these proxies into the annual compliance cost under the three control options, rough estimates are obtained of the *per-unit* production cost increase caused by the candidate NESHAP. Third, for each control option, dividing

each facility's annual compliance cost by its total baseline cost of sterilization produces an *upper-bound* for the *percentage* increase in production cost caused by the NESHAP under each control option. Finally, dividing each facility's annual compliance cost under each control option by its total sales produces a *lower-bound* estimate of the percentage production cost increase. Each facility's actual percentage production cost increase attributable to the candidate NESHAP under each control option lies somewhere between its upper- and lower-bound estimates.

8.6.3.1 Industry Grouping. The 188 affected facilities were divided into seven industry groups based on their SIC Code: medical device suppliers, other health-related manufacturers, pharmaceuticals manufacturers, spice manufacturers, museums and libraries, laboratories, and contract sterilizers. The firms within each of these subgroups produce a more homogeneous mix of goods than does the aggregate group. Nevertheless, the product mix is still quite diverse within the industry groups, as is demonstrated in Section 8.1.

8.6.3.2 Chamber Volume as an Output Measure. The sum of the volumes of all sterilization chambers at a facility is one measure of the facility's sterilization capacity. If sterilization cycles for all sizes and types of chambers are of equal duration, then a facility with twice the chamber volume of another facility also have twice the sterilization capacity. If this assumption is not true, then the direct relationship will not hold. For example, if larger chambers undergo longer cycles, then chamber volume will overstate sterilization capacity for large chambers and understate capacity for small chambers. If small chambers undergo longer cycles, then the reverse will hold.

Chamber volume can be used not only as a measure of capacity but also as a measure of output under the following two additional assumptions.

1. All facilities within an industry group perform about the same number of sterilization cycles per year; and

2. The sterilization chambers are always filled with products to approximately the same level.

Under these assumptions, chamber volume would be highly correlated with the volume of goods sterilized.

How valid are these two assumptions? Data from the EPA commercial sterilization data base indicates that facilities do not perform equal numbers of sterilization cycles per chamber, even within industry groups.[1] These data indicate that the first assumption is not true. Therefore, chamber volume may be a poor output measure.

8.6.3.3 <u>EO Use as a Measure of Output.</u> Ethylene oxide use is the second surrogate output measure. The EPA commercial sterilization data base provides data on the amount of EO used per facility during 1986 (1988 or 1985 for some facilities).[1] Ethylene oxide use is a better output measure than chamber volume because EO use varies directly with the volume of goods sterilized, even if firms do not run a consistent number of sterilization cycles per chamber. However, using EO as a measure of the volume of products sterilized requires making the following two assumptions:

1. The concentration of EO per unit of chamber volume is roughly the same for all chambers; and

2. Sterilization chambers are filled with products to roughly the same level for each cycle.

Again, the assumptions necessary for EO use to be a valid measure of output are probably not met. First, the concentration of EO per unit of chamber volume varies depending on the type of gas mixture used. Sterilization with pure EO requires a lower concentration of EO than does sterilization using 12/88. Also, although we have no supporting data, we can speculate that sterilization chambers may not always be filled with products to the same level. Probably facilities running frequent sterilization cycles would always fill their chambers to capacity to minimize costs. However, facilities that sterilize infrequently may run some cycles at less than capacity because they face sporadic orders for sterilized goods and shipment

deadlines. To the extent that this occurs, EO use may overstate the volume of goods sterilized by small-volume sterilizers. If so, this overstatement of facilities' output would make the industry supply curve appear flatter (i.e., more price-elastic) than it actually is.

To this point, a potentially important problem with the output measures has been ignored. As mentioned above, many types of products are sterilized with EO. Chamber volume and EO use are measures of the physical volume of products sterilized, but with such a diverse group of products, volume is not an appropriate measure of output. For example, one facility may sterilize pacemakers while another sterilizes scalpels. Output (in physical or monetary units) per cubic meter of chamber volume will likely differ substantially between pacemakers and scalpels. A similar conclusion seems reasonable regarding EO use as an output measure. In summary, the diversity of products sterilized in the seven industry groups undermines the usefulness of chamber volume and EO use as proxies for facility output.

In addition to measures of total annualized compliance cost (TAC) per unit of output, approximated by the measures described above, two measures are computed that approximate TAC as a percentage of the total baseline cost of producing sterilized products. Ideally, TAC would be reported as a percentage of the total cost of producing sterilized products. However, no data on such costs at the affected facilities are available. Therefore, TAC is reported as a percentage of the total annualized baseline cost of sterilization at a facility (TAC/C) and TAC as a percentage of total facility sales (TAC/S). Because the total cost of producing sterilized products (hereafter referred to as total production cost) equals or exceeds the sterilization cost for any facility, TAC/C is an upper bound for TAC/total production cost. Conversely, total production cost is generally less than or equal to facility sales, particularly because most affected facilities produce a mix of sterilized and unsterilized products. Therefore, TAC/S is a lower bound for TAC/total production cost. The denominators of these two measures,

baseline sterilization costs and facility sales, are described in the following two sections.

8.6.3.4 Baseline Cost of Sterilization. The total annual costs of sterilization for each facility were calculated using a model chamber approach. Specifically, the capital cost and operating cost per cycle are calculated for representative size chambers in the following chamber categories: 12/88, pure EO, nonflammable EO/CO_2, and flammable EO/CO_2. Four representative chamber sizes for the 12/88 gas type were chosen, four for pure EO, three for flammable EO/CO_2, and two for nonflammable EO/CO_2. Representative chamber sizes were selected by first minimizing the total variance between the representative chamber sizes and the sizes of chambers currently in use, as reported in the EPA commercial sterilization data base. Then the selection of representative chamber sizes was finalized by reviewing scatter plots of actual chamber sizes and talking with a vendor of sterilization chambers.

A sterilization chamber vendor provided estimates of capital and operating costs for each model chamber. Capital costs include the cost of the sterilization chamber, the cost of installing the chamber, and the cost of explosion protection equipment for use with flammable sterilant gases. Chamber operating costs include labor, electricity, and sterilant gas costs.

After determining the capital and operating costs for the model chambers, the chambers were divided at the affected facilities into the four gas types outlined above. The operating cost per cycle and capital cost for each chamber were determined by interpolating between the model chambers based on chamber size. Multiplying the operating cost per cycle by the annual number of cycles for the chamber, as reported in the EPA commercial sterilization data base, produced the annual operating cost of the chamber. The capital cost was annualized using a useful life of 10 years and an interest rate of 10 percent, and the annualized capital cost and the annual operating cost were added to obtain the annual sterilization cost for the chamber.

Next, determining the annual baseline cost of sterilization at the facility involved aggregating the annual sterilization costs for individual chambers at each facility. Then, for facilities with controls in place at baseline, the annualized cost of these controls was added. Finally, because the compliance costs are given in last quarter 1987 dollars, the Producers' Price Indices were used for all commodities for 1986 and 1987 to adjust the baseline facility costs from 1986 dollars to 1987 dollars. The costs, therefore, represent 1986 data in 1987 prices.[17]

8.6.3.5 Facility Sales. Total facility sales provide an upper-bound estimate of the total costs of producing sterilized goods for several reasons. First, total sales for a facility include sales of sterilized and unsterilized products. For facilities that sterilize only a small portion of output, total sales may substantially exceed sales of sterilized products. Second, sales reflect the price of final products multiplied by the output of these products. They do not directly measure production costs. In general, sales equal production costs plus producer surplus. Producer surplus is only zero when the supply curve is horizontal or the firm is the marginal firm in its industry; therefore, using sales to measure production costs implies one of these two conditions. If producer surplus is not zero, then total sales will overstate total production costs.

As noted, sales are reported on a facility-specific basis. When a facility did not report its own sales and the parent company sales were available, the amount of sales per employee for the parent company was multiplied by the number of employees at the facility. This calculation assumes that the amount of sales per employee at the parent company and the facility are the same, which would not be true, for example, if the facility were more capital-intensive than the parent company. No information regarding the validity of this assumption is available.

Where neither sales nor employment information was available, estimating facility sales was accomplished by using an ordinary least-squares regression of facility sales on facility EO use. Dummy variables were included to represent the seven

industry groups, and a log-log functional form was used. As with baseline annual sterilization costs, facility sales were adjusted from 1986 dollars to 1987 dollars, using the Producers' Price Indices for all commodities for 1986 and 1987.[17]

8.6.4 Results

As explained in the previous section, the economic analysis was based on the annual cost of complying with the candidate NESHAP controls under each of three control options. The three control options represent increasing levels of stringency of control, as described in Section 8.6.1. The control costs under each control option are evaluated relative to chamber volume, EO use, total baseline sterilization costs, and total facility sales. The summary statistics on these values are presented in this section.

8.6.4.1 Total Annualized Cost (TAC). Total annualized cost measures the annual engineering cost of compliance with the candidate NESHAP controls under each of the three control options, as described in Chapter 7 of the Background Information Document. Total annualized cost under Option 1 equals the capital cost of an acid water scrubber and other necessary hardware annualized over a 10-year period at an interest rate of 10 percent, plus annual operating costs for the scrubber, including labor, materials, and ethylene glycol disposal costs. Electric and water costs for scrubber operation were assumed to be insignificant and are not included. Emissions from the vacuum pump drain were assumed to be controlled using a water-sealed vacuum pump(s) with closed-loop recirculation and a liquid-gas separator. Costs for these were estimated, as were costs for the piping for manifolding the chambers at a facility to the existing control device or to a scrubber.[30]

The total annualized compliance costs under Option 2 include the costs described under Option 1 plus the additional costs of controlling the emissions from the chamber in which the product is aerated. For the cost analysis, it was assumed that a facility could use insulated shipping containers as modular aeration units, replacing all existing aeration processes

conducted in aeration rooms over 84 cubic meters. For these facilities, the number of modular units needed was estimated as were the costs for purchasing and installing these units. Costs were assessed for both catalytic oxidation units and gas/solid reactant systems that might be used to control the emissions, for any manifolding required, and for materials, labor, and other operating costs. The least costly approach, a gas/solid reactant system, was selected for the impact analysis.[31]

Finally, the total annualized compliance cost under Option 3 includes the compliance costs under Option 2 plus, for those facilities with rear chamber exhausts on some or all of their chambers, the costs of controlling the emissions from that source. Facilities with total sterilizer volumes less than 7 m^3 probably do not have rear chamber exhausts and therefore were not included in this cost analysis.[32] Several control methods were considered for rear chamber exhaust emissions, including installing dedicated scrubbers and manifolding the rear chamber exhaust emissions to the aeration room control. This impact analysis used the least costly method, the dedicated add-on scrubbers.

Table 8-14 reports the median and range of TAC per facility for each of the seven industry groups under each control option and includes only facilities incurring positive total annual compliance costs. As shown in Table 8-15, under Option 1, 29 facilities do not incur compliance costs. Under Option 2, only two facilities escape compliance costs, and under Option 3, all facilities but one incur at least some compliance cost.

Under Option 1, the median TAC's range from $8,400 to $44,000. The highest median TAC, $44,000, is incurred by contract sterilizers. Spice manufacturers experience the second highest median TAC, $35,000. Other industries with relatively high TAC's are other health-related manufacturers (median TAC of $31,900) and medical device suppliers (median TAC of $28,000).

A medical device supplier incurs the maximum TAC of any facility--$128,000. Other industry groups having individual

TABLE 8-14. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS[a] [b]

Industry group	Option 1		Option 2		Option 3	
	Median, $\$10^3$	Range, $\$10^3$	Median, $\$10^3$	Range, $\$10^3$	Median, $\$10^3$	Range, $\$10^3$
Miscellaneous/laboratories	13.5	8.3 - 38.2	22.8	17.6 - 61.5	22.8	17.6 - 90.4
Spice manufacturers	35.0	8.3 - 71.6	47.1	17.6 - 90.7	65.8	17.6 - 109.6
Pharmaceuticals manufacturers	23.8	2.5 - 106.0	35.2	9.3 - 180.4	52.6	17.6 - 211.1
Other health-related	31.9	8.3 - 75.6	47.1	17.6 - 206.6	65.5	17.6 - 238.4
Medical equipment suppliers	28.0	0.6 - 128.0	38.6	9.3 - 240.0	55.4	17.6 - 271.7
Contract sterilizers	44.0	26.4 - 104.0	63.1	39.4 - 210.0	89.5	58.8 - 240.8
Museums and libraries	8.4	8.3 - 29.5	17.7	17.6 - 38.8	17.7	17.6 - 57.5

[a]Total annual compliance cost is "cumulative" in the sense that the TAC under Option 2 equals the TAC under Option 1 plus the incremental annualized compliance costs associated with Option 2, and the TAC under Option 3 equals the TAC under Option 2 plus the incremental annualized compliance costs associated with Option 3.

[b]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. See Table 9-15 for the total number of facilities in each industry group and the number incurring no compliance costs as a result of each control option.

TABLE 8-15. COUNT OF FACILITIES HAVING POSITIVE AND ZERO CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS[a]

Industry group	Option 1		Option 2		Option 3	
	TAC=0	TAC > 0	TAC = 0	TAC > 0	TAC = 0	TAC > 0
Miscellaneous/laboratories	0	10	0	10	0	10
Spice manufacturers	4	19	0	23	0	23
Pharmaceuticals manufacturers	3	36	1	38	1	38
Other health-related	3	21	1	23	0	24
Medical equipment suppliers	13	49	0	62	0	62
Contract sterilizers	6	11	0	17	0	17
Museums and libraries	0	13	0	13	0	13

[a]Total annual compliance cost is "cumulative" in the sense that the TAC under Option 2 equals the TAC under Option 1 plus the incremental annualized compliance costs associated with Option 2, and the TAC under Option 3 equals the TAC under Option 2 plus the incremental annualized compliance costs associated with Option 3.

facilities that experience high TAC's include pharmaceutical manufacturers, with a maximum TAC of $106,000, and contract sterilizers, with a maximum TAC of $104,000.

At the same time, facilities in six of the seven industry groups do not incur compliance costs under Option 1 (see Table 8-15). These are facilities that already have the required controls in place. Under Option 1, the lowest positive TAC for an affected facility is a medical device supplier, with a TAC of $600. The lowest TAC for an affected contract sterilizer, on the other hand, is a relatively high $26,400.

Under Option 2, the median TAC ranges from $17,700 for museums and libraries to $63,100 for contract sterilizers. Also experiencing relatively high median TAC under Option 2 are spice manufacturers and other health-related manufacturers, each with a median TAC of $47,100. Under this control option, the highest TAC facility is again a medical device supplier, with a TAC of $240,000. Contract sterilizers and other health-related manufacturers also have facilities with TAC's over $200,000. The lowest cost-controlled facilities, each with a TAC of $9,300 under Option 2, are found in the pharmaceuticals manufacturers and medical device suppliers groups.

Finally, under Option 3, facilities with a chamber fitted with rear chamber exhausts incur incremental control costs, compared to Option 2. The highest median TAC, again for contract sterilizers, rises to $89,500. Spice manufacturers and other health-related manufacturers incur a median TAC under Option 3 of $65,800 and $65,500, respectively. Museums and libraries, on the other hand, incur a median TAC of only $17,700 under Option 3. The maximum value for a TAC is incurred by a medical device supplier: $271,700. Pharmaceuticals manufacturers, other health-related manufacturers, and contract sterilizers also contain facilities that incur a TAC over $200,000 under Option 3. The highest TAC experienced by a museum or library, on the other hand, is only $57,500 even under Option 3.

8.6.4.2 <u>TAC Relative to Chamber Volume.</u> Table 8-16 reports the median and range of total annualized costs per cubic meter of

TABLE 8-16. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER CUBIC METER OF FACILITY CHAMBER VOLUME, FOR AFFECTED INDUSTRY GROUPS[a]

Industry group	Option 1		Option 2		Option 3	
	Median, $\$10^3/M^3$ ($\$10^3/ft^3$)	Range, $10^3/M^3$ ($\$10^3/ft^3$)	Median, $\$10^3/M^3$ ($\$10^3/ft^3$)	Range, $\$103/M^3$ ($\$10^3/ft^3$)	Median, $\$10^3/M^3$ ($\$10^3/ft^3$)	Range, $\$10^3/M^3$ ($\$10^3/ft^3$)
Miscellaneous/laboratories	6.4 (226.0)	2.4 - 293.8 (84.8 - 10,375.5)	10.4 (367.3)	3.8 - 622.2 (134.2 - 21,972.8)	10.4 (367.3)	5.6 - 622.2 (197.8 - 21,972.8)
Spice manufacturers	2.0 (70.6)	0.4 - 97.9 (14.1 - 3,457.3)	2.7 (95.3)	0.2 - 207.4 (7.1 - 7324.2)	3.8 (134.2)	0.5 - 207.4 (17.7 - 7,324.2)
Pharmaceuticals manufacturers	3.0 (105.9)	0.0 - 59.2 (0.0 - 2,090.6)	4.0 (141.3)	0.4 - 124.9 (14.1 - 4,410.8)	5.6 (197.8)	0.7 - 124.9 (24.7 - 4,410.8)
Other health-related	1.8 (63.6)	0.6 - 21.0 (21.2 - 741.6)	2.3 (81.2)	0.2 - 44.4 (7.1 - 1,568.0)	3.0 (105.9)	0.3 - 44.4 (10.5 - 1,568.0)
Medical device suppliers	2.3 (81.2)	0.0 - 297.7 (0.0 - 10,513.2)	2.6 (91.8)	0.1 - 626.1 (3.5 - 22,110.5)	4.1 (144.8)	0.3 - 626.1 (10.5 - 22,100.5)
Contract sterilizers	1.5 (53.0)	0.7 - 2.3 (24.7 - 81.2)	1.6 (56.5)	0.2 - 3.5 (7.1 -123.6)	1.8 (63.6)	0.3 - 4.3 (10.5 - 151.9)
Museums and libraries	8.2 (289.6)	2.1 - 16.4 (74.2 - 579.2)	17.4 (614.5)	2.8 - 34.7 (98.9 - 1,225.4)	17.4 (614.4)	4.2 - 34.7 (148.3 - 1,225.4

[a]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have positive TAC, but the TAC/CV is less than 0.05 percent.

chamber volume per facility (TAC/CV) under each of the control options. Under all three control options, the highest medians are experienced by the museums and libraries group of facilities, while the laboratories industry group contains the highest single value of TAC/CV. These two industries incur relatively low compliance costs, but they also have extremely low chamber volume. Thus, their TAC/CV is high. Under Option 1, museums and libraries have a median TAC/CV of \$8,200/m^3 (\$289,581/ft^3), while laboratory facilities incur a median TAC/CV of \$6,400/m^3 (\$2,260,142/ft^3). Four of the other five industry groups experience median values for TAC/CV of \$2,200/m^3 (\$77,692/ft^3) or less. The maximum TAC/CV under Option 1 is experienced by a medical device supplier: \$297,700/m^3 (\$10,513,194/ft^3).

Under Options 2 and 3, the median TAC/CV for the museums and libraries group increases to \$17,400/m^3 (\$614,476/ft^3), while the median TAC/CV experienced by the laboratories group is \$10,400/m^3 (\$367,273/ft^3). The highest single TAC/CV is again experienced by a medical device supplier: \$626,100/m^3 (\$22,107,018/ft^3). Finally, under Option 3, the museums and libraries group again experiences a median of \$17,400 (\$614,476/ft^3) and the maximum again is \$626,100 (\$22,110,549/ft^3), experienced by a medical device supplier.

8.6.4.3 <u>TAC Relative to EO Use.</u> Table 8-17 shows summary statistics for total annualized compliance cost per metric ton of facility EO use (TAC/EO) under each of the three control options. As with TAC/CV, the museums and libraries and the laboratories incur the largest impacts, when measured by TAC/EO. As with TAC/CV, these facilities' relatively low compliance costs combine with extremely low EO use to yield high TAC/EO values. Under Option 1, the median TAC/EO incurred by the museum and library facilities is \$1,216,100/Mg (\$1,196,894/ton). The median experienced by the laboratories group of facilities is \$163,100/Mg (\$160,524/ton). The other five industry groups experience much lower median TAC/EO, ranging from \$8,100/Mg (\$7,972/ton) for contract sterilizers to \$31,100/Mg (\$30,609/ton) for spice manufacturers. The maximum TAC/EO experienced by any

TABLE 8-17. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER METRIC TON OF ETHYLENE OXIDE USED BY FACILITY, FOR AFFECTED INDUSTRY GROUPS[3,a]

Industry group	Option 1		Option 2		Option 3	
	Median, $\$10^3$/Mg ($\$10^3/ft^3$)	Range, 10^3/Mg ($\$10^3/ft^3$)	Median, $\$10^3$/Mg ($\$10^3/ft^3$)	Range, $\$10^3$/Mg ($\$10^3/ft^3$)	Median, $\$10^3$/Mg ($\$10^3/ft^3$)	Range, $\$10^3$/Mg ($\$10^3/ft^3$)
Miscellaneous/laboratories	163.1 (160.5)	4.4 - 3,050.7 (4.3 - 3,002.5)	240.0 (236.2)	7.1 - 6,460.7 (7.0 - 6,358.7)	292.7 (288.1)	10.4 - 6,460.7 (10.2 - 6,358.7)
Spice manufacturers	31.1 (30.6)	7.0 - 2,033.8 (6.9 - 2,001.7)	28.3 (27.9)	1.8 - 4,307.1 (1.8 - 4,239.0)	37.6 (37.0)	2.4 - 4,307.1 (2.4 - 4,239.1)
Pharmaceuticals manufacturers	18.3 (18.0)	0.0 - 1,076.7 (0.0 - 1,059.7)	19.8 (19.5)	1.1 - 2,280.2 (1.1 - 2,244.2)	26.9 (26.5)	1.7 - 2,280.2 (1.7 - 2,244.2)
Other health-related	11.0 (10.8)	0.6 - 3,660.8 (.59 - 3,603.0)	14.3 (14.1)	1.6 - 7,752.8 (1.6 - 7,630.4)	16.8 (16.5)	1.8 - 7,752.8 (1.8 - 7,630.4)
Medical device suppliers	12.4 (8.0)	0.0 - 1,525.3 (0.0 - 1,501.2)	13.2 (13.0)	1.2 - 3,230.3 (1.2 - 3,179.3)	19.5 (19.2)	2.0 - 3,230.3 (2.0 - 3,179.3)
Contract sterilizers	8.1 (8.0)	1.1 - 20.9 (1.1 - 20.6)	6.1 (6.0)	2.0 - 39.1 (2.0 - 38.5)	7.3 (7.2)	2.5 - 54.4 (2.5 - 53.5)
Museums and libraries	1,216.1 (1,196.9)	183.0 - 9,152 (180.1 - 9,007.5)	2,352.8 (2,315.6)	385.5 - 19,382 (379.4 - 19,076.0)	2,352.8 (2,315.6)	38.5 - 19,382 (37.9 - 19,076)

[a]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/EO is less than 0.05 percent.

facility under Option 1 is $9,152,000/Mg ($9,007,458/ton), experienced by a museum and library facility. Other industry groups reveal maximum TAC/EO values ranging from $20,900/Mg ($20,576/ton) for contract sterilizers to $3,660,800/Mg (3,604,048/ton) for other health-related manufacturing. The minimum TAC/EO is $0 for six of the seven industry groups under Option 1 but is $183,000/Mg ($180,110/ton) for the museums and libraries group.

Under Options 2 and 3, the same basic pattern is evident. The highest median TAC/EO is experienced by the museums and libraries industry, $2,352,800/Mg ($2,315,641/ton) under both control options. The second highest median TAC/EO under Options 2 and 3 is experienced by the laboratories industry group: $240,000/Mg ($236,210/ton) under Option 2 and $292,700/Mg ($288,077/ton) under Option 3. The maximum TAC/EO value for any facility is experienced by a museum and library facility, $19,382,000/Mg ($19,075,890/ton) under both control options. Maximum TAC/EO values for other industry groups range from $39,100/Mg ($35,530/ton) for contract sterilizers to $7,752,800/Mg ($7,630.356/ton) for other health-related manufacturing groups under Option 2 and from $54,400/Mg ($53,541/ton) for contract sterilizers to $7,752,800/Mg ($7,630,356/ton) for other health-related manufacturing groups under Option 3.

8.6.4.4 <u>TAC Relative to Baseline Annual Sterilization Cost</u>. Table 8-18 reports the medians and ranges of total annualized compliance cost as a percentage of baseline annual sterilization costs (TAC/C) under the three control options. As mentioned above, TAC/C represents an upper-bound estimate of TAC relative to total production cost, the desired impact measure.

Under Option 1, the median values for TAC/C range from 16.0 percent for medical device suppliers to 48.3 percent for museums and libraries. The second highest median TAC/C for Option 1 is 44.7 percent, experienced by spice manufacturers. The laboratories industry group has a median TAC/C of 27.6 percent, while contract sterilizers have a median TAC/C of

TABLE 8-18. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF BASELINE ANNUAL STERILIZATION COSTS, FOR AFFECTED INDUSTRY GROUPS[a] [b]

Industry group	Option 1		Option 2		Option 3	
	Median, %	Range, %	Median, %	Range, %	Median, %	Range, %
Miscellaneous/laboratories	27.6	3.2 - 67.4	46.0	5.2 - 101.4	56.0	7.6 - 142.3
Spice manufacturers	44.7	18.8 - 118.1	52.3	1.9 - 144.9	68.4	4.0 - 198.8
Pharmaceuticals manufacturers	20.2	0.4 - 117.2	31.6	2.5 - 166.7	40.1	7.9 - 182.0
Other health related	20.4	1.0 - 45.0	19.1	1.3 - 95.3	25.5	1.1 - 95.3
Medical device suppliers	16.0	0.1 - 83.3	16.6	1.3 - 118.6	24.4	2.0 - 177.8
Contract sterilizers	16.3	4.5 - 78.6	10.9	1.2 - 63.4	13.8	2.0 - 91.8
Museums and libraries	48.3	11.4 - 115.8	100.4	24.1 - 152.4	100.4	24.1 - 225.8

[a]Baseline annual sterilization costs include annual operating costs, annualized capital costs, and annualized costs of any emissions controls present at baseline. Baseline costs represent 1986 data adjusted from 1986 dollars to 1987 dollars using the Producers' Price Indices for all commodities for 1986 and 1987.

[b]Including only facilities with positive compliance costs. This includes 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/C is less than 0.05 percent.

20.2 percent under Option 1. Other health-related manufacturers have a median TAC/C of 20.4 percent, while contract sterilizers have a median TAC/C of 16.3 percent. Although some facilities in six of the seven industry groups experience no compliance cost under Option 1, other facilities experience TAC/C as high as 118.1 percent. This maximum TAC/C is incurred by a spice manufacturing facility. Other facilities with TAC/C over 100 percent are found in the pharmaceuticals manufacturing industry (maximum TAC/C of 117.2 percent) and museums and libraries (maximum TAC/C of 115.8 percent).

Under Options 2 and 3, the median facility in the museums and libraries industry experiences sterilization costs doubled by the controls (TAC/C of 100.4 percent). The median TAC/C for the other six industry groups ranges from 10.9 percent for contract sterilizers to 52.3 percent for spice manufacturers under Option 2, and from 13.8 percent for contract sterilizers to 68.4 percent for spice manufacturers under Option 3.

The highest TAC/C for any facility under Option 2 is 166.7 percent, experienced by a pharmaceuticals manufacturer. Other high TAC/C facilities are found in the museums and libraries group (152.4 percent) and the spice manufacturing group (144.9 percent). Even in the contract sterilizer industry, one facility experiences a TAC/C of 63.4 percent. Under Option 3, the maximum impacts range from 91.8 percent for contract sterilizers to 225.8 percent for museums and libraries, and four of the seven industry groups have facilities that experience 177 percent TAC/C values, or higher. The lowest TAC/C facilities in six of the seven industry groups incur TAC/C less than 8 percent under Options 2 and 3, but the lowest TAC/C facility in the museums and libraries group has a value of 24.1 percent under both Options 2 and 3.

The relatively low TAC/CV, TAC/EO, and TAC/C for the contract sterilizers under all three control options support the hypothesis that the contract sterilizers may experience economies of scale in controlling EO emissions. In other words, the candidate NESHAP controls may cause lower per-unit increases in

production costs for contract sterilizers than for facilities in the other groups.

8.6.4.5 TAC Relative to Total Facility Sales. Table 8-19 reports the total annualized compliance cost as a percentage of total annual facility sales (TAC/S) under the three control options. As described above, this measure represents the lower-bound estimate of total annualized compliance cost as a percentage of total annual baseline production cost.

Under Option 1, the median TAC/S values range from less than 0.1 percent (for museums and libraries and pharmaceuticals manufacturers) to 2.0 percent for contract sterilizers. The highest TAC/S under Option 1 is experienced by a contract sterilizer: 12.8 percent. Medical equipment suppliers have the next highest maximum TAC/S under Option 1. One medical device supplier experiences a TAC/S of 5.5 percent. The maximum TAC/S for the other industry groups ranges from 1.6 percent, for the other-health-related-and-miscellaneous-and-libraries groups, to 4.2 percent for museums and libraries.

Under Option 2, the contract sterilizers have a median TAC/S of 3.9 percent, while all other industry groups experience median TAC/S values between 0.0 percent and 0.5 percent. The maximum TAC/S incurred under Option 2 is again a contract sterilizer. For this facility, TAC represents 25.9 percent of annual sales under Option 2. The maximum TAC/S values experienced by other industry groups range from 2.3 percent, for other health-related manufacturers, to 8.8 percent, for museums and libraries.

Under Option 3, the median TAC/S for contract sterilizers rises to 4.6 percent. Again, all the other industry groups have median TAC/S values less than one percent. The highest maximum value is again a contract sterilizer, which incurs TAC/S of 29.7 percent. Industry maximums for TAC/S for the other six industry groups range from 3.0 percent to 9.6 percent.

8.7 EFFECTS OF THE REGULATION ON SMALL BUSINESSES

8.7.1 Requirements of the Regulatory Flexibility Act

The Regulatory Flexibility Act requires the awareness and consideration of small entities as regulations are being

TABLE 8-19. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF ANNUAL FACILITY SALES, FOR AFFECTED INDUSTRY GROUPS[a b d]

Industry group	Option 1		Option 2		Option 3	
	Median, %	Range, %	Median, %	Range, %	Median, %	Range, %
Miscellaneous/laboratories	0.1	0.0 - 1.6	0.2	0.0 - 2.6	0.2	0.0 - 3.8
Spice manufacturers	0.4	0.0 - 2.7	0.5	0.0 - 6.2	0.7	0.0 - 8.0
Pharmaceuticals manufacturers	0.0	0.0 - 3.2	0.1	0.0 - 4.6	0.1	0.0 - 4.6
Other health related	0.2	0.0 - 1.6	0.3	0.0 - 2.3	0.4	0.0 - 3.0
Medical device suppliers	0.1	0.0 - 5.5	0.1	0.0 - 6.9	0.2	0.0 - 9.6
Contract sterilizers	2.0	0.3 - 12.8	3.9	0.3 - 25.9	4.6	0.5 - 29.7
Museums and libraries[c]	0.0	0.0 - 4.2	0.0	0.0 - 8.8	0.0	0.0 - 8.8

[a]Facility sales amounts represent 1986 data adjusted from 1986 dollars to 1987 dollars using the Producers' Price Indices for all commodities for the years 1986 and 1987.
[b]Some facility sales figures were unavailable and were estimated using parent company sales or a regression of facility sales on EO use.
[c]Rather than facility sale, operating budgets were estimated for each facility in this group.
[d]Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/S is less than 0.05 percent.

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developed. The RFA requires a determination of whether there is a "significant economic impact" on a "substantial number" of small entities. The EPA has issued RFA guidelines containing the following criteria for use in determining what is a significant economic impact:

1. Annualized compliance costs increase total cost of production by more than 5 percent;

2. Compliance costs as a percentage of sales for small plants are at least 10 percentage points higher than for large plants;

3. Capital costs of compliance represent a significant portion of capital available to small entities; and

4. The requirements of the regulation are likely to result in closures of small entities.

Normally, a substantial number of small entities are said to incur significant impacts, if at least 20 percent of the small entities experiencing increased costs as a result of the regulation meet the above criteria. However, even if 20 percent of affected small entities meet the above criteria, if that 20 percent represents only a very small absolute number of affected entities, a substantial number of affected small entities do <u>not</u> incur significant impacts.

8.7.2 <u>Small Businesses Performing Ethylene Oxide Sterilization</u>

Because EO sterilization is the major line of business for contract sterilizers, these firms will probably incur relatively large impacts. In the other industry groups, EO sterilization is only one of many operations performed in the course of producing another good or service. For most of these firms, EO sterilization represents a small share of their total production costs. Therefore, firms in these sectors are not expected to incur significant economic impacts. In addition, in many of the other sectors, firms performing EO sterilization are larger than those in the contract sterilizer sector. For these reasons, the contract sterilizer sector's impacts and firm sizes were first examined in detail. Then, small business impacts were considered in the other industry groups.

8.7.3 Small Businesses in the Contract Sterilizer Industry Group

Firms in the contract sterilizer sector are considered small if they have annual sales of less than $3.5 million. Nine of the 17 facilities included in the contract sterilizer industry group were contacted to obtain information on facility sales and credit availability and cost, to characterize the contract sterilizers' clients, and to investigate the possibility of substituting other sterilization techniques for EO sterilization. Of the nine, eight responded, with one of the eight indicating that it no longer used EO. Additional information about firm sales was obtained from Dun and Bradstreet's "Dun's Market Identifiers."

As expected, many of the contract sterilizers are small. Based on sales information obtained from the facilities or from Dun and Bradstreet where available, and on our sales estimates when no data are available from the other sources, 12 of the remaining 16 facilities in the contract sterilizer sector still performing EO sterilization are small. To estimate the increase in total production costs for these small businesses, baseline sterilization costs were used as a proxy for total production cost. This yields a conservative estimate of the total production cost increase. Under control Option 1, eight of the 12 small businesses are expected to incur compliance costs exceeding 5 percent of baseline sterilization costs. Under control Option 2 and 3, 11 of 12 are expected to incur compliance costs exceeding five percent of baseline sterilization costs.

Initially, therefore, a substantial number of small entities may be significantly affected by the regulation. In talking to the facilities, however, several things were discovered that will mitigate the severity of the impacts. First, some of the facilities contacted indicated that EO sterilization is only a part of their business. Several mentioned that they also offer other types of sterilization and that they are encouraging their customers to substitute these other types for EO wherever possible. Thus, even if the facilities stopped offering EO sterilization, they might not close. Secondly, and potentially more importantly, six of the eight facilities contacted indicated

that if their client industries were also regulated, they expected demand for their services to increase. Their estimates for the increases in their business ranged from 20 percent to 200 percent.

Because of the relatively lower per-unit compliance costs incurred by contract sterilizers, some facilities currently sterilizing in-house will probably choose, as a result of the regulation, to stop sterilizing in-house and substitute contract sterilization. If such a substitution occurs, then both the revenues and the costs of contract sterilizers may increase as a result of the regulation, and revenues may increase by more than costs. The following section discusses substituting contract for in-house sterilization in more detail.

8.7.4 Substitution of Contract Sterilization for In-House Sterilization

As discussed above, EO sterilization is performed in-house by facilities that specialize in producing other goods or services, of which sterilization is a small but necessary part, and by contract sterilizers who specialize in sterilizing goods for other producers. In this analysis, in-house sterilization is performed by medical device suppliers, spice manufacturers, pharmaceuticals manufacturers, other health-related manufacturers, laboratories, and museums and libraries.

The cost of using contract sterilization includes some additional costs not experienced in in-house sterilization. These additional costs include the cost of transporting the products to and from the contract sterilizer, the inventory cost of products while in transit, the reliability and negotiation costs of dealing with an outside supplier, and the cost of products damaged or not properly sterilized. These are referred to as transactions costs. The per-unit cost of actually performing the sterilization is expected to be lower for contract sterilizers because their higher volume enables them to take advantage of economies of scale.

Figure 8-4 shows the market for contract sterilization prior to the regulation. Because in-house sterilization is demanded by

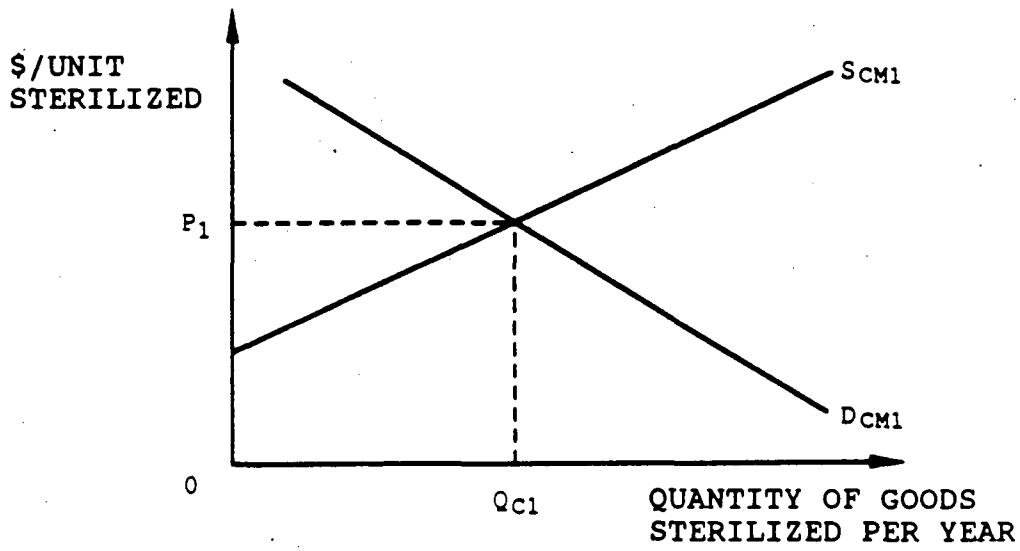

Figure 8-4. The market for contract sterilization without the air emission standard in place.

the same facility that performs it, in-house sterilization services are not marketed, so in-house services have no market price. Facilities that produce goods that need sterilization compare the cost of sterilizing them in-house with the cost of using a contract sterilizer, including the transactions costs described above. Without the air emissions standard in place, the market for contract sterilization services is in equilibrium at a price P_1. At this price, producers of Q_{C1} goods requiring sterilization have found that the cost of sterilizing them in-house exceeds the cost of using a contract sterilizer, including the transactions costs, and have chosen to substitute contract sterilization for in-house sterilization.

Imposing emissions controls on EO sterilizers will increase the marginal costs of both in-house and contract sterilization. Figure 8-5 shows the effect of the regulation on the sterilization supply curves of a typical contract sterilizer and a typical in-house sterilizer. These supply curves show the relationship between the marginal cost of sterilization and the number of goods sterilized per unit of time. The upward slope indicates that, as more goods are sterilized per unit of time, the cost of sterilizing each additional good (the marginal cost) increases.

Marginal cost curve MC_{C1} shows the contract sterilizer's marginal cost of sterilizing each quantity of goods without the air emission standard in place, while MC_{C2} shows the marginal cost of sterilizing each quantity of goods with the air emission standard in place. The vertical distance between the two curves is the total annual compliance cost per unit sterilized (TAC/unit) for each quantity sterilized. For example, suppose the contract sterilizer sterilizes Q_C quantity of goods. (This quantity is arbitrarily chosen; without information about the market price of contract sterilization, it is not known what quantity of goods the facility sterilizes.) If this sterilizer processes Q_C quantity of goods, the marginal cost of sterilization without the regulation in effect is OA. The marginal cost of sterilization at output level Q_C with the

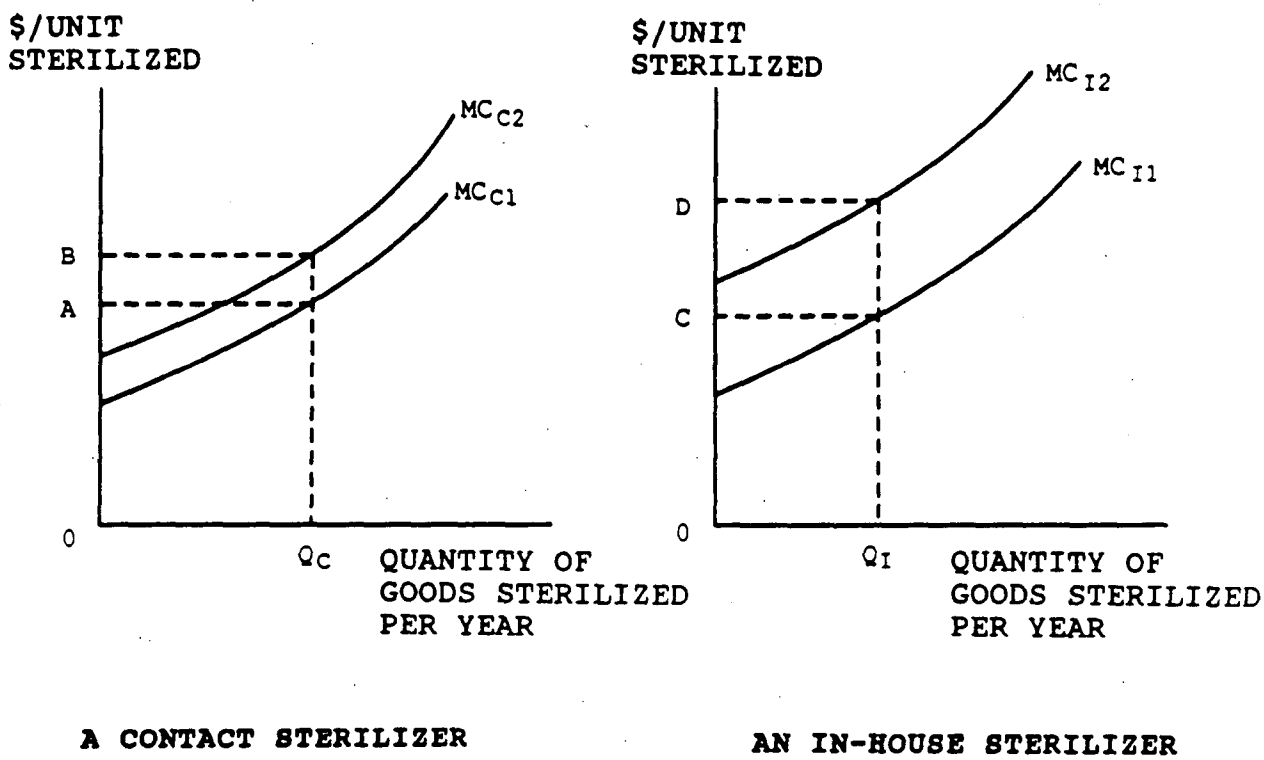

Figure 8-5. Marginal cost curves for a contract sterilizer and an in-house sterilizer, with and without the air emission standard in effect.

regulation in effect is OB. The distance BA measures the TAC/unit for that quantity sterilized. Similarly, if the in-house sterilizer sterilizes Q_I quantity of goods (again, an arbitrarily selected quantity), OC measures the marginal cost of sterilization without the regulation in effect, OD measures the marginal cost of sterilization at output level Q_I with the regulation in place, and DC measures the TAC/unit for that quantity sterilized.

The compliance cost per Mg of EO used should be lower for the contract sterilizers, on average, than for in-house sterilizers. Because of economies of scale in controlling the emissions, larger emitters, such as the contract sterilizers, will incur lower TAC per unit of product sterilized. This expectation is embodied in the relatively larger upward shift in the supply curve for the in-house sterilizer (DC is greater than AB). The economies of scale in compliance are reflected in our estimated costs of compliance. As shown in Tables 8-17 and 8-18, contract sterilizers have the lowest median TAC per Mg of EO used and the lowest median TAC per dollar of annual sterilization cost.

If nothing else changes, the air emission standard results in a higher equilibrium price and a smaller total quantity of contract sterilization performed. However, the demand for contract sterilization is expected to change. Because of their higher per-unit TAC, some of the in-house sterilizers will find that their cost of sterilizing in-house, with the compliance costs imposed, now exceeds the cost of using a contract sterilizer. This condition will increase the market demand for contract sterilization. At baseline, 16 contract sterilizers use approximately 335 Mg (330 tons) of EO per year, and approximately 170 in-house sterilizers use about 1,482 Mg (1,459 tons) of EO per year. If the quantity of EO used is closely related to quantity of goods sterilized, then in-house sterilization accounts for approximately 81 percent of the total quantity of goods sterilized annually. Depending on the cost functions and compliance costs of the individual in-house sterilizers, many of

them may choose to substitute contract for in-house sterilization, resulting in a substantial increase in the market demand for contract sterilization.

Figure 8-6 shows a new equilibrium in the contract sterilization market, with the market supply curve, S_{CM2}, shifted upward by the per-unit TAC of the regulation. The market demand curve, D_{CM2}, is shifted outward as a result of former in-house sterilizers who have decided to substitute contract sterilization for in-house sterilization. In this figure, both the price and quantity of contract sterilization have increased.

This absolute increase in contract sterilization may or may not occur, depending on the actual positions and shapes of the supply and demand curves. Contract sterilization's share of total sterilization will definitely increase, however, because their lower average TAC per unit sterilized will cause some in-house sterilizers to decide to switch to contract sterilization. In this example, contract sterilizers' revenues increase by more than their compliance costs as a result of the regulation. Revenues without the regulation in place are shown by the rectangle OP_1AQ_{C1}, and revenues with the regulation in effect are shown by OP_2CQ_{C2}. The change in revenues is shown by the difference in these two rectangles, shaded in on the graph. The TAC/unit is the vertical distance between the two market supply curves, CB, so the compliance costs as a result of the regulation are shown in the rectangle, DP_2CB. The change in revenues in this case exceeds the compliance costs for the contract sterilization sector.

In summary, adopting the emissions controls on EO sterilization will increase the unit cost of sterilization for both in-house sterilizers and contract sterilizers. Because of economies of scale in controlling emissions, the TAC per unit sterilized will be higher for the in-house sterilizers than for the contract sterilizers. In the new market equilibrium, some in-house sterilizers will probably decide to substitute contract sterilization for their in-house sterilization. The share of contract sterilization in the sterilization market will increase

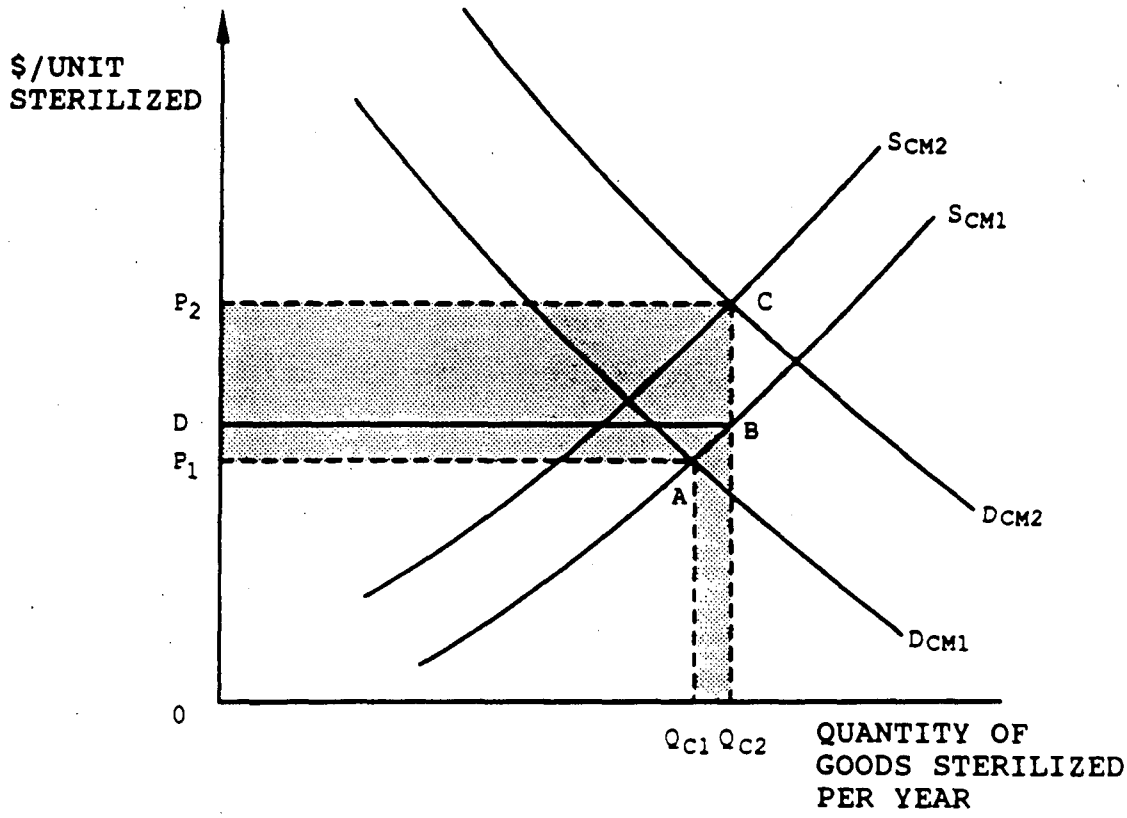

Figure 8-6. The market for contract sterilization with the air emission standard in effect.

as a result of the regulation, and the absolute quantity sterilized may actually increase. In fact, the market price may increase by more than the TAC per unit sterilized for contract sterilizers so that their revenues will increase by more than their costs as a result of the regulation. For these reasons, a regulatory flexibility analysis for contract sterilizers, a more detailed examination of small entity impacts, is not required.

8.7.5 Small Business Impacts in Other Industry Groups

Many of the other industry groups in our analysis include SIC codes for which the actual size definitions in the Federal Register, 13 CFR Part 121, specify numbers of employees, rather than sales. Unfortunately, no employee data for any of the firms are in the data base. Therefore, the sales criterion used for the contract sterilizers was applied. The results are shown in Table 8-20.

Of the approximately 170 facilities in the other industry groups, only 22 are defined as small, based on their estimated sales revenues. Using facility sales as a proxy for total production costs, the number of these facilities that would experience an increase in total production costs of more than 5 percent was estimated. Given this criteria for a significant impact, 1 of the 22 experiences significant impacts under Option 1, 6 of the 22 under Option 2, and 8 of the 22 under Option 3. Another factor to consider when examining the impacts of these small facilities is whether a facility is a major or an area source. If a facility is an area source, it is possible that the facility will be required to adopt less stringent controls than major sources or may even be exempt from the regulation. For this regulation, an area source is a facility that emits less than 10 tons of EO per year. Given this definition, 20 of the 22 small businesses are classified as an area source. As a result of the information presented above and because only a small absolute number of small entities in each industry experience significant impacts as a result of the regulation, it is concluded that a regulatory flexibility analysis is not required.

TABLE 8-20. SMALL BUSINESSES IN THE INDUSTRY GROUPS PERFORMING IN-HOUSE STERILIZATION

Industry group	No. of small entities	No. of significant impacts		
		Option 1	Option 2	Option 3
Laboratories	2	0	1	1
Spice manufacturers	3	0	1	1
Pharmaceuticals manufacturers	2	0	1	1
Other health-related	5	0	0	0
Med. device suppliers	6	1	2	3
Museums and libraries	4	0	1	2

8.7.6 Summary

The majority of contract sterilizers are small businesses, and most of the small businesses in the contract sector will experience compliance costs exceeding 5 percent of baseline sterilization costs. Because contract sterilizers, on average, sterilize larger quantities than in-house sterilizers, they will, on average, experience economies of scale in controlling their emissions. This condition will result in lower total annual compliance costs per unit sterilized for contract sterilizers than for in-house sterilizers, which in turn will result in contract sterilizers having a larger share of the sterilization market with the regulation in effect than they have at baseline. Depending on the extent to which supply and demand for contract sterilization change in response to the regulation, and the characteristics of the supply and demand relationships, contract sterilizers may find that their revenues increase by more than their costs as a result of the regulation. Finally, depending on the positions and shapes of the supply and demand curves, the absolute quantity of contract sterilization performed may actually increase as a result of the regulation. In the other industry groups, only a small absolute number of small firms is significantly affected by the regulation. For these reasons, it is concluded that a regulatory flexibility analysis is not required.

8.8 CONCLUSIONS

In this section conclusions are summarized regarding the economic effects of the candidate NESHAP controls, under each control option, on existing and new facilities.

8.8.1 Effects on Existing Facilities

This study suggests that the candidate NESHAP controls will increase the cost of performing EO sterilization at affected facilities. The incremental costs involved in moving from one control option to the next appear to be substantial, on average. As described at the beginning of this section, the increased cost of sterilization (resulting in shifting the supply curve for sterilized products upward) will probably result in reductions in

the quantities produced of products sterilized using EO and an increase in their prices. Because the data required to estimate the elasticities of supply and demand for the products sterilized using EO are not available, it is not possible to make quantitative estimates of these quantity and price changes.

Faced with the increased costs of sterilization with EO, facilities may choose one of the following four alternatives:

1. Pay the increased costs, implement the controls, and continue to sterilize using EO;

2. Switch from EO sterilization to another onsite sterilization process;

3. Discontinue onsite sterilization and switch to contract sterilization; or

4. Discontinue producing the sterilized product.

Without quantitative estimates of the changes in price and quantity for sterilized products, and without adequate data about the relative costs of the alternatives facing the facility, it is not possible to determine which alternative facilities will choose. However, some facilities will probably decide to discontinue EO sterilization as a result of the candidate NESHAP controls.

Based on the median values reported in Section 8.6.4, the candidate NESHAP is likely to significantly affect three industry groups: museums and libraries, spice manufacturers, and contract sterilizers. The candidate NESHAP will have a substantial effect on all facilities in the museums and libraries group. These facilities have very small chambers and use a very small quantity of EO. Consequently, the TAC/CV and TAC/EO values for museums and libraries are relatively high under all three control options. The TAC/C values indicate that the candidate NESHAP controls will increase sterilization costs by more than 50 percent for many facilities under Option 1 and will more than double sterilization costs for many museums and libraries under Options 2 and 3. Furthermore, the TAC/S values indicate that the costs of the candidate NESHAP controls represent a significant percentage of the operating budget for many of the

museums and libraries. To the extent that museums and libraries do not have ready access to capital markets, they may also have difficulty getting the capital needed to acquire the relevant control devices.

Museums and libraries do, however, have possible substitutes for EO. As discussed in Section 8.1, sulfuryl fluoride, marketed under the trade name Vikane™, may be an acceptable substitute for EO in sterilizing nonmetallic objects. Converting to Vikane as a sterilant involves some costs, including those of chamber modification and training the operators to be certified to apply Vikane™, a registered pesticide. Other possible substitutes include deep freezing, CO_2 fumigation, and vacuum treatment. Converting from EO to any of these would entail some conversion costs. Conversion costs must be compared with the costs of implementing the candidate NESHAP controls and the costs of switching from onsite sterilization to using a contract sterilizer. Depending on the relative costs, some facilities may choose to continue onsite sterilization, others may switch to Vikane, and still others may use a contract sterilizer. Alternatively, some museums and libraries may decide to use the services of a contract sterilizer or discontinue fumigation altogether, because of a lack of the capital needed either to implement the candidate NESHAP controls or to switch to Vikane™. Also, some facilities may conclude that the value they receive from fumigation does not justify the additional cost of implementing controls, employing a contract sterilizer, or converting to Vikane™.

The TAC/CV and TAC/EO are also fairly large for the facilities in the laboratories group, because of the below-average size of their sterilization chambers and relatively small quantity of EO they use. Nevertheless, the TAC/S and TAC/C values for this group are low, suggesting that sterilization costs are a very small part of total production costs at these facilities. Without knowing the precise figure, an animal-breeding laboratory indicated that sterilization costs are "surely less than 1 percent of total production cost."[33]

The TAC/C median values for the medical device suppliers, other health-related suppliers, and pharmaceutical manufacturers range from 16.0 percent to 20.4 percent under Option 1, from 16.6 percent to 31.6 percent under Option 2, and from 24.4 percent to 40.1 percent under Option 3. Thus, the candidate NESHAP controls will substantially increase sterilization costs in the industry groups. However, sterilization costs are generally very small relative to the total cost of producing sterilized products in these industries. For example, a pharmaceutical manufacturer estimated that sterilization costs represent only about 3 percent of total production costs.[8] Consequently, the candidate NESHAP controls probably will not significantly increase production costs for most medical device suppliers, other health-related manufacturers, or pharmaceutical manufacturers. The very low TAC/S values for these industry groups support this expectation. Although median values do not indicate significant impacts, individual facilities in each of these industries might incur significant adverse impacts.

Spice manufacturers incur relatively low unit compliance costs, as shown by TAC/CV and TAC/EO. At the same time, they incur some significant increases in sterilization costs, as measured by TAC/C. Their median TAC/C is the second highest, almost 45 percent under Option 1, 52 percent under Option 2, and 68 percent under Option 3. Also, the most severely affected facilities in this sector incur compliance costs greater than their baseline costs under Option 1, nearly 1.5 times their baseline costs under Option 2, and nearly twice their baseline costs under Option 3. Fortunately, sterilization represents a small proportion of total production costs in this industry (TAC/S is less than one percent, even under Option 3). Also, a good substitute exists for EO fumigation in the spice manufacturing industry: radiation. As described in Section 8.1, an industry source stated that radiation has several advantages over EO fumigation.[16] These advantages include killing all bacteria, rather than only a large percentage of bacteria. Second, radiation can be done under ambient conditions. Third,

radiation leaves no residue and requires no aeration. It does, however, entail the costs of purchasing the equipment needed to irradiate the product and training employees to use the new equipment. No information is available about the relative costs of radiation and EO as sterilization techniques. The candidate NESHAP will probably significantly affect many contract sterilizers. For the other industry groups in this study, sterilization is one of many steps in the production process. In contrast, sterilization is nearly the entire "product" for contract sterilizers. (As discussed in Section 8.1, many contract sterilizers may also perform some packaging, testing, and distribution services that are linked to their sterilization operations.) Thus, the candidate NESHAP will probably cause a more pronounced increase in contract sterilizers' production costs, which is reflected in the relatively high median TAC/S (2 percent under Option 1, 3.9 percent under Option 2, and 4.6 percent under Option 3) for contract sterilizers. [As noted earlier, one of the shortcomings of total sales is that it includes sales of sterilized and nonsterilized products; because virtually all sales from contract sterilizers involve sterilized products, this shortcoming would tend to result in higher TAC/S for these facilities than for facilities in the other industry groups.]

In addition to significantly increasing their sterilization costs, the candidate NESHAP may result in increased demand for contract sterilization services. Because contract sterilizers on average have larger chambers than the other industry groups and run more EO through them, the per-unit cost of the candidate NESHAP is less for contract sterilizers than for the other groups. This conclusion is supported by the data in Tables 8-14 through 8-19, which indicate that contract sterilizers have the lowest median TAC/CV, TAC/EO, and TAC/C of the seven industry groups under all three control options. As explained in Section 8.7, the contract sterilizers' lower per-unit control costs may actually cause them to gain additional business if

firms switch from in-house sterilization to contract sterilization.

Aside from the effects of the candidate NESHAP controls on the museums and libraries group, the contract sterilizers group, and perhaps the spice manufacturers group, significant effects may occur at some individual facilities in the other five industry groups. In general, these are the facilities with the highest TAC/S values in the groups. These facilities may choose to incur the relatively high control costs, to switch to another sterilization process, to switch from in-house to contract sterilization, or to discontinue their production of sterilized products. Without further information on these facilities, there is no way to predict which response will be chosen in each case.

8.8.2 Effects on New Facilities

Up to this point the analysis has focused on the economic effects of the candidate NESHAP controls on existing facilities. Without data on possible control costs for new (not-yet-constructed) facilities in each industry group, making any quantitative estimates of the potential effects of the candidate NESHAP, under each control option, on these facilities was not possible. Nevertheless, some general conclusions may be reached on this matter based on the information presented earlier in this chapter.

The supply curve for products sterilized using EO will shift upward as a result of the candidate NESHAP controls. If the demand curves for these products are at all elastic, the quantity of the products sold will decrease. This decrease will delay investment in new facilities that would use EO.

The effect on investment by contract sterilizers is more difficult to predict. Because some facilities in the other six industry groups may decide to switch from in-house sterilization to contract sterilization, the demand curve for contract sterilization may shift out as a result of the candidate NESHAP controls. The market share of contract sterilization will increase, and the absolute quantity of contract sterilization may increase. Depending on the change in the profitability of

contract sterilizers resulting from the candidate NESHAP controls, some additional investment by contract sterilizers might occur.

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APPENDIX A.

EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT

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TABLE A-1. EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT

Date	Event
October 2, 1985	The EPA announces intent to list ethylene oxide (EO) as a hazardous air pollutant under Section 112 of the Clean Air Act (Act) (50 FR 40286).
October 1985	Collection of background information begun by Midwest Research Institute.
January 8, 1986	Site visit to Sterilization Services of Tennessee to observe sterilization and gas reclamation facilities.
January 13, 1986	Site visit to North Carolina Archives and Records to observe EO fumigation chamber and obtain data on EO use.
January 16, 1986	Site visit to McCormick and Company, Inc., to observe EO fumigation chambers and Deoxx™ control system.
April 2, 1986	Meeting with Johnson and Johnson (J&J) International and Damas Corporation to discuss the EO scrubber manufactured by Damas and used by J&J.
April 1986	Data received from a Health Industry Manufacturers' Association (HIMA) survey performed in November of 1985 are compiled in the Commercial Sterilization data base.
July 1986	Questionnaires sent to miscellaneous sterilization and fumigation facilities. Responses were received from 113 of these facilities.
August 1987	Mail out Chapters 3-5 of the background information document (BID) for review.
August 27, 1987	Work Group briefing.
September 30, 1987	Meeting with HIMA short-term exposure limit task force to discuss industry's response to the EO and chlorofluorocarbon (CFC) BID mailouts.
November 13, 1987	Second Work Group briefing.
March 11, 1988	NAPCTAC mailout of BID chapters and Appendices.
March 23, 1988	Docket No. A-88-03 (Commercial Sterilization) is submitted.

TABLE A-1. (continued)

Date	Event
May 19, 1988	NAPCTAC meeting.
July 1988	Questionnaires sent out to miscellaneous sterilization and fumigation facilities. Responses were received from 44 facilities.
December 9, 1988	Site visit to Iolab, Inc., to obtain information about the DM3 Catcon catalytic oxidation system used to control emissions from the aeration room.
December 9, 1988	Site visit to Medtronic, Inc., to obtain information about the acid-impregnated carbon adsorbtion system used to control emissions from the aeration room.
February 21, 1989	Teleconference with HIMA to discuss progress on the standard.
November 3, 1989	Meeting with HIMA to discuss progress on the standard.
December 4-6, 1989	Vendor-sponsored test of Donaldson Eto Abator™ catalytic oxidizer.
December 12, 1989	Review of a summary of the prevalence of chamber exhaust use among HIMA members.
June 14, 1990	Site visit to Isomedix Operations, Inc., to obtain information about their sterilization processes.
August 7, 1990	Work Group meeting on regulatory alternatives.
January 30, 1991	NAPCTAC meeting.

APPENDIX B.

INDEX TO ENVIRONMENTAL CONSIDERATIONS

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INDEX TO ENVIRONMENTAL CONSIDERATIONS

This appendix consists of a reference system which is cross-indexed with the October 21, 1974, Federal Register (39 FR 37419) containing Agency guidelines for the preparation of Environmental Impact Statements. This index can be used to identify sections of the document which contain data and information germane to any portion of the Federal Register guidelines.

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APPENDIX B.
INDEX TO ENVIRONMENTAL IMPACT CONSIDERATIONS

Agency guidelines for preparing regulatory action environmental impact statements (39 FR 37419)	Location within the background information document (BID).
1. Background and description	
Summary of the regulatory alternatives	The regulatory alternatives are summarized in Chapter 1.
Statutory authority	Statutory authority is given in Chapter 1 and Chapter 2.
Industry affected	A description of the industry to be affected in given in Chapter 8.
Sources affected	Descriptions of the various sources to be affected are given in Chapter 3.
Availability of control technology	Information on the availability of control technology is given in Chapter 4.
2. Regulatory alternatives	
Regulatory alternative A	
Environmental impacts	Environmental effects of regulatory alternative A are considered in Chapter 6.
Costs	Costs associated with regulatory alternative A are considered in Chapter 7.
Regulatory alternative B	
Environmental impacts	Environmental effects of regulatory alternative B emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative B emission control systems are considered in Chapter 7.

Agency guidelines for preparing regulatory action environmental impact statements (39 FR 37419)	Location within the background information document (BID).
Regulatory alternative C	
Environmental impacts	Environmental effects of regulatory alternative C emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative C emission control systems are considered in Chapter 7.
Regulatory alternative D	
Environmental impacts	Environmental effects of regulatory alternative D emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative D emission control systems are considered in Chapter 7.
Regulatory alternative E	
Environmental impacts	Environmental effects of regulatory alternative E emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative E emission control systems are considered in Chapter 7.

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APPENDIX C.

EMISSION SOURCE TEST DATA

APPENDIX C.
EMISSION SOURCE TEST DATA

This appendix contains summaries of performance tests EPA and industry conducted on four acid-water scrubbers and one catalytic oxidizer designed to control ethylene oxide (EO) emissions from sterilizer exhaust and aeration room gas streams, respectively. Performance tests to determine control device efficiency were conducted on two types of acid-water scrubber systems, Damas™ and DEOXX™. Detailed descriptions of these types of scrubbers are presented in Chapter 4. The sterilizers tested use pure EO and a 12/88 mixture of EO and chlorofluorocarbons (CFC's) as sterilant gases. The results of the five tests are presented in the following sections of this appendix:

C.1--EPA test of a DEOXX™ system at Burron Medical;

C.2--Independent laboratory test of a DEOXX™ system at McCormick and Company, Inc.;

C.3--Independent laboratory test of a DAMAS™ system at Johnson and Johnson, Inc.;

C.4--Independent laboratory test of a DEOXX™ system at Chesebrough-Pond's DEOXX™ facility; and

C-5--Vendor test of an EtO ABATOR™ system at Seamless, Inc.

A summary of the test results and selected test conditions for the first four tests is provided in Table C-1.

C.1 EPA TEST OF A DEOXX™ SYSTEM AT BURRON MEDICAL

C.1.1 Facility Description[1]

An EPA-sponsored test was conducted on a Deoxx™ acid-water scrubber in September 1987. The test took place at Burron Medical, a medical supply sterilization facility located in Allentown, Pennsylvania. The facility has three 28 cubic meters

TABLE C-1. SUMMARY OF TEST RESULTS

Plant	Scrubber type	Chamber size, m^3 (ft^3)	Sterilant	No. of runs	Flow rate, m^3/s (ft^3/min)	Range of EO inlet concentrations, ppmv	Range of EO outlet concentrations, ppmv	Average percent removal
Burron Medical	DEOXX™	28.3 (1,000)	12/88	10[a]	b	b	b	99.96[c]
McCormick & Company	DEOXX™	35.3 (1,248)	Pure EO	3	d	26,800 - 385,000	<5 - 458	99.988
Johnson & Johnson	Damas™	b	12/88	6	0.031 (66)	b	14 - 1,938	99.25
			12/88	3	0.047 (100)	b	12 - 1,853	99.26
Chesebrough-Pond's, Inc.	DEOXX™	35.7 (1,260)	12/88	3	d	1,000 - 250,000	<1 - 10,000	>99.93
		35.7 (1,260)	Pure EO	1	d		<1-10,000	>99.99

[a]Seventeen tests were performed; data from 10 of these tests were used in the report.
[b]Data not provided.
[c]Based on throughput efficiency for empty chamber runs.
[d]Flow rate varies widely for the various runs and evacuations.

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(m^3) (1,000 cubic feet [ft^3]) sterilizers that use 12/88. The gas is supplied from a common header serving all four units and is controlled by a liquid flow meter.

A sterilization cycle typically uses 140 liters (L) (38 gallons [gal]) of 12/88 gas mixture. On a weight basis, a sterilization charge consumes 167 kilograms (kg) (368 pounds [lb]) of gas, of which approximately 20 kg (44 lb) are EO. The initial charge of EO to the chamber was calculated using the weight of the supply cylinders before and after charging the chamber.

The exhaust from the sterilizers is controlled by a DEOXX™ system. At the time of the test, the scrubber contained a dilute mixture of phosphoric and sulfuric acid. Each chamber is equipped with a total recirculating liquid vacuum pump. These pumps are equipped with gas/liquid separators, which emit the gas to the DEOXX™ system and recirculate the liquid to the pump inlet. Chambers Nos. 1 and 2 are equipped with oil-sealed pumps. Chamber 3 is equipped with a water-sealed pump. All of the tests were conducted using the chambers (Nos. 1 and 2) equipped with oil-sealed pumps.

The sterilization cycle is controlled automatically by a programmable microprocessor system. The control system can control and record the parameters of the sterilization cycle including chamber temperature, chamber pressure, and elapsed time from the start of the cycle.

The sterilization process begins with a humidifying step, which takes place in a separate room. After the humidifying step, each load to be sterilized is transferred to the sterilization chamber. The sterilization cycle is a batch process that takes 4 to 6 hours. A sterilizer load begun during the morning shift exhausts at about 2:00 p.m. In a typical plant operating mode, seven poststerilization evacuations occur over a 3-hour period. After the chamber is repressurized, following the seventh evacuation, the product is removed from the chamber and allowed to off-gas. Although the control system is designed to handle the exhaust from two sterilizers venting simultaneously,

the tested sterilization cycles were scheduled so that only one sterilizer vented at a time.

Three different sterilization programs were used for testing: one for the empty chamber tests, one for the full chamber tests, and one for the last full chamber test (Test 13). The testing of both full (loaded) and empty chambers was carried out to examine the effects of product retention of EO on the EO emissions. A total of 17 tests were performed, 5 with product in the chamber (full chamber tests) and 12 without product (empty chamber tests). Seven of these tests were considered invalid according to the testing lab, therefore, data from 10 of these tests (4 with and 6 without product) were summarized in the final report. Table C-2 summarizes operating data from the 10 valid tests.

Before the start of each test (except Test 13), the chamber was evacuated to 2 pounds per square inch absolute (psia) and then pressurized to 3.1 psia with steam. The humidifying step was maintained at 3.1 psia for 1 hour for the loaded chamber tests, but the humidifying step was shortened to 5 minutes for the empty chamber tests. After the humidifying, the chamber was charged to 23.9 psia with 12/88 gas. The exposure at 23.9 psia was maintained for 4 hours for the loaded chamber tests but was shortened to 5 minutes for the empty chamber tests. During the last full chamber test (Test 13), the chamber was evacuated to 7 psia and pressurized to 32.9 psia.

Each test program contained seven poststerilization evacuations; an initial chamber evacuation, six air in-bleeds with subsequent evacuations, and a final air in-bleed. Except in Test 13, the chamber was evacuated to 2 psia and pressurized with air to 13.9 psia during each evacuation and air in-bleed cycle. The initial chamber evacuation and pump down lasted 26 to 27 minutes. Each subsequent evacuation lasted 12 to 14 minutes, and each air in-bleed required 12 to 14 minutes. During Test 13, the chamber was evacuated to 7.0 psia, which reduced each evacuation and air in-bleed time by 7 minutes.

TABLE C-2. SUMMARY OF FIELD TESTS AT BURRON MEDICAL[1]

Test No.	Product present	Chamber No.	Weight of 12/88 used, lb	Test date	Test start time	Test end time
6[a]	Yes	2	368	87/10/06	21:39	00:38
7[b]	No	1	365	87/10/07	10:19	14:04
8[a]	Yes	2	388	87/10/07	15:10	18:11
9[b]	No	1	346	87/10/08	09:25	12:42
10[b]	No	1	353	87/10/08	14:41	17:48
11[a]	Yes	2	392	87/10/08	18:00	21:01
12[b]	No	1	346	87/10/09	12:44	15:53
13[c]	Yes	2	442	87/10/09	16:16	18:03
14[b]	No	1	350	87/10/10	08:54	12:01
15[b]	No	1	343	87/10/10	13:35	16:43

[a]The chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidification step lasted 1 hour, and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 4 hours. Poststerilization chamber pressure cycled between 2 psia and 13.9 psia.

[b]The chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidification step lasted 5 minutes, and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 5 minutes. Poststerilization chamber pressure cycled between 2 psia and 13.9 psia.

[c]The chamber was evacuated to 7 psia before being pressurized with steam to 8 psia. Humidification step lasted 1 hour, and then the chamber was charged to 32.9 psia with 12/88. Exposure lasted 5 hours. Poststerilization chamber pressure cycled between 7 psia and 13.5 psia.

C.1.2 Sampling Procedures[1]

The sampling and analysis procedure used in these field tests involved semicontinuous direct sampling of scrubber inlet and outlet gas streams with on-line gas chromatographic analysis to determine EO concentrations. Volumetric flow rates both entering and exiting the scrubber were determined with orifice plates. However, some difficulty was encountered when measuring the inlet volumetric flow rate due to the high EO concentration and low flow rate of the gas stream.

C.1.3 Test Results[1]

Table C-3 presents uncontrolled and controlled emissions (i.e., the amount of EO entering and exiting the control unit) for the six empty chamber tests. Emission measurements were considered for the six empty chamber tests because the total amount of EO entering the scrubber were more consistent for these runs. These emissions measurements were used to evaluate the EO control efficiency of the DEOXX™ system.

Efficiencies were calculated for the six test runs. Throughput efficiency was calculated using the gas stream EO concentrations and volumetric flow rates into and out of the DEOXX™ unit. This method calculates the efficiency of the control device, i.e., the difference in mass of EO into and out of the control device. However, the method used to determine this efficiency suffered due to the inability of the orifice plates to accurately measure the flow rate into the scrubber. The second method of determining control efficiency, recovery efficiency, was calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control unit.

Both of the analytical methods used to determine control efficiency were hindered by the difficulty in determining the GC peak for EO scrubber outlet concentration measurements. This problem arose from a shift in the EO retention time (in the column of the GC) as EO concentrations exiting the scrubber decreased. The difficulty in identifying the EO peak was further

TABLE C-3. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR EMPTY CHAMBER TESTS AT BURRON MEDICAL[1]

Test No.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg (lb)	EO entering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent[a]	Recovery efficiency, percent [b]
7[c]	19.9 (43.8)	0.19 (0.42)	10.98 (24.19)	0.020 (0.043)	99.82	99.90
9	18.8 (41.5)	0.68 (1.50)	27.51 (60.59)[d]	0.005 (0.011)	99.98	99.97
10	19.2 (42.4)	0.10 (0.22)	28.20 (62.12)[d]	0.013 (0.029)	99.95	99.93
12	18.8 (41.5)	0.07 (0.16)	19.98 (44.00)	0.005 (0.011)	99.98	99.97
14	19.1 (42.0)	0.07 (0.16)	22.16 (48.80)	0.010 (0.021)	99.96	99.95
15	18.7 (41.2)	0.03 (0.07)	23.98 (52.82)	0.006 (0.014)	99.97	99.97

[a]Calculated using the measured EO entering and exiting the control device.
[b]Calculated using the weight of the original EO charge and the measured EO emitted at the outlet of the control device.
[c]During Test 7, there was a leak in the inlet sampling pump during the first 10 minutes of the evacuation, and the flame ionization detector (FID) flame was extinguished during portions of the third and fourth evacuations. Loss of these samples may explain the lower mass of EO entering the control unit during this test.
[d]The EO standard calibration curve for inlet samples on October 8, 1987 was lower than on the other test days. This unusually low value would have raised the measured EO concentrations and caused the EO mass flow into the control unit to be overestimated.

complicated by the large range of EO concentrations exiting the scrubber.

Statistical tests were performed to evaluate the effect of product in the chamber on determining the efficiency of the control unit. These tests showed that the presence of product in the chamber had no significant effect on the efficiency determinations.

The absolute difference between measured emissions and expected emissions (based on the initial EO charge to the chamber) was greater than 40 percent for three tests and less than 10 percent for only one test. In five of the six empty chamber tests, the measured emission levels were higher than the expected levels. From these observations, actual uncontrolled EO emissions may therefore be expected to be from 50 to 150 percent of the actual emissions.

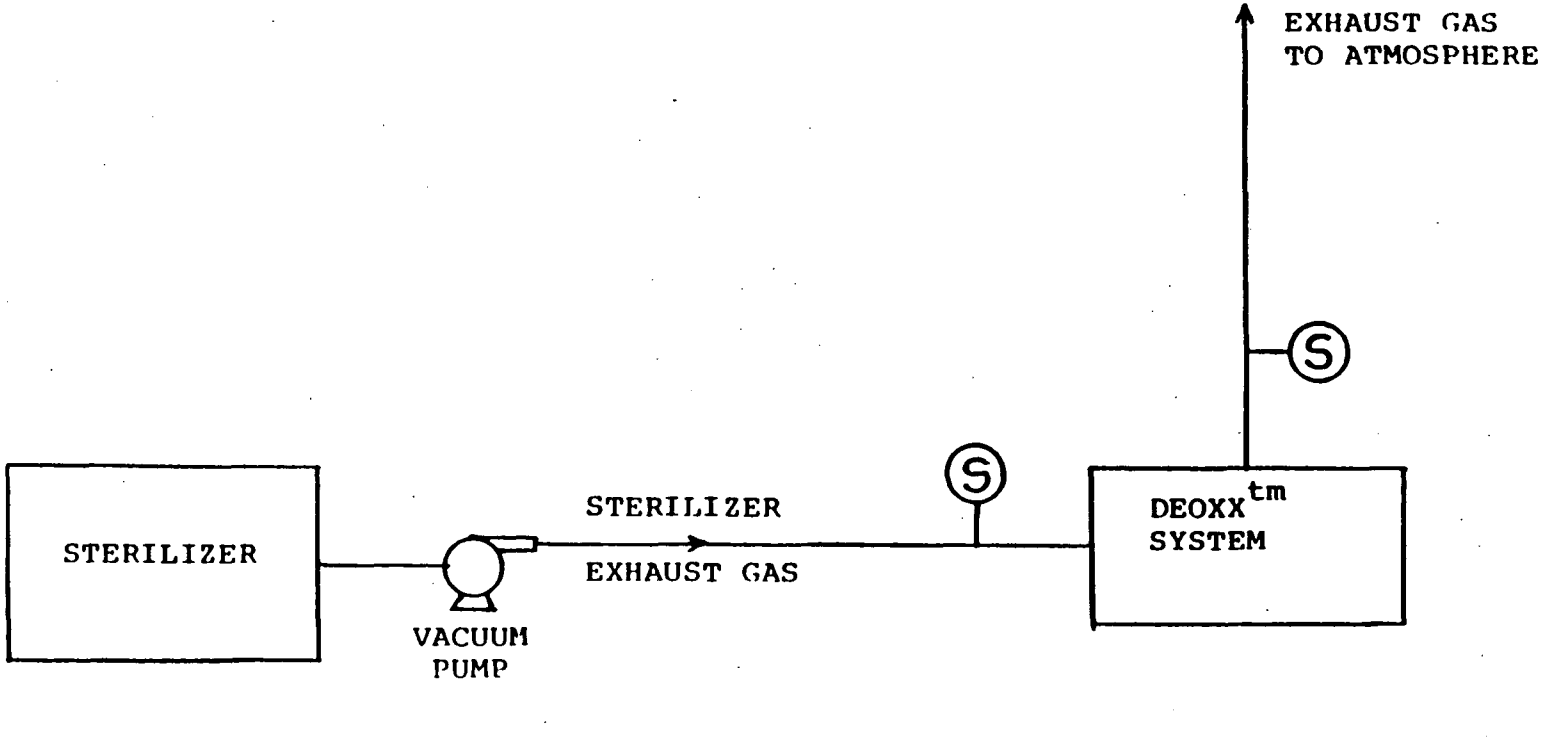
C.2 INDEPENDENT LABORATORY TEST OF A DEOXX™ SYSTEM AT McCORMICK AND COMPANY, INC.

C.2.1 Facility Description[2]

A DEOXX™ detoxification system was installed at the Hunt Valley Spice Mill of McCormick and Company to control EO emissions from sterilizers. The DEOXX™ system was tested by an independent laboratory the week of October 14, 1985, to evaluate performance.

The sterilizers at the Hunt Valley Spice Mill are used to process a variety of spices. Pure EO is used as the sterilant. Each sterilizer is equipped with a total-recirculation liquid ring vacuum pump system to evacuate the chamber and achieve the desired levels of vacuum. At the completion of the sterilization cycle, sterilizer gas is exhausted to the atmosphere through the DEOXX™ system.

A test program consisting of four tests was conducted using Sterilizer B, which had a volume of 35.3 m^3 (1,248 ft^3). The first test was used to check the equipment and instrumentation operation. The remaining three tests (Test Nos. 2, 3, and 4) were used to evaluate the DEOXX™ system performance. Figure C-1 provides locations of the sampling points.



S : SAMPLING POINT TO MEASURE

- ETO CONCENTRATION
- VOLUMETRIC GAS FLOWRATE
- GAS TEMPERATURE
- GAS STATIC PRESSURE

Figure C-1. Sampling point locations.[2]

The sterilization cycle operating conditions for the three performance tests are summarized below:

Initial evacuation conditions:

Pressure, psia (in. Hg)	14.2 (28.9)
Time, min	25

Total EO charged to chamber, kg (lb):

Test 1	13.2 (29.0)
Test 2	13.2 (29.0)
Test 3	12.7 (28.0)

Exposure conditions:

Pressure, psia (in. Hg)	10.4 (21.2)
Temperature, °C (°F)	43.3 (110)

Following the sterilization cycle, the chamber was evacuated to 7.0 psia (14.3 in. Hg) over a period of 12 minutes. Two additional evacuations lasted 10 minutes each, and the air washes required less than 1 minute each.

C.2.2 Sampling Procedures[2]

The sterilization chamber was kept empty during the test cycles. This eliminated possible variations in EO emissions during the exhaust phase due to product off-gassing without adversely affecting the performance evaluation of the DEOXX™ system.

For each performance test cycle, the amount of EO charged to the sterilizer was determined by measuring the weight of the EO supply cylinder before and after charging EO to the sterilizer chamber.

The weights of EO entering and leaving the DEOXX™ system were determined for each chamber evacuation by continuously monitoring the total volumetric gas flow rate and EO concentration at the inlet and the outlet of the DEOXX™ system. The volumetric gas flow rate was measured by using an orifice meter at each location. The gas pressure drop across the orifice plate was monitored throughout the exhaust cycle for accurate measurement of gas flow rate. The EO concentrations were

measured with two gas chromatographs, one each at the inlet and the outlet of the DEOXX™ system.

C.2.3 Test Results

The weights of EO entering and leaving the DEOXX™ system for each evacuation, as well as the removal efficiencies associated with each test run, are presented in Table C-4.

C.3 INDEPENDENT LABORATORY TEST OF A DAMAS™ SYSTEM AT JOHNSON & JOHNSON, INC.[3]

C.3.1 Facility Description

A Damas™ scrubber is used to control EO emissions from the sterilization operations at Johnson & Johnson's Ethicon, Inc., facility in Somerville, New Jersey. During the week of August 27, 1984, a Damas™ scrubber at this facility was tested by an independent laboratory. The sterilizer uses a 12/88 mixture of EO/CFC as the sterilant. All concentrations reported are based on gas chromatograph (GC) analyses.

C.3.2 Sampling Procedures

Nine analyses were performed on the scrubber outlet: six with a scrubber flow rate of 0.031 cubic meters/second (m^3/sec) (66 cubic feet per minute [ft^3/min]) (Set 1) and three with a flow rate of 0.047 m^3/sec (100 ft^3/min) (Set 2). These two sets of analyses were performed on August 29 and August 30, 1984, respectively. Samples were collected by drawing a small amount of the scrubber emission stream through a Teflon™-lined pump to a mobile laboratory using a Teflon™ sample line. A collection sump with a sampling port allowed samples to be drawn with a syringe for injection into a GC with a flame ionization detector. These syringe samples were taken once every 2 minutes during each analysis. The scrubber outlet emission stream was also continuously monitored using an infrared analyzer.

The scrubber inlet gas stream was tested on August 30, 1984, using a scrubber flow rate of 0.047 m^3/sec (100 ft^3/min). Three grab samples were collected (during one evacuation) in Tedlar™ bags and analyzed in the same manner as the scrubber outlet samples. The EO concentration at the scrubber inlet was based on an average concentration of these three samples.

TABLE C-4. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR TESTS AT THE McCORMICK AND COMPANY, INC., SPICE MILL[2]

Test no.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg (lb)	EO entering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent[a]	Recovery efficiency, percent[b]
2	13.2 (29.0)	0.32 (0.71)	12.19 (26.85)	0.00130 (0.00287)	99.989	99.990
3	13.2 (29.0)	0.30 (0.67)	12.02 (26.47)	0.00140 (0.00309)	99.988	99.989
4	12.7 (28.0)	0.32 (0.70)	11.99 (26.41)	0.00169 (0.00372)	99.986	99.987

[a]Calculated using the emission entering and exiting the control device.
[b]Calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control device.

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C.3.3 Test Results

The peak outlet concentration for each analysis was used to calculate the removal efficiency of the scrubber. The average scrubber efficiency was 99.25 percent for Set 1 and 99.28 percent for Set 2. The average removal efficiency for all nine runs was 99.26 percent.[3] (The average removal efficiency determined by infrared analysis of the scrubber outlet EO concentration was 99.16 percent.)

The use of concentration differences, rather than a percent weight removal, as a basis for calculating the removal efficiency did not significantly affect the efficiency estimate; the efficiency still should be equal to or greater than 99.0 percent. The use of an average inlet concentration, which was based on the highest gas flow rate, and the peak outlet concentration to determine the efficiency would provide a conservative estimate as long as the outlet flow rate is less than or equal to the inlet flow rate. However, if the outlet flow exceeds the inlet flow (e.g., if there is dilution at the stack), then the methodology would overestimate the efficiency. It could not be determined from the data provided whether the outlet and inlet flow rates were different, and there were no indications in the report that flow rates were monitored.[3]

Some uncertainties exist regarding the efficiencies obtained in this test because of the conditions under which the scrubber was tested. First, the test was performed on a scrubber that was using fresh scrubbing liquor (i.e., no ethylene glycol in the scrubbing liquor). Secondly, it was unclear from the test report whether all the runs each day (i.e., number of evacuations) were for a single sterilization cycle. Finally, there were no indications that gas stream flow rates were monitored during the test.

C.4 INDEPENDENT LABORATORY TEST OF A DEOXX™ SYSTEM AT CHESEBROUGH-POND'S DEOXX™ FACILITY[4]

C.4.1 Facility Description

A DEOXX™ system was installed on sterilizer 4 at Chesebrough-Pond's Sherburne, New York, plant in 1982 to control EO emissions. Four tests were conducted on December 1982 over three different sterilization cycles to evaluate the performance of the system. These tests were performed using pure EO and 12/88 sterilant, and were all conducted on an empty chamber.[4] This chamber had a volume of 35.7 m^3 (1,260 ft^3) and was capable of using either pure EO or a mixture of 12/88 EO/CFC as the sterilant gas.

C.4.2 Sampling Procedures

A total of four performance tests was conducted on the DEOXX™ system: three using the 12/88 mixture and one using pure EO gas. The scrubber outlet emission stream was sampled once every minute by routing two sampling streams from the scrubber exhaust to two separate GC's. The volumetric flow rate of the scrubber outlet emission stream was also monitored using an orifice plate. Volumetric flow vs EO concentration profiles were then developed to calculate the mass of EO exiting the scrubber.

The amount of EO entering the scrubber was determined by weighing the sterilant supply cylinders before and after use, and then subtracting the remaining sterilant in the chamber after the cycle. The EO concentration remaining in the chamber was measured with a GC, and the chamber pressure was measured; the ideal gas low was used to determine the weight of EO left in the chamber.

C.4.3 Test Results

A summary of the emission measurements and control efficiencies for these emissions tests is presented in Table C-5. The efficiencies were calculated based on the total weight of EO entering and exiting the scrubber over the entire cycle. The removal efficiencies for the three 12/88 mixtures were 99.0 percent, 98.7 percent, and 99.4 percent, respectively, for

TABLE C-5. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR EMPTY CHAMBER TESTS AT CHESEBOROUGH PONDS[4]

Test no.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg(lb)	EO centering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent[a]	Recovery efficiency percent[b]
1	13.7 (30.1)	0.10 (0.22)	13.6 (29.9)	0.14 (0.31)	99.0	98.9 +
2	28.8 (63.4)	0.08 (0.18)	28.7 (63.2)	0.37 (0.81)	98.7	98.7
3	24.0 (53.0)	0.01 (0.02)	24.0 (53.0)	0.0004 (0.001)	99.9 +	99.9 +
4	30.6 (67.4)	0.04 (0.10)	30.5 (67.3)	0.19 (0.42)	99.4	99.4

[a]Calculated using the emissions entering and exiting the control device.
[b]Calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control device.

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an average of 99.0 percent. For the pure EO mixture, the EO removal efficiency was greater than 99.99 percent.[4]

C.5 VENDOR TEST OF AN ETO ABATOR™ SYSTEM AT SEAMLESS, INC.[5]

C.5.1 Facility Description

A Donaldson EtO Abator™ catalytic oxidizer was installed to control aeration room emissions at Seamless' Ocala, Florida, facility. Testing was performed on the catalytic oxidizer on December 4 through 6, 1989. The control system was installed to demonstrate to the State that Seamless could comply with the State's 1 ppm standard at 50 feet from the fenceline.[6] This facility sterilizes products in any one of three sterilizer chambers using pure EO or 12/88 (EO/freon) sterilant, depending on which sterilizer is used. After the product is sterilized, it is taken to the aeration room, where it is then allowed to off-gas for at least 24 hours.

The aeration room is maintained at a temperature of 38°C (100°F), and the EO emissions are controlled by two 56 m^3/min (2,000 ft^3/min) catalytic oxidizers. These units run continuously and provide enough heated, recirculated air to maintain the aeration room at a temperature of 38°C (100°F).

C.5.2 Sampling Procedures

Velocity measurements were performed using Pitot tubes situated at 12 traverse points along the cross-section of the duct both upstream and downstream of the control device. Emission stream temperature measurements were also made at these locations. The averages for each set of measurements were used to determine the emission stream flow rates to and from the control device, respectively.

Six 1-liter grab samples were taken simultaneously both upstream and downstream of the control device via test ports. Two additional 4-liter grab samples (taken in 10-liter Tedlar™ bags) were simultaneously taken both upstream and downstream of the control device. Of the eight sets of samples, five were taken approximately 3 hours prior to introducing sterilized product into the aeration room, two were taken just prior to introducing sterilized product into the aeration room, and one

was taken one-half hour after sterilized product was introduced to the aeration room. These samples were analyzed within a 20-hour period of obtaining the samples using a gas chromatograph with a flame ionization detector (FID). All of the product introduced to the aeration room was previously sterilized with pure EO.

C.5.3 Test Results

Six of the eight sets of grab samples were used to determine the control device efficiency. From the results of the GC analysis provided in the test report the efficiency of the control device was determined to be 99.9+ percent for each of the tests performed. However, these efficiencies are based on EO concentration only and do not reflect the mass of EO entering and exiting the control device. Also, the supporting information provided with the test report is very limited and does not substantiate the 99.9 percent claimed.

Other uncertainties exist in this test report. In all of the downstream grab samples, the EO concentration was determined to be zero (instead of the lower detection limit of the FID). Also, the control inlet EO concentrations are high (10 ppm minimum) for aeration room emission concentrations which typically tend to have an EO concentration of less than 2 ppm.[7]

C.6 REFERENCES

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3. Evaluation of the Efficiency of an Ethylene Oxide Scrubber. Scott Environmental Services, Plumsteadville, PA. October 2, 1984.

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6. Telecon. Friedman, B., MRI, with L. Cutright. Professional Medical Products Seamless Division. January 13 and 19, 1990. Discussion about the factors affecting the probable ethylene oxide levels in the aeration room.

7. Memorandum. deOlloqui, V., MRI, to Commercial Sterilization Files. Responses to the July 1988 Section 114 Letter. August 22, 1990.

APPENDIX D.

EMISSION MEASUREMENT AND CONTINUOUS MONITORING

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APPENDIX D.
EMISSION MEASUREMENT AND CONTINUOUS MONITORING

D.1 METHODS FOR DETERMINING ETHYLENE OXIDE EMISSIONS FROM ETHYLENE OXIDE STERILIZERS EQUIPPED WITH CONTROL DEVICES

Since the early 1980's, concern about the toxicity of ethylene oxide (EO) has spurred the development of methods to accurately measure emissions from sterilizing units that use EO as a sterilant. The U. S. Environmental Protection Agency (EPA), the California Air Resources Board (CARB), manufacturers of EO control devices, and EO sterilizer operators have independently moved toward developing such a method by conducting tests of emission control technologies. The methodologies used in several of these tests are summarized in the following sections. Test methods used to evaluate dilute acid hydrolytic EO scrubbing units are discussed in Reports 1 through 6, and test methods used to evaluate catalytic oxidation units are discussed in Reports 7 through 9. Report 10 is a summary of CARB Method 431.

The reports summarized below were generated by control device vendors gathering data to support efficiency claims, purchasers of control devices to either verify the manufacturer's claims or to comply with State regulations, or by EPA in support of method and standard development. These reports are referenced fully in Section D.4.

D.1.1 Report 1

In this test effort,[1] dilute acid hydrolytic scrubber efficiencies were determined using (1) calculated values for EO emissions vented to the scrubber (inlet) and (2) measured values for EO emissions exhausted from scrubber (outlet). Sampling was

performed over the entire evacuation cycle, which included the initial evacuation and four air washes.

D.1.1.1 Determination of EO Mass Vented to the Scrubber. The mass of EO vented from the sterilizer to the scrubber was calculated by subtracting the residual mass of EO left in the chamber from the mass of EO charged to the chamber. The mass of EO charged to the chamber was determined by weighing the charging cylinder prior to and after chamber charging. Residual EO concentrations were measured after the sterilization cycle was complete using the following procedure: a diaphragm pump was used to remove a slipstream of gas through a heated Teflon™ line, which was analyzed using a gas chromatograph (GC) equipped with a thermal conductivity detector (TCD). The residual EO mass was calculated based on the chamber volume, temperature, pressure, and the residual EO concentration.

D.1.1.2 Determination of EO Mass Emitted from the Scrubber. The mass of EO emitted from the scrubber was calculated from repeated measurement of the EO concentration and volumetric flow rate found in the scrubber exhaust. Ethylene oxide concentrations were determined by removing a slipstream of exhaust gas through Teflon™ tubing using a diaphragm pump. A sample of the slipstream was analyzed once every 3 minutes throughout the sterilization cycle using a GC equipped with a flame ionization detector (FID).

The volumetric flow rate of the exhaust gas was measured once each minute throughout the sterilization cycle using an orifice meter installed in the exhaust stack. The gas flow rate changed continuously during the exhaust cycles.

Ethylene oxide concentrations and volumetric flow rate data were then plotted for the initial exhaust and subsequent air wash cycles. Mass emissions of EO were calculated for each exhaust cycle and totalled. Control device efficiency was determined based on the calculated total emissions to the scrubber and measured total emissions from the scrubber.

D.1.1.3 Results. The results of three scrubber efficiency tests performed while a 12/88 mixture of EO and

dichlorodi-fluoromethane was used as a sterilant showed an average EO removal efficiency of 99.1 percent. Removal efficiencies ranged from 98.7 to 99.4 percent. More than 78 percent of the total EO was emitted during the first exhaust cycle.

A single scrubber efficiency test was performed using 100 percent EO as a sterilant. This test demonstrated a removal efficiency of 99.998 percent. Due to technical problems, data for the initial evacuation and the first air wash cycles were not available; thus, the reported amount of 0.00105 pound of EO exhausted was determined from measurements of subsequent air washes.

D.1.2 Report 2

D.1.2.1 Methodology. Report 2 discusses the test methods and results of three efficiency test runs performed on a dilute acid hydrolytic scrubber.[2] During testing, the sterilizer chamber was empty of product, and 100 percent EO was used as the sterilant. The weights of EO entering and leaving the scrubber were determined by continuously measuring the total volumetric gas flow rate at both the inlet and outlet of the scrubber with orifice meters. Sampling was performed over the entire evacuation cycle, which included the initial evacuation and two air wash cycles. The inlet EO mass was calculated using the difference by weight of the EO supply cylinders and residual EO left in the chamber (see Section D.1.1). However, because it was unclear exactly how residual chamber concentrations were determined, the calculation method will not be discussed.

D.1.2.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. Samples were withdrawn continuously from the two locations through heated Teflon™ lines using Teflon™-lined pumps. Slipstreams of gas were sampled with gas sampling valves at approximately 1-minute intervals into two GC's. A GC/TCD was used to measure the inlet slipstream and a GC/FID was used to measure the outlet slipstream.

Volumetric flow rate measurements were performed at both sampling locations. Two orifice meters of different sizes were

used at each location to supply flow measurements over the range of expected velocities.

D.1.2.3 Results. The three scrubber performance tests yielded an average removal efficiency of 99.988 percent by weight, with individual values ranging from 99.986 to 99.989 percent. The EO in the initial evacuation accounted for 20 percent or less of the total mass of EO emitted during the sterilization cycle.

D.1.3 Report 3

D.1.3.1 Methodology. In this test program, dilute acid hydrolytic scrubber efficiencies were determined using calculated and measured inlet values for the EO emissions vented to the scrubber and measured values for the EO emissions exhausted from the scrubber.[3] Sampling was performed over the entire evacuation cycle, which consisted of the initial evacuation and six air washes. This report compared the "throughput" and "recovery" methods of calculating dilute acid hydrolytic scrubber efficiency (see Section D.1.3.3). Data from 10 test runs were reported. Four test runs were conducted with an empty chamber. All runs used 12/88 as the sterilant.

D.1.3.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. The concentration of EO entering and leaving the scrubber was measured semicontinuously at the inlet and outlet with a GC/FID. Sample gas was continuously removed from the sampling locations and analyzed at 4-minute intervals. The volumetric flow rate at the outlet of the control device was measured by a vane anemometer in series with orifice plates; the flow rate at the inlet was calculated as discussed below.

D.1.3.3 Efficiency Determinations. The throughput efficiency was calculated using measured EO emissions from the inlet and outlet of the scrubber. Ethylene oxide concentration was measured at the inlet by GC/FID, and inlet volumetric flow rates were calculated using the chamber volume and chamber pressures and temperatures.

The recovery method calculated EO control efficiency based on the weight of EO charged to the sterilization chamber. The EO

charge cylinder was weighed prior to and after charging the chamber, and the weight of EO charged was determined by the difference. The measured outlet EO emissions were used to calculate the recovery efficiency.

D.1.3.4 Results. Only the results for the empty chamber tests will be discussed since tests where the sterilization chamber was loaded with product showed similar removal efficiencies. Throughput efficiencies for the empty chamber tests ranged from 99.82 to 99.98 percent. Recovery efficiencies for the empty chamber tests ranged from 99.90 to 99.97 percent. A one-way analysis of variance (ANOVA) performed on data from the empty chamber tests showed no difference between the recovery method and the throughput method in determining control efficiency.

D.1.4 Report 4

D.1.4.1 Methodology. This report focused on several issues raised by the testing described in Report 3.[4] The first issue concerned the stability of EO samples in 1-liter (L) (0.264 gallons [gal]) polyvinylfluoride gas bags, 5-milliliter (mL) (0.3 cubic inches [in^3]) gas-tight syringes, and evacuated aerosol cans. The second issue investigated was EO concentration profiles plotted at 1-minute intervals throughout the sterilization cycle using both pure EO and 12/88 mixtures. The third issue was the evaluation of various analytic columns.

The sampling and analytical methods reported varied slightly from those in Report 3. Scrubber exhaust samples were removed from the exhaust stack through a heated Teflon™ line with a diaphragm pump. Samples were placed into 1-L polyvinyl fluoride bags, 5-mL gas-tight syringes, or evacuated aerosol cans.

The linearity, efficiency, resolution, retention time, sample stability, and limits of quantitation and detection were evaluated for three columns.

D.1.4.2 Results. Report 4 concludes that a 5 percent fluorinated oil column is adequate for measuring percent levels of EO and dichlorodifluoromethane, the levels expected at the exhaust of an uncontrolled sterilizer or the inlet of a scrubber.

A 1 percent polyethylene glycol and substituted terephthalic acid column is recommended for measuring part-per-million-by-volume (ppmv) levels of EO, the levels expected at the outlet of a scrubber. The report recommends that a 3-percent polyethylene glycol and substituted terephthalic acid column operated at 45°C (116°F) be investigated for quantifying sub-ppm levels of EO, the levels expected in ambient air at sterilization facilities.

The stability of 12/88 and 100 percent EO samples in Tedlar™ bags were investigated by measurement at time zero and selected intervals thereafter. Both types of samples were not stable over a 4-day period; concentrations of the 12/88 mixture differed by 23 to 96 percent, while the concentrations of the 100 percent EO differed by 15 to 30 percent. Only the 12/88 samples were analyzed at a shorter time interval. After 1 day, the 12/88 mixture concentrations differed 3 to 27 percent from those at time zero, which indicated poor stability.

Aerosol cans containing 100 percent EO were analyzed at time zero and 4 days later. Over this period the EO concentrations differed an average of 15 percent (range +2.82 to -44.6). Syringe samples were analyzed at time zero and after 4 days and were also not found to be stable. The percent difference in concentration for both the 100 percent EO and 12/88 mixtures averaged 23 percent.

Concentration profiles showed that EO concentrations in sterilizer exhaust increased linearly between 5 and 13 minutes after the start of the cycle, reached a plateau between 13 and 20 minutes, and dropped off after 20 minutes.

D.1.5 Report 5

D.1.5.1 Methodology. Report 5 addresses six test runs conducted at a scrubber exhaust flow rate of 1.8 cubic meters per minute (m^3/min) (66 cubic feet per minute [ft^3/min]) and three conducted at a scrubber exhaust flow rate of 2.8 m^3/min (100 ft^3/min).[5] Flow through the scrubber appears to have been set for this test program, as no record of volumetric flow rate measurement is present in the report. A 12/88 EO mixture was

used as the sterilant. The number of evacuations tested in each sterilization cycle was not reported.

Scrubber inlet samples were acquired three times during the entire test effort. Grab samples were taken using polyvinylfluoride bags and analyzed in GC/FID, as described below. The EO concentrations of the three grab samples were 15.0, 27.4, and 29.0 percent. The average concentration of the three samples (23.8 percent) was used as the scrubber inlet concentration. The removal efficiencies were calculated using the average inlet concentration and the peak outlet concentrations.

The scrubber outlet emissions were sampled using a heated Teflon™ line and a Teflon™-coated pump. Grab samples were removed from the sample line at approximately 2-minute intervals using a syringe. The remaining sample passed into an infrared (IR) spectrometer. The syringe samples were analyzed by a standardized GC/FID. The IR spectrometer used to provide a second measure of scrubber outlet EO concentrations was set at a wavelength of 3.3 microns to reduce interferences.

D.1.5.2 Results. All of the efficiency results were based on the average measured inlet concentration of 23.8 percent EO and the maximum outlet EO concentration measured for a particular sterilization cycle. The variation in EO inlet concentrations indicates poor precision in determining scrubber inlet EO concentrations by this method. The efficiency determined by using the GC averaged 99.26 percent (99.16 to 99.32 percent range). The average efficiency determined by using IR spectroscopy was 99.16 percent (99.03 to 99.21 percent range).

D.1.6 Report 6

D.1.6.1 Methodology. In Report 6, EO removal efficiencies for a dilute acid hydrolytic scrubber were calculated by measuring EO concentrations at the scrubber inlet and outlet, scrubber outlet volumetric flow rates, and scrubber inlet and outlet temperatures.[6] Testing was performed under laboratory conditions on a full-scale acid-hydrolysis system. Each test cycle included two evacuations and use of a 12/88 mixture of sterilant.

Inlet and outlet EO concentrations were measured by GC/FID. The sample gas was removed from both ducts via Teflon™ tubing. Grab samples were removed from the tubing with a syringe every 40 seconds. Volumetric flow rate was measured at the scrubber outlet location using a calibrated dry test meter. Scrubber inlet flow rate was calculated by adding the EO volumetric flow rate. Using the measurements of EO concentration, temperature, and flow rate, the EO removal efficiency was calculated based on the total amount of EO that entered and left the scrubber system.

Four runs were performed on actual sterilizer exhaust, and three were performed with simulated sterilizer exhaust. For the simulated exhaust, a 12/88 mixture of sterilant gas was injected into the ductwork leading to the scrubber.

D.1.6.2 Results. Destruction efficiencies for the runs with actual exhaust ranged from 99.995 to 99.998 percent. The destruction efficiency for the EO injection runs averaged 99.999 percent. It was noted that of the EO charged to the sterilizer chamber, 25 to 56 percent was exhausted to the scrubber during the initial evacuation. A more accurate inlet flow rate determination would provide more representative efficiency results.

D.1.7 Report 7

D.1.7.1 Methodology. Report 7 describes the method used to determine the EO removal efficiency of a catalytic oxidation unit controlling aeration room emissions.[7] The sterilant was 100 percent EO, and six test runs were performed. Presurvey testing was conducted where a 12/88 mixture was used and four runs were performed.

D.1.7.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. The volumetric flow rates of the inlet and outlet sample gas streams was measured by traversing the ducts with a standard pitot tube according to EPA Methods 1 and 2 (40 CFR Part 60, Appendix A). Gas temperature and relative humidity were measured at the same locations.

Inlet and outlet grab samples were collected simultaneously in polyvinylfluoride gas bags using heated Teflon™ sampling lines

and Teflon™-coated pumps. The bag samples were analyzed by GC/FID within 20 hours of sample acquisition.

D.1.7.3 Results. The concentrations at the control device outlet were below the detection limit of the GC, and EO removal efficiencies were assumed to be greater than 99.9 percent. The EO removal efficiencies determined using presurvey samples ranged from 99.4 to 99.6 percent. The report speculated that the variation in efficiencies was due to the type of sterilant used and differences in chamber operating parameters.

D.1.8 Report 8

D.1.8.1 Methodology. Report 8 presents the results of seven efficiency test runs performed on a catalytic oxidation system used to control EO emissions from a sterilizer.[6] Three test runs were performed on actual sterilizer exhaust and four test runs were conducted while EO cylinder gas was injected into the ductwork leading to the catalytic oxidation system inlet. Each test cycle included two evacuations, and the sterilant was a 12/88 mixture.

The gas stream entering the catalytic oxidation system was continuously monitored for EO using a total hydrocarbon analyzer equipped with an FID. Additional inlet EO concentration measurements were made on grab samples using GC. An EO concentration profile for the catalytic oxidizer outlet was derived from GC analysis of grab samples. The sample gas streams were removed at the catalytic oxidizer inlet and exhaust and sampled using Teflon™ tubing and a pump. Grab samples were removed from this tubing with gas-tight syringes at 40-second intervals during the exhaust cycle.

Flow rate measurements were performed at the catalytic oxidizer inlet using a standard Pitot tube. A traverse of the duct was performed, and the volumetric flow rate was measured subsequently at a point of average velocity of the traverse. The outlet flow rate was assumed to be equal to the inlet flow rate. This sampling point was located after ambient air was added to the unit. Although the flow rate exhausted from the sterilizer diminished over each evacuation cycle, the flow at the catalytic

oxidizer test point did not change significantly. In comparison to dilute acid hydrolytic scrubbers, catalytic oxidizers exhibit relatively stable inlet and outlet flow rates because ambient air is added prior to the unit. Catalytic oxidizer inlet and outlet gas temperatures were also monitored.

Using the measurements of EO concentration (inlet and outlet), temperature, and flow rate, the EO removal efficiency was calculated based upon the total mass of EO that entered the catalytic oxidizer and the total mass of EO that left the unit.

D.1.8.2 Results. The EO removal efficiencies for the sterilizer discharge tests ranged from 99.16 to 99.40 percent. Removal efficiencies for the duct injection tests ranged from 99.89 to 99.98 percent

D.1.9 Report 9

D.1.9.1 Methodology. Report 9 describes the methods used to determine the EO removal efficiency of a catalytic oxidation unit used to control aeration room exhaust.[8] Since EO concentrations to the catalytic oxidizer were approximately 2 ppmv under normal operating conditions, pure EO cylinder gas was added at the inlet duct to yield EO concentrations of 100 ppmv. Gas samples were acquired at the inlet to the control device, after each of the three catalyst beds, and at the exhaust stack. A volumetric flow rate was reported for the exhaust stack, but no mention was made regarding the methods used to acquire these data.

Samples were collected using hydrogen bromide (HBr)-coated charcoal tubes over a period of 24 hours at each of the five locations described above. Each sampling train consisted of a Teflon™ tube connected to two or more charcoal tubes in series, connected to a sampling pump. Inlet sampling was conducted for a 20-minute period every 2 hours for the entire 24-hour test run. Samples were recovered from the charcoal tubes in a manner similar to NIOSH Method 1614, and the analysis was performed by GC/FID.

D.1.9.2 Results. The annual EO emissions to the atmosphere were calculated to be <0.043 kilograms per year (kg/yr)

(<0.095 pounds per year [lb/yr]), based on a volumetric flow rate of 19 actual m^3/min (694 actual cubic feet per minute [aft^3/min]). The EO removal efficiency of the catalytic oxidizer was calculated to be >99.99 percent.

As the methodology for determining volumetric flow rate was not presented in this report, this discussion is limited to the sampling and analytical methodology, specifically, the use of HBR-coated charcoal tubes in conjunction with an integrated sampling rate.

Direct GC/FID analysis of EO gas samples (Reports 1 through 9) yields a detection limit of approximately 1 ppmv. Use of the HBR-coated charcoal tubes allows concentration of the EO sample and a consequent decrease in the detection limit for EO in the gas stream to 3 parts per billion by volume (ppbv). This permits more accurate quantitation of EO concentrations in the diluted exhaust gas streams from catalytic oxidation emission control devices.

D.1.10 Report 10

Report 10 is not a test report but rather a summary of CARB Method 431, "Determination of Ethylene Oxide Emissions From Stationary Sources."[9] Method 431 was based on the same methodologies described in Reports 3 and 4 (References 1 and 2), with the exception that turbine (vane anemometer) or Roots-type flow meters rather than orifice meters are used to determine volumetric flow rate. Emission testing is performed on sterilizers containing normal product loads. Volumetric flow rate and EO concentrations of the vent gas are measured repeatedly for the duration of the sterilization cycle. Total emissions are calculated from curves representing flow and concentration versus time.

As mentioned above, the CARB method requires the use of vane anemometers or Roots-type meters to measure volumetric flow rate; these are certified to 1.5 percent accuracy by the manufacturer. Two or more meters may be installed in parallel if necessary to achieve this requirement over the entire expected range of flow rates. A valve is used to switch between the two meters as flow

rates change. Also required are measurements from temperature and pressure sensors to convert the measured flow rate to standard temperature and pressure conditions.

The sample gas is continuously removed from the exhaust stack via heated fluoroethylene or polytetrafluoride sample line at a rate in excess of 1 L/min (0.036 ft^3/min). A slipstream is removed from this line and directed to the GC sampling loop via a gas sampling valve. The sample is analyzed as frequently as possible (1-minute intervals for 100 percent EO and 3- to 4-minute intervals for EO mixtures). Sample loop pressure, sample flow rate, and slipstream flow rate must be measured/recorded during this process. Excess sample is bubbled through a sulfuric acid solution prior to discharge. A GC is required for the analysis.

Also suggested are calibration gas concentrations for both percent and ppm level analysis. Some lateral freedom is given with respect to calibration gas makeup and concentration. It is required that a similar midrange audit standard be used to verify calibration gas composition and GC performance. Audit standards and calibration gases must be supplied and certified by separate suppliers.

Additional guidelines for a pretest site survey, GC preparation, flow metering, sample train setup and operation, data reduction, and integration of the mass flow rate curve are also provided.

D.2 MONITORING SYSTEMS AND DEVICES

The following parameters may be monitored to indicate proper control device operation. All monitoring equipment should be installed, calibrated, maintained, and operated according to the manufacturer's specifications.

The following parameters indicate proper control device operation for counter-current packed scrubber and reaction/detoxification towers and thus will be monitored:

1. The EO charged to the sterilizer by weighing cylinders or by monitoring liquid flow rate using a rotameter or orifice; and

2. The ethylene glycol concentration in the scrubber liquor using liquid level indicators or specific gravity detectors in the tank. If the ethylene glycol concentration exceeds 60 weight percent, the scrubber liquid must be changed.

The following parameters indicate proper control device operation for catalytic oxidation and should be monitored:

1. The gas temperature both upstream and downstream of the catalyst bed using a device that continuously measures these temperatures while the control device is in operation; and

2. The amount of diluent air using a Pitot tube or other flow measurement device.

Proper operation of a flare is indicated by the continuous presence of a flame. Therefore, a heat-sensing device, such as an ultra-violet beam sensor or thermocouple, shall be installed at the pilot light to indicate the continuous presence of a flame.

D.3 PERFORMANCE TEST METHODS

D.3.1 Test Method Background

The EPA EO test method will reference the EPA Method 2 series and EPA Method 18 (40 CFR 60, Appendix A) as its base. Methods 2, 2A, 2C, and 2D apply for measuring flow rates from control device exhaust. The particular method applied depends on the size of the duct. If orifice meters (or a similar device) are used, it may be necessary to install more than one size in series to measure over flow rate variations.

Method 18 applies for measuring EO concentrations entering and exiting both catalytic oxidizers and dilute acid hydrolytic scrubbers. Using appropriate chromatographic columns and temperature programming eliminates interferences from dichlorodifluoromethane and potential EO degradation products.

D.3.2 Test Method Advantages/Disadvantages

Listed below is a summary of the different methodologies that have been addressed in D.1 and the advantages and disadvantages of each technique. These factors have been considered in developing the EPA test method.

D.3.2.1 Calculation of Inlet Mass. To determine the inlet mass of EO emissions entering the control device by calculation, the amount of sterilant entering the control device must be measured by weighing the cylinder before and after charging the sterilizer. The residual EO left in the chamber can be determined using the ideal gas law and would be subtracted from the cylinder weight to calculate the inlet mass.

The principal advantage of this technique is that it avoids the hazards of handling high levels of EO. The principal disadvantage is that a system leak will diminish the accuracy. However, a leak is unlikely since sterilizer sources must also comply with health and safety rules requiring continuous monitoring of worker exposure to EO.

D.3.2.2 Measuring the Inlet Mass or Outlet Mass. Direct measurement of the outlet mass emission rates requires determination of the flow rate and EO concentration. Direct measurement of the inlet mass emission rate would require an additional set of equipment and would have the additional hazards of handling high levels of EO. However, direct measurement would eliminate the potential for bias created by a leak in the system.

The EO concentration can be determined by semicontinuous sampling with a GC. However, the elution time for EO mixtures such as 12/88 is 3 minutes, which is not frequent enough to define the emission profile of a sterilizer. One-minute analyses are possible for pure EO. Grab samples may be taken at any interval and later analyzed by GC to better define the emission profile. However, the stability of EO in bags, syringes, and vacu-samplers needs additional investigation.

Removing the sample gas through a heated, inert sampling line and analyzing it immediately eliminates the potential for sample degradation and condensation.

An orifice meter is capable of providing continuous volumetric flow rate information. It is appropriate for measuring volumetric flow rate in a system where flow rates vary rapidly. Multiple orifice meters can be used to cover a wide range of flow rates.

The presence of other components in the vent gas stream creates two problems. First, components eluting near the EO peak may create confusion in identifying and quantitating the EO peak. Second, components that elute after EO and dichlorodifluoromethane extend the analysis time and decrease the number of on-line samples that can be analyzed.

D.3.2.3 Efficiency Determinations. An efficiency determination based on the initial evacuation of a sterilizer does not necessarily evaluate the scrubber efficiency during subsequent air washes. Integrating the EO concentration curve instead of using a peak concentration value is more representative of overall efficiency; using the peak concentration will negatively bias the results.

D.4 REFERENCES

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8. Engineering Science. Report of Air Pollution Source Testing conducted at IOLAB Corporation. December 7, 1988.

9. California Air Resources Board Source Test Method 431, Determination of Ethylene Oxide Emissions From Stationary Sources.

APPENDIX E.

SUPPLEMENTAL INFORMATION TO THE COST ANALYSIS

APPENDIX E.

SUPPLEMENTAL INFORMATION TO THE COST ANALYSIS

This Appendix contains supplemental information used in analyzing costs associated with the regulation of ethylene oxide (EO) commercial sterilization facilities. Included in this appendix are: (1) costs for acid-water scrubbers (Section E.1); (2) sample calculations of the equations used to develop capital and annual costs for acid-water scrubbers (Section E.2); (3) aeration room cost analysis (Section E.3); (4) capital and annual control costs for the sterilizer chamber, chamber exhaust, and aeration room vent(s) at an example facility (Section E.4); (5) a breakdown of manifolding costs for these three vents (Section E.5); and (6) the cost indices and conversion factors used to convert costs to fourth quarter 1987 dollars (Section E.6).

E.1 COSTS FOR ACID-WATER SCRUBBERS

TABLE E-1. COST OF DAMAS SCRUBBER MODELS (F.O.B.)[1,2]
(4th Quarter 1987 Dollars)

Model No.	Chamber size, m^3 (ft^3)[a]	Flow rate (acfm)	Conversion capacity of scrubber, kg (lb) of EO	Automated scrubber cost, $	Cost of explosion-proof valves for scrubber, $[b]
25	< 1.4 (<50)	40	227 (500)	8,980	N/A[c]
50	1.4 to 2.8 (50 to 100)	60	454 (1,000)	13,500	N/A[c]
100	<11.3 (<400)	50-100	908 (2,000)	46,800	12,800
200	11.3 to 17.0 (400 to 600)	>100-200	1,816 (4,000)	67,700	13,800
300	17.0 to 22.7 (600 to 800)	>200-300	2,724 (6,000)	88,500	14,900
400	22.7 to 45.3 (800 to 1,600)	>400	3,632 (8,000)	98,900	16,000
500	45.3 to 56.6 (1,600 to 2,000)	>500	4,540 (10,000)	141,000	18,100
600	>56.6 (>2,000)	>600	5,448 (12,000)	156,000	19,100

[a]The size of sterilization chamber that can be served by the model number, assuming the smallest appropriate vacuum pump is used.[3]
[b]Explosion-proof valves are necessary if the sterilization chamber that is vented to the scrubber uses a gas mixture greater than 20 percent by weight EO.[4,5]
[c]Price of explosion-proof valves included in cost of these models.
[d]Acfm actual cubic feet per minute.

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TABLE E-2. CAPITAL AND ANNUALIZED COSTS OF INSTALLING SCRUBBERS[1]
(4th Quarter 1984 Dollars)

	Item	Cost
A.	CAPITAL COSTS[a]	
	Installed equipment costs	
	Automated scrubber	N/A[b]
	Explosion-proof valves for scrubber	b
	Chlorine filter house	b
	Purchased equipment costs, total	b
	Installation of scrubber	b
	Installation of chlorine filters	b
	Taxes: 5 percent of equipment cost	b
	Freight: 5 percent of equipment cost	b
	Vacuum pump[c]	19,700
	Manifolding of chambers (includes check valve)	b
	Total capital costs, 1984 dollars	19,700
B.	ANNUALIZED COSTS[a]	
	Direct operating costs	
	Labor[d]	b
	Materials	
	50 percent H_2SO_4	
	50 percent NaOH	b
	Chlorine filters	b
	Taxes: 5 percent of materials cost	b
	Freight: 5 percent of materials cost	b
	Compressed air	b
	Disposal of ethylene glycol	b
	Indirect operating costs	
	Overhead: 0.80 x labor	b
	Property tax, insurance, and administration[e]	788
	Capital recovery costs[c]	3,210
	Total annualized costs	4,000
C.	COST EFFECTIVENESS	
	Reduce, Mg EO yr	43.56
	Cost effectiveness, 1984, $/Mg EO	92

[a]Rounded to three significant figures.
[b]Not applicable.
[c]Four vacuum pumps at $4,935 each.
[d]Labor was calculated for 0.25 person-hours/shift, 3 shifts/d, 365 d/yr for system inspection and 16 person-hours for each regeneration of the scrubber at $11.60/person-hour.
[e]Calculated as 4 percent of total capital cost.

TABLE E-3. DATA USED TO CALCULATE SCRUBBER EQUIPMENT CAPITAL COSTS[1]
(4th Quarter 1987 Dollars)

Item	Cost factor
Automated scrubber	--[a]
Explosion-proof valves for scrubber	--[a b]
Chlorine filter house	($41.50 each) x (No. of tanks)[c]
Scrubber installation	50 percent of scrubber cost
Chlorine filter installation	($20.00) x (No. of tanks)[c]
Taxes	5 percent of total equipment cost
Freight	5 percent of total equipment cost
Vacuum pump(s)	$5,170 per pump
Manifolding of chambers	--[d]
Check valve	--[e]

[a]Function of chamber size (see Section E.1).
[b]Explosion-proof valves are necessary if the chamber that is vented to the scrubber uses a gas mixture greater than 20 percent (by weight) EO. (See Section E.1).
[c]Number of scrubber tanks required = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO).
[d]See Section E.5.
[e]See Table E-4.

TABLE E-4. CAPITAL COST OF CHECK VALVE FOR CHAMBER

Cost item	Cost 1987, $	Richardson reference[2]
Swing check valve	367	15-43, p. 31
Labor hours to install	1.1	15-43, p. 31
Labor costs at $21.47/labor hour	24	15-0, p. 2
Overhead costs at $13.31/labor hour	15	1-0, p. 5
Total direct costs	391	
Administration: 10 percent of total direct costs	39	1-0, p. 5
Taxes: 5 percent of equipment cost	18	1-0, p. 6
Total indirect costs	72	
Total installed cost	463	
Annualized capital recovery cost[a]	75	GARD, p. 3-18[3]

[a]Calculated as 0.16275 x (total installed cost), for an interest rate of 10 percent and a 10-year recovery period.

TABLE E-5. DATA USED TO CALCULATE CONTROL DEVICE ANNUALIZED COSTS[1]
(4th Quarter 1987 Dollars)

Item	Cost factor
Direct operating costs	
Labor	\$3,188 + (\$11.65) x (16 person-hours) x (No. of scrubber regenerations)[a b]
Materials:	
50 percent H_2SO_4	(\$0.0702/lb) x (594 lb/drum) x (No. of drums required) x (1.15)[c-e]
50 percent NaOH	(Cost/lb) x (700 lb/drum) x (No. of drums required) x (1.15)[c, f, g]
Chlorine filters	(\$15/filter) x (No. of tank regenerations) x (No. of tanks)[c h]
Taxes	5 percent of materials cost
Freight	5 percent of materials cost
Compressed air	0[i]
Disposal of ethylene glycol	--[j]
Indirect operating costs	
Overhead	(0.6) x (labor costs)
Property tax, insurance, and administration	4 percent of total capital costs
Capital recovery costs	(0.16275) x (total capital costs)[k]

[a]Number of scrubber regenerations = amount of EO to be treated divided by the conversion capacity of the scrubber (See Example Calculation No. 6 in Section E.2)

[b]The \$3,188 is for visual inspection of the system 15 minutes per shift, 3 shifts per day, 365 days per year at \$11.65/person-hour. It was assumed that each regeneration of the scrubber solution would require two people at 8 person-hours each, independent of scrubber size.

[c]Number of scrubber tanks = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO). Number of tank regenerations = number of scrubber regenerations multiplied by the number of scrubber tanks.

[d]Each tank regeneration requires one 55-gallon drum of 50 percent H_2SO_4.

[e]Fifteen percent extra is allowed for spillage.

[f]Each tank regeneration requires 250 pounds of NaOH for neutralization.

[g]Cost basis for 50 percent NaOH (350 pounds NaOH per drum):

[f]No. of drums >9, cost/lb = \$0.0110.
If No. of drums = 3 to 9, cost/lb = \$0.0802.
If No. of drums <2, cost/lb = \$0.0752.

[h]Each chlorine filter can dechlorinate approximately 200 gallons (one tank) of H_2O; replace filter at each tank regeneration.

[i]The cost of 10 seconds of in-house compressed air per cycle is considered negligible.

[j]Unit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at regeneration, approximately 4,845 lb (see Example Calculation No. 3 in Section E.2.
If the total weight <42,000 lb, disposal cost = (weight) x (\$0.110/lb).
If the total weight ≥42,000 lb, disposal cost = (weight) x (\$0.068/lb).

[k]Assumes an interest rate of 10 percent and a 10-year recovery period.

TABLE E-6. MISCELLANEOUS OPERATING COSTS[1]

Item description	Cost, 1987 $
Operating materials	
1. 50 percent H_2SO_4, electrolyte-grade	0.0702/lb
2. 50 percent NaOH, industrial grade:	
<2 drums	0.110/lb
3-9 drums	0.0802/lb
>9 drums	0.0752/lb
3. Chlorine filters:	
Filter housing	41.50 each
Filter	15.00 each
Installation	20.00 each
Shipping charges for waste disposal	
Weight of solution for disposal:	
<42,000 lb (drums)	0.110/lb
≥42,000 lb (bulk)	0.068/lb

TABLE E-7. COST OF EtO ABATOR™ CATALYTIC OXIDIZERS (F.O.B.)[1-3]
(1987 Dollars)

Design flow rate, m^3/min (ft^3/min)	Cost, $[a b]
28 (1,000)	48,000
84 (3,000)	81,000
168 (6,000)	112,000
252 (9,000)	148,000
336 (12,000)	189,000

[a]Costs in 1989 dollars were corrected to 1987 dollars using the "Chemical Engineering" Plant Cost indices.
[b]Cost of replacement catalyst is $1,500/cell in 1989 dollars, or approximately $1,240/cell in 1987 dollars.[2,4,5]

E.1 COSTS OF ACID-WATER SCRUBBERS

REFERENCES

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2. Telecon. Srebro, S., MRI, with D. Smith. Damas Corp. December 12, 1989. Discussion about costs of Models 25 and 50 Damas acid/water scrubbers.

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E.2 SAMPLE COST CALCULATIONS FOR ACID-WATER SCRUBBERS

E.2 SAMPLE COST CALCULATIONS FOR ACID-WATER SCRUBBERS

	Sterilization chambers at the facility				
	No. 1	No. 2	No. 3	No. 4	No. 5
Size, m^3 (ft^3)	19 (667)	19 (667)	34 (1,200)	37 (1,334)	37 (1,334)
Gas type	100	100	12/88	100	100
EO USE, kg (lb)	12,700 (28,000)	12,700 (28,000)	540 (1,200)	21,000 (46,000)	21,000 (46,000)
EO-EMIT, kg (lb)	12,100 (26,600)	12,100 (26,600)	520 (1,140)	19,800 (43,700)	19,800 (43,700)
MEO-EMIT, Mg (tons)	12.07 (13.52)	12.07 (13.52)	0.52 (0.58)	19.82 (22.20)	19.82 (22.20)

	Facility totals
EO-FAC, kg (lb)	64,310 (141,740)
MEO-FAC, Mg (tons)	64.30 (72.02)
EO-TOT, kg (lb)	67,695 (149,200)
MEO-TOT, Mg (tons)	67.7 (74.6)
CON-EM, Mg (tons)	0.64 (0.70)
REDUCE, Mg (tons)	63.66 (70.15)

1. The size, gas type, and EO use are those for an actual commercial sterilization facility represented in the EPA data base. (See Section 3.1 of this report for a description of how this data base was developed.) The other values were calculated using the following assumptions:

a. EO-EMIT (lb) = EO (lb) emitted annually from an individual sterilization chamber to the vacuum pump drain and to the atmosphere. As shown in Section 3.4 of this document, sterilizer vent emissions and vacuum pump drain emissions were assumed to be 50 percent and 45 percent of EO use (lb), respectively. Residual EO in the sterilized product prior to aeration was assumed to be 5 percent of EO-USE (lb). This 5 percent of the EO use is not included as part of EO-EMIT (lb).

b. MEO-EMIT (Mg EO) = EO-EMIT (lb)/2,204.6

c. EO-FAC (lb) and MEO-FAC (Mg) are the amount of EO released annually by the facility to the vacuum pump drain and to the atmosphere, i.e., the sum of EO-EMIT and the sum of MEO-EMIT, respectively.

d. EO-TOT (lb) is the total amount of EO (lb) used annually by the facility, i.e., the sum of EO use. MEO-TOT (Mg) = EO-TOT (lb)/2,204.6.

e. CON-EM (Mg) is the amount of EO that would be released annually after control, i.e., MEO-TOT*(1-0.99)*0.95. Note that the 5 percent residual EO in the sterilized product, which is later released from the aeration room vent, is excluded from this calculated emission estimate.

f. REDUCE (Mg) is the incremental amount of EO that would be reduced if controls are implemented, i.e., (MEO-FAC)-(CON-EM).

2. For all calculations, a conversion efficiency of 99.0 percent was assumed for the scrubber.

3. Each tank of the scrubber initially holds 0.75 m^3 (198 gal) H_2O and 0.075 m^3 (19.8 gal) H_2SO_4. The manufacturer recommends that the tank be regenerated (i.e., drained, rinsed, and refilled) after 907 kg (2,000 lb) EO have been treated.

a. 0.075 m^3 (19.8 gal) H_2SO_4 = 1.42 kg-mole H_2SO_4 (ρ = 1.834; MW = 98.08) $2NaOH + H_2SO_4$ T $Na_2SO_4 + 2H_2O$; 1.42 kg-mole H_2SO_4 requires 2.84 kg mole NaOH to neutralize. Neutralization will produce 2.84 kg-moles H_2O and 1.42 kg mole Na_2SO_4. Use 50 percent (w/w) NaOH to neutralize; each 0.21-m^3 (55-gal) drum of 50 percent NaOH weighs 318 kg (700 lb), i.e., 159 kg (350 lb) NaOH (MW = 40); need 2.84 kg-moles or 114 kg (250 lb) NaOH to neutralize.

b. C_2H_4O (EO) + H_2O T $C_2H_4(OH)_2$ (ethylene glycol); 907 kg (2,000 lb) EO = 20.51 kg-moles EO (MW = 44.1).

c. At 99 percent conversion, yield is 20.365 kg-moles or 1.14 m^3 (301 gal) ethylene glycol (EG) (MW = 62.07; ρ = 1.1088).

d. At 99 percent conversion, 20.365 kg-moles H_2O have reacted. 41.64 kg moles H_2O originally available (MW = 18; ρ = 1); 21.275 kg-moles or 0.38 m^3 (100 gal) H_2O remain unreacted.

e. Weight of neutralized solution per tank: 1.42-kg mole Na_2SO_4 = 202 kg Na_2SO_4 (MW = 142.04); 2.84 kg-moles H_2O (from neutralization) = 51 kg (112 lb) H_2O; 250 lb (113 kg) H_2O = from 50 percent NaOH solution; 0.38 m^3 (100 gal) unreacted H_2O

= 378 kg H_2O (833 lb); 1.14 m^3 (301 gal)EG = 1,264 kg (2,786 lb) EG; total wt = 2,008 kg = 4,427 lb.

f. Solution is 63 percent (w/w) EG. Add about 0.19 m^3 (50 gal) rinse water for each tank = 189 kg (416 lb); total wt (+ rinse H_2O) = 2,198 kg (4,844 lb); total gal (+ rinse H_2O) = 1.87 m^3 (495 gal) = nine 0.21 m^3 (55-gal) drums; wt per 0.21 m^3 (55-gal) drum = 244 kg (538 lb).

4. Find scrubber model and cost from Table E-1, based on the sum of the volumes of the two largest chambers at the facility:

Chambers 4 and 5 75 m^3 (2,668 ft3) Model 600 $157,500

5. Because at least one chamber uses 100 percent EO, explosion-proof valves are necessary.

6. Find number of regenerations of scrubber required per year:

a. Number of scrubber tanks = scrubber model/100 = 6 (scrubber consists of modular tanks).

b. Conversion capacity of scrubber = (No. of tanks) x 2,000 lb = 12,000 lb.

c. Number of scrubber regenerations = EO-FAC (lb)/12,000, i.e., the amount of EO (lb) to be treated per year divided by the conversion capacity of the scrubber.

141,700/12,000 = 11.81 scrubber regenerations/yr

d. Number of tank regenerations = (No. of scrubber regenerations) x (No. of tanks per scrubber) = (11.81) x (6) = 70.87.

7. Cost of chlorine filter housing = (41.50) x (No. of tanks) = $(41.50) x (6) = $249.

8. Installation costs:

a. Scrubber installation = (0.5) x (cost of scrubber) = $78,750

b. Chlorine filter housing installation = (20) x (No. of tanks) = $120.

9. The incremental capital costs of manifolding are presented in Table E-14 of this report.

10. Vacuum pumps. A closed-loop recirculating water vacuum pump is required on each of the five chambers. The cost of modifying the first vacuum pump is included in the cost of the scrubber; the cost of modifying the other four vacuum pumps is $4,935 each.

11. Calculate direct operating costs:

a. Labor = 3,177 + (11.60)x(16) x (No. of regenerations). The $3,177 is for general inspection of the system 15 minutes/shift, 3 shifts/d, 365 d/yr at $11.60/person-hour. For the purposes of these cost analyses, it was assumed that each regeneration of the scrubber would require 2 people at 8 person-hours each, independent of scrubber size. System inspection was also assumed to be independent of scrubber size.

b. Sulfuric acid (50 percent H_2SO_4-electrolyte grade). Assumed: 1 55-gal drum of 50 percent H_2SO_4, i.e., 19.4 gal H_2SO_4, per scrubber tank.

No. of drums required = No. of tank regenerations = (No. of scrubber regenerations) x (No. of tanks per scrubber) = 70.87
Cost of acid = (No. of drums) x (594 lb/drum) x ($0.069/lb)

c. Caustic (50 percent NaOH-industrial grade). First, the unit cost of NaOH was calculated.

NaOH required per year = [No. of tank regenerations] x [NaOH (lb) required per tank] = 70.87 x 250 = 17,718 lb/yr

Total drums/yr required by facility = total NaOH (lb)/350 lb per drum; total drums = 50.6

If total drums >9, cost/lb = 0.0738

If total drums = 3 to 9, cost/lb = 0.0787

If total drums = <2, cost/lb = 0.108

Cost of caustic = (No. of drums) x (cost/lb) x (700 lb/drum)

d. Cost of chlorine filters. Each filter can dechlorinate f200 gal H_2O (or 1 scrubber tank); replace at each scrubber regeneration.

Cost = (No. of scrubber regenerations) x (No. of tanks) x ($15/filter)

e. Disposal. Unit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at the time of regeneration, including rinse water (see 3.f).

Total wt = 70.87 x 4,844 lb/tank = 343,943 lb/yr

If total wt <42,000 lb, disposal cost = wt (lb) x ($0.096/lb)

If total wt ≥42,000 lb, disposal cost = wt (lb) x ($0.059/lb)

f. Compressed air. The cost of 10 seconds of in-house air per cycle was considered negligible and was not computed for these cost analyses.

12. The capital and annualized costs are reported in Tables E-3 and E-5.

REFERENCES

1. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Cost Effectiveness of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. March 21, 1991.

2. Richardson Engineering Services, Inc. Process Plant Construction Estimating Standards. 1984.

3. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc. Niles, IL. Publication No. EPA-450/5-80-002. December 1978.

E.3 AERATION ROOM COST ANALYSIS

TABLE E-8. AERATION ROOM GAS/SOLID REACTANT CONTROL COST ANALYSIS

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
1.50	1	0	1	0	44200	63600	30000	0.0000202	1500000000
2.00	1	0	1	0	44200	63600	30000	0.0000269	1100000000
2.98	1	0	1	0	44200	63600	30000	0.0000401	750000000
4.80	1	0	1	0	44200	63600	30000	0.0000647	460000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	370000000
7.50	1	0	1	0	44200	63600	30000	0.0001010	300000000
9.00	1	0	1	0	44200	63600	30000	0.0001212	250000000
12.00	1	0	1	0	44200	63600	30000	0.0001617	190000000
16.80	1	0	1	0	44200	63600	30000	0.0002263	130000000
17.80	1	0	1	0	44200	63600	30000	0.0002398	130000000
27.36	1	0	1	0	44200	63600	30000	0.0003686	81000000
32.40	1	0	1	0	44200	63600	30000	0.0004365	69000000
32.40	1	0	1	0	44200	63600	30000	0.0004365	69000000
32.40	1	0	1	0	44200	63600	30000	0.0004365	69000000
61.34	1	0	1	0	44200	63600	30000	0.0008264	36000000
64.00	1	0	1	0	44200	63600	30000	0.0008622	35000000
64.80	1	0	1	0	44200	63600	30000	0.0008730	34000000
65.00	1	0	1	0	44200	63600	30000	0.0008757	34000000
70.00	1	0	1	0	44200	63600	30000	0.0009430	32000000
93.60	1	0	1	0	44200	63600	30000	0.0012610	24000000
100.80	1	0	1	0	44200	63600	30000	0.0013580	22000000
105.00	1	0	1	0	44200	63600	30000	0.0014145	21000000
110.00	1	0	1	0	44200	63600	30000	0.0014819	20000000
111.00	1	0	1	0	44200	63600	30000	0.0014954	20000000
113.00	1	0	1	0	44200	63600	30000	0.0015223	20000000
115.00	1	0	1	0	44200	63600	30000	0.0015493	19000000
126.00	1	0	1	0	44200	63600	30000	0.0016975	18000000
160.80	1	0	1	0	44200	63600	30000	0.0021663	14000000
162.00	1	0	1	0	44200	63600	30000	0.0021824	14000000
185.25	1	0	1	0	44200	63600	30000	0.0024957	12000000
188.00	1	0	1	0	44200	63600	30000	0.0025327	12000000
192.00	1	0	1	0	44200	63600	30000	0.0025866	12000000
194.00	1	0	1	0	44200	63600	30000	0.0026135	11000000
195.00	1	0	1	0	44200	63600	30000	0.0026270	11000000
200.00	1	0	1	0	44200	63600	30000	0.0026944	11000000
201.60	1	0	1	0	44200	63600	30000	0.0027159	11000000
264.00	1	0	1	0	44200	63600	30000	0.0035566	8400000
291.60	1	0	1	0	44200	63600	30000	0.0039284	7600000
312.00	1	0	1	0	44200	63600	30000	0.0042032	7100000
312.00	1	0	1	0	44200	63600	30000	0.0042032	7100000
324.00	1	0	1	0	44200	63600	30000	0.0043649	6900000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
388.80	1	0	1	0	44200	63600	30000	0.0052378	5700000
390.00	1	0	1	0	44200	63600	30000	0.0052540	5700000
395.00	1	16000	1	0	44200	63600	33700	0.0053214	6300000
432.00	1	0	1	0	44200	63600	30000	0.0058198	5200000
456.00	1	0	1	0	44200	63600	30000	0.0061432	4900000
504.00	1	0	1	0	44200	63600	30000	0.0067898	4400000
520.00	1	0	1	0	44200	63600	30000	0.0070054	4300000
557.30	1	0	1	0	44200	63600	30000	0.0075079	4000000
562.00	1	0	1	0	44200	63600	30000	0.0075712	4000000
581.00	1	0	1	0	44200	63600	30000	0.0078271	3800000
686.00	1	0	1	0	44200	63600	30000	0.0092417	3200000
804.00	1	0	1	0	44200	63600	30000	0.0108314	2800000
850.00	1	0	1	0	44200	63600	30000	0.0114511	2600000
875.00	1	0	1	0	44200	63600	30000	0.0117879	2500000
1092.00	1	0	1	0	44200	63600	30000	0.0147112	2000000
1155.00	1	16000	1	0	44200	63600	33700	0.0155600	2200000
1231.00	1	0	1	0	44200	63600	30000	0.0165838	1800000
1300.00	1	0	1	0	44200	63600	30000	0.0175134	1700000
1334.00	1	0	1	0	44200	63600	30000	0.0179714	1700000
1521.00	1	0	1	0	44200	63600	30000	0.0204907	1500000
1600.00	1	0	1	0	44200	63600	30000	0.0215549	1400000
1714.00	1	0	1	0	44200	63600	30000	0.0230907	1300000
1714.00	1	0	1	0	44200	63600	30000	0.0230907	1300000
1750.00	1	0	1	0	44200	63600	30000	0.0235757	1300000
1750.00	1	0	1	0	44200	63600	30000	0.0235757	1300000
1800.00	1	0	1	0	44200	63600	30000	0.0242493	1200000
1944.00	1	0	1	0	44200	63600	30000	0.0261892	1100000
1965.00	1	0	1	0	44200	63600	30000	0.0264721	1100000
1980.00	1	0	1	0	44200	63600	30000	0.0266742	1100000
2016.00	1	0	1	0	44200	63600	30000	0.0271592	1100000
2142.00	1	0	1	0	44200	63600	30000	0.0288567	1000000
2254.00	1	0	1	0	44200	63600	30000	0.0303655	1000000
2280.00	1	0	1	0	44200	63600	30000	0.0307158	1000000
2376.00	1	0	1	0	44200	63600	30000	0.0320091	940000
2419.20	1	0	1	0	44200	63600	30000	0.0325911	920000
2450.00	1	0	1	0	44200	63600	30000	0.0330060	910000
2527.00	1	0	1	0	44200	63600	30000	0.0340433	880000
2599.20	1	0	1	0	44200	63600	30000	0.0350160	860000
3120.00	1	0	1	0	44200	63600	30000	0.0420321	710000
3135.00	1	0	1	0	44200	63600	30000	0.0422342	710000
3240.00	1	0	1	0	44200	63600	30000	0.0436487	690000
3640.00	1	0	1	0	44200	63600	30000	0.0490375	610000
3755.00	1	0	1	0	44200	63600	30000	0.0505867	590000
4200.00	1	0	1	0	44200	63600	30000	0.0565817	530000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
4200.00	1	0	1	0	44200	63600	30000	0.0565817	530000
4286.90	1	0	1	0	44200	63600	30000	0.0577524	520000
4320.00	1	0	1	0	44200	63600	30000	0.0581983	520000
4368.00	1	0	1	0	44200	63600	30000	0.0588450	510000
4667.00	1	0	1	0	44200	63600	30000	0.0628730	480000
4860.00	1	0	1	0	44200	63600	30000	0.0654731	460000
5016.00	1	16000	1	0	44200	82000	33700	0.0675747	500000
5088.00	1	0	1	0	44200	63600	30000	0.0685447	440000
5189.00	1	16000	1	0	44200	82000	33700	0.0699053	480000
5250.00	1	16000	1	0	44200	82000	33700	0.0707271	480000
5258.00	1	16000	1	0	44200	82000	33700	0.0708349	480000
5739.00	1	16000	1	0	44200	82000	33700	0.0773148	440000
5850.00	1	16000	1	0	44200	82000	33700	0.0788102	430000
6000.00	1	16000	1	0	44200	82000	33700	0.0808310	420000
6048.00	1	16000	1	0	44200	82000	33700	0.0814776	410000
6176.00	1	16000	1	0	44200	82000	33700	0.0832020	410000
6451.00	1	16000	1	0	44200	82000	33700	0.0869068	390000
6840.00	1	16000	1	0	44200	82000	33700	0.0921473	370000
6900.00	1	16000	1	0	44200	82000	33700	0.0929556	360000
7194.00	1	16000	1	0	44200	82000	33700	0.0969164	350000
7350.00	1	16000	1	0	44200	82000	33700	0.0990180	340000
7387.00	1	16000	1	0	44200	82000	33700	0.0995164	340000
8390.00	1	16000	1	0	44200	82000	33700	0.1130287	300000
8400.00	1	16000	1	0	44200	82000	33700	0.1131634	300000
8736.00	1	16000	1	0	44200	82000	33700	0.1176899	290000
9676.00	1	16000	1	0	44200	82000	33700	0.1303534	260000
10002.00	1	0	1	0	44200	63600	33700	0.1347453	250000
10613.00	1	16000	1	0	44200	82000	33700	0.1429765	240000
10800.00	1	16000	1	0	44200	82000	33700	0.1454958	230000
11016.00	1	16000	1	0	44200	82000	33700	0.1484057	230000
11400.00	2	32000	1	0	44200	121000	41700	0.1535789	270000
11440.00	2	32000	1	0	44200	121000	41700	0.1541178	270000
11547.00	2	32000	1	0	44200	121000	41700	0.1555592	270000
11984.00	2	32000	1	0	44200	121000	41700	0.1614464	260000
12020.00	2	32000	1	0	44200	121000	41700	0.1619314	260000
12249.00	2	32000	1	0	44200	121000	41700	0.1650165	250000
13000.00	2	32000	1	0	44200	121000	41700	0.1751338	240000
13000.00	2	32000	1	0	44200	121000	41700	0.1751338	240000
13059.00	2	32000	1	0	44200	121000	41700	0.1759286	240000
14352.00	2	32000	1	0	44200	121000	41700	0.1933477	220000
14400.00	2	32000	1	0	44200	121000	41700	0.1939944	210000
14860.00	3	48000	1	0	44200	143000	46100	0.2001914	230000
14862.00	3	48000	1	0	44200	143000	46100	0.2002184	230000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
15040.00	2	32000	1	0	44200	121000	41700	0.2026163	210000
15600.00	1	16000	1	0	44200	82000	33700	0.2101606	160000
15724.00	2	32000	1	0	44200	121000	41700	0.2118311	200000
16426.00	1	0	1	0	44200	63600	30000	0.2212883	140000
16956.00	2	32000	1	0	44200	121000	41700	0.2284284	180000
18000.00	2	32000	1	0	44200	121000	41700	0.2424930	170000
18057.00	4	64000	1	0	44200	165000	50500	0.2432609	210000
18268.00	1	32000	1	0	44200	121000	41700	0.2461034	170000
18963.00	2	48000	1	0	44200	143000	46100	0.2554663	180000
19090.00	2	48000	1	0	44200	143000	46100	0.2571773	180000
21135.00	2	48000	1	0	44200	143000	46100	0.2847272	160000
22560.00	2	48000	1	0	44200	143000	46100	0.3039245	150000
23954.00	2	48000	1	0	44200	143000	46100	0.3227043	140000
24000.00	2	48000	1	0	44200	143000	46100	0.3233240	140000
24082.00	2	48000	1	0	44200	143000	46100	0.3244286	140000
26549.00	4	64000	1	0	44200	165000	50500	0.3576637	140000
29500.00	4	64000	1	0	44200	165000	50500	0.3974190	130000
29700.00	4	64000	1	0	44200	165000	50500	0.4001134	130000
30034.00	4	64000	1	0	44200	165000	50500	0.4046130	120000
30570.00	5	80000	0	1	74800	231000	75300	0.4118339	180000
32040.00	4	64000	1	0	44200	165000	50500	0.4316375	120000
34034.00	5	80000	0	1	74800	231000	75300	0.4585003	160000
35040.00	5	80000	0	1	74800	231000	75300	0.4720530	160000
36231.00	5	80000	0	1	74800	231000	75300	0.4880979	150000
38799.00	5	80000	0	1	74800	231000	75300	0.5226936	140000
39105.00	4	64000	1	0	44200	165000	50500	0.5268160	96000
40188.00	5	80000	0	1	74800	231000	75300	0.5414060	140000
41320.00	9	144000	0	1	74800	319000	93300	0.5566561	170000
43050.00	8	128000	0	1	74800	297000	88800	0.5799623	150000
45804.00	3	48000	1	0	44200	143000	46100	0.6170638	75000
50000.00	7	112000	0	1	74800	275000	84300	0.6735916	130000
52547.36	7	112000	0	1	74800	275000	84300	0.7079092	120000
52950.00	7	112000	0	1	74800	275000	84300	0.7133335	120000
54391.00	7	112000	0	1	74800	275000	84300	0.7327464	120000
55567.00	8	128000	0	1	74800	297000	88800	0.7485893	120000
56860.00	9	144000	0	1	74800	319000	93300	0.7660083	120000
64044.00	6	96000	0	1	74800	253000	79800	0.8627900	92000
66503.00	9	144000	0	1	74800	319000	93300	0.8959172	100000
78580.00	1	0	1	0	44200	63600	30000	1.0586165	28000
88000.00	11	176000	0	1	74800	363000	102000	1.1855212	86000
93450.00	11	176000	0	1	74800	363000	102000	1.2589427	81000
100524.00	13	208000	1	1	11900	470000	141000	1.3542424	100000
108408.00	18	288000	0	2	150000	626000	184000	1.4604543	130000
109897.00	6	96000	0	1	74800	253000	79800	1.4805139	54000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
125084.00	9	144000	0	1	74800	319000	93300	1.6851106	55000
134956.00	19	304000	0	2	150000	648000	189000	1.8181045	100000
149000.00	10	160000	0	1	74800	340000	97500	2.0073029	49000
162287.00	10	160000	0	1	74800	340000	97500	2.1863031	45000
184511.60	11	176000	0	1	74800	363000	102000	2.4857092	41000
184766.00	11	176000	0	1	74800	363000	102000	2.4891364	41000
197260.00	22	352000	0	2	150000	713000	201000	2.6574535	76000
215000.00	15	240000	1	1	119000	514000	150000	2.8964438	52000
240030.00	16	256000	1	1	119000	537000	155000	3.2336437	48000
283998.00	17	272000	0	2	150000	603000	179000	3.8259732	47000

Notes for Table E-8

1. The field "AROOM" indicates facilities used in the model with an "*".

2. The field "EO_TOT" is the annual EP use at the facility.

3. The field "NUM CELLS" is the number of aeration cells assigned to that facility.

4. The field "COST CELLS" gives the cost of aeration cells.

5. The field "NUM_1000" is the number of 1,000 ft^3/min control units.

6. The field "NUM_3000" is the number of 3,000 ft^3/min control units.

7. The field "SAFE FOB" is the capital cost (FOB) of a gas/solid reactor control.

8. The field "TCC" gives the total capital cost for the facility.

9. The field "TAC" is the total annual control cost for the facility.

10. The field "ARRED" is the annual emission reduction (mg).

11. The field "CEFF" gives the cost effectiveness ($/Mg).

TABLE E-9. AERATION ROOM CATALYTIC OXIDATION CONTROL COST ANALYSIS

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
1.50	1	0	1	0	17100	27500	9300	0.0000202	460000000
2.00	1	0	1	0	17100	27500	9300	0.0000269	350000000
2.98	1	0	1	0	17100	27500	9300	0.0000401	230000000
4.80	1	0	1	0	17100	27500	9300	0.0000647	140000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
7.50	1	0	1	0	17100	27500	9300	0.0001010	92000000
9.00	1	0	1	0	17100	27500	9300	0.0001212	77000000
12.00	1	0	1	0	17100	27500	9300	0.0001617	58000000
16.80	1	0	1	0	17100	27500	9300	0.0002263	41000000
17.80	1	0	1	0	17100	27500	9300	0.0002398	39000000
27.36	1	0	1	0	17100	27500	9300	0.0003686	25000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
61.34	1	0	1	0	17100	27500	9300	0.0008264	11000000
64.00	1	0	1	0	17100	27500	9300	0.0008622	11000000
64.80	1	0	1	0	17100	27500	9300	0.0008730	11000000
65.00	1	0	1	0	17100	27500	9300	0.0008757	11000000
70.00	1	0	1	0	17100	27500	9300	0.0009430	9900000
93.60	1	0	1	0	17100	27500	9300	0.0012610	7400000
100.80	1	0	1	0	17100	27500	9300	0.0013580	6800000
105.00	1	0	1	0	17100	27500	9300	0.0014145	6600000
110.00	1	0	1	0	17100	27500	9300	0.0014819	6300000
111.00	1	0	1	0	17100	27500	9300	0.0014954	6200000
113.00	1	0	1	0	17100	27500	9300	0.0015223	6100000
115.00	1	0	1	0	17100	27500	9300	0.0015493	6000000
126.00	1	0	1	0	17100	27500	9300	0.0016975	5500000
160.80	1	0	1	0	17100	27500	9300	0.0021663	4300000
162.00	1	0	1	0	17100	27500	9300	0.0021824	4300000
185.25	1	0	1	0	17100	27500	9300	0.0024957	3700000
188.00	1	0	1	0	17100	27500	9300	0.0025327	3700000
192.00	1	0	1	0	17100	27500	9300	0.0025866	3600000
194.00	1	0	1	0	17100	27500	9300	0.0026135	3600000
195.00	1	0	1	0	17100	27500	9300	0.0026270	3500000
200.00	1	0	1	0	17100	27500	9300	0.0026944	3500000
201.60	1	0	1	0	17100	27500	9300	0.0027159	3400000
264.00	1	0	1	0	17100	27500	9300	0.0035566	2600000
291.60	1	0	1	0	17100	27500	9300	0.0039284	2400000
312.00	1	0	1	0	17100	27500	9300	0.0042032	2200000
312.00	1	0	1	0	17100	27500	9300	0.0042032	2200000
324.00	1	0	1	0	17100	27500	9300	0.0043649	2100000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
388.80	1	0	1	0	17100	27500	9300	0.0052378	1800000
390.00	1	0	1	0	17100	27500	9300	0.0052540	1800000
395.00	1	16000	1	0	17100	45900	13000	0.0053214	2400000
432.00	1	0	1	0	17100	27500	9300	0.0058198	1600000
456.00	1	0	1	0	17100	27500	9300	0.0061432	1500000
504.00	1	0	1	0	17100	27500	9300	0.0067898	1400000
520.00	1	0	1	0	17100	27500	9300	0.0070054	1300000
557.30	1	0	1	0	17100	27500	9300	0.0075079	1200000
562.00	1	0	1	0	17100	27500	9300	0.0075712	1200000
581.00	1	0	1	0	17100	27500	9300	0.0078271	1200000
686.00	1	0	1	0	17100	27500	9300	0.0092417	1000000
804.00	1	0	1	0	17100	27500	9300	0.0108314	860000
850.00	1	0	1	0	17100	27500	9300	0.0114511	810000
875.00	1	0	1	0	17100	27500	9300	0.0117879	790000
1092.00	1	0	1	0	17100	27500	9300	0.0147112	630000
1155.00	1	0	1	0	17100	27500	9300	0.0155600	600000
1231.00	1	0	1	0	17100	27500	9300	0.0165838	560000
1300.00	1	0	1	0	17100	27500	9300	0.0175134	530000
1334.00	1	0	1	0	17100	27500	9300	0.0179714	520000
1521.00	1	0	1	0	17100	27500	9300	0.0204907	450000
1600.00	1	0	1	0	17100	27500	9300	0.0215549	430000
1714.00	1	0	1	0	17100	27500	9300	0.0230907	400000
1714.00	1	0	1	0	17100	27500	9300	0.0230907	400000
1750.00	1	0	1	0	17100	27500	9300	0.0235757	390000
1750.00	1	0	1	0	17100	27500	9300	0.0235757	390000
1800.00	1	0	1	0	17100	27500	9300	0.0242493	380000
1944.00	1	0	1	0	17100	27500	9300	0.0261892	360000
1965.00	1	0	1	0	17100	27500	9300	0.0264721	350000
1980.00	1	0	1	0	17100	27500	9300	0.0266742	350000
2016.00	1	0	1	0	17100	27500	9300	0.0271592	340000
2142.00	1	0	1	0	17100	27500	9300	0.0288567	320000
2254.00	1	0	1	0	17100	27500	9300	0.0303655	310000
2280.00	1	0	1	0	17100	27500	9300	0.0307158	300000
2376.00	1	0	1	0	17100	27500	9300	0.0320091	290000
2419.20	1	0	1	0	17100	27500	9300	0.0325911	290000
2450.00	1	0	1	0	17100	27500	9300	0.0330060	280000
2527.00	1	0	1	0	17100	27500	9300	0.0340433	270000
2599.20	1	0	1	0	17100	27500	9300	0.0350160	270000
3120.00	1	0	1	0	17100	27500	9300	0.0420321	220000
3135.00	1	0	1	0	17100	27500	9300	0.0422342	220000
3240.00	1	0	1	0	17100	27500	9300	0.0436487	210000
3640.00	1	0	1	0	17100	27500	9300	0.0490375	190000
3755.00	1	0	1	0	17100	27500	9300	0.0505867	180000
4200.00	1	0	1	0	17100	27500	9300	0.0565817	160000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
4200.00	1	0	1	0	17100	27500	9300	0.0565817	160000
4286.90	1	0	1	0	17100	27500	9300	0.0577524	160000
4320.00	1	0	1	0	17100	27500	9300	0.0581983	160000
4368.00	1	0	1	0	17100	27500	9300	0.0588450	160000
4667.00	1	0	1	0	17100	27500	9300	0.0628730	150000
4860.00	1	0	1	0	17100	27500	9300	0.0654731	140000
5016.00	1	16000	1	0	17100	45900	13000	0.0675747	190000
5088.00	1	0	1	0	17100	27600	9300	0.0685447	140000
5189.00	1	16000	1	0	17100	45900	13000	0.0699053	190000
5250.00	1	16000	1	0	17100	45900	13000	0.0707271	180000
5258.00	1	16000	1	0	17100	45900	13000	0.0708349	180000
5739.00	1	16000	1	0	17100	45900	13000	0.0773148	170000
5850.00	1	16000	1	0	17100	45900	13000	0.0788102	160000
6000.00	1	16000	1	0	17100	45900	13000	0.0808310	160000
6048.00	1	16000	1	0	17100	45900	13000	0.0814776	160000
6176.00	1	16000	1	0	17100	45900	13000	0.0832020	160000
6451.00	1	16000	1	0	17100	45900	13000	0.0869068	150000
6840.00	1	16000	1	0	17100	45900	13000	0.0921473	140000
6900.00	1	16000	1	0	17100	45900	13000	0.0929556	140000
7194.00	1	16000	1	0	17100	45900	13000	0.0969164	130000
7350.00	1	16000	1	0	17100	45900	13000	0.0990180	130000
7387.00	1	16000	1	0	17100	45900	13000	0.0995164	130000
8390.00	1	16000	1	0	17100	45900	13000	0.1130287	120000
8400.00	1	16000	1	0	17100	45900	13000	0.1131634	110000
8736.00	1	16000	1	0	17100	45900	13000	0.1176899	110000
9676.00	1	16000	1	0	17100	45900	13000	0.1303534	100000
10002.00	1	0	1	0	17100	27500	9300	0.1347453	69000
10613.00	1	16000	1	0	17100	45900	13000	0.1429765	91000
10800.00	1	16000	1	0	17100	45900	13000	0.1454958	89000
11016.00	1	16000	1	0	17100	45900	13000	0.1484057	88000
11400.00	2	32000	1	0	17100	74600	18800	0.1535789	120000
11440.00	2	32000	1	0	17100	74600	18800	0.1541178	120000
11547.00	2	32000	1	0	17100	74600	18800	0.1555592	120000
11984.00	2	32000	1	0	17100	74600	18800	0.1614464	120000
12020.00	2	32000	1	0	17100	74600	18800	0.1619314	120000
12249.00	2	32000	1	0	17100	74600	18800	0.1650165	110000
13000.00	2	32000	1	0	17100	74600	18800	0.1751338	110000
13000.00	2	32000	1	0	17100	74600	18800	0.1751338	110000
13059.00	2	32000	1	0	17100	74600	18800	0.1759286	110000
14352.00	2	32000	1	0	17100	74600	18800	0.1933477	97000
14400.00	2	32000	1	0	17100	74600	18800	0.1939944	97000
14860.00	3	48000	1	0	17100	94800	22900	0.2001914	110000
14862.00	3	48000	1	0	17100	94800	22900	0.2002184	110000
15040.00	2	32000	1	0	17100	74600	18800	0.2026163	93000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
15600.00	1	16000	1	0	17100	45900	13000	0.2101606	62000
15724.00	2	32000	1	0	17100	74600	18800	0.2118311	89000
16426.00	1	0	1	0	17100	27500	9300	0.2212883	42000
16956.00	2	32000	1	0	17100	74600	18800	0.2284284	82000
18000.00	2	32000	1	0	17100	74600	18800	0.2424930	78000
18057.00	4	64000	1	0	17100	115000	27000	0.2432609	110000
18268.00	1	32000	1	0	17100	74600	18800	0.2461034	76000
18963.00	2	48000	1	0	17100	94800	22900	0.2554663	90000
19090.00	2	48000	1	0	17100	94800	22900	0.2571773	89000
21135.00	2	48000	1	0	17100	94800	22900	0.2847272	80000
22560.00	2	48000	1	0	17100	94800	22900	0.3039245	75000
23954.00	2	48000	1	0	17100	94800	22900	0.3227043	71000
24000.00	2	48000	1	0	17100	94800	22900	0.3233240	71000
24082.00	2	48000	1	0	17100	94800	22900	0.3244286	71000
26549.00	4	64000	1	0	17100	115000	27000	0.3576637	75000
29500.00	4	64000	1	0	17100	115000	27300	0.3974190	69000
29700.00	4	64000	1	0	17100	115000	27300	0.4001134	68000
30034.00	4	64000	1	0	17100	115000	27300	0.4046130	67000
30570.00	5	80000	0	1	37000	167000	46400	0.4118339	110000
32040.00	4	64000	1	0	17100	115000	27400	0.4316375	63000
34034.00	5	80000	0	1	37000	167000	46400	0.4585003	100000
35040.00	5	80000	0	1	37000	167000	46400	0.4720530	98000
36231.00	5	80000	0	1	37000	167000	46400	0.4880979	95000
38799.00	5	80000	0	1	37000	167000	46400	0.5226936	89000
39105.00	4	64000	1	0	17100	115000	28000	0.5268160	53000
40188.00	5	80000	0	1	37000	167000	46400	0.5414060	86000
41320.00	9	144000	0	1	37000	248000	62900	0.5566561	110000
43050.00	8	128000	0	1	37000	228000	58900	0.5799623	100000
45804.00	3	48000	1	0	17100	94800	24300	0.6170638	39000
50000.00	7	112000	0	1	37000	208000	54800	0.6735916	81000
52547.36	7	112000	0	1	37000	208000	54800	0.7079092	77000
52950.00	7	112000	0	1	37000	208000	54800	0.7133335	77000
54391.00	7	112000	0	1	37000	208000	54800	0.7327464	75000
55567.00	8	128000	0	1	37000	208000	58900	0.7485893	79000
56860.00	9	144000	0	1	37000	248000	32900	0.7660083	43000
64044.00	6	96000	0	1	37000	188000	50800	0.8627900	59000
66503.00	9	144000	0	1	37000	248000	62900	0.8959172	70000
78580.00	1	0	1	0	17100	27500	13200	1.0586165	12000
88000.00	11	176000	0	1	37000	289000	71900	1.1855212	61000
93450.00	11	176000	0	1	37000	289000	72300	1.2589427	57000
100524.00	13	208000	1	1	54100	357000	88600	1.3542424	65000
108408.00	18	288000	0	2	73900	489000	124000	1.4604543	85000
109897.00	6	96000	0	1	37000	188000	52900	1.4805139	36000
125084.00	9	144000	0	1	37000	248000	66300	1.6851106	39000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
134956.00	19	304000	0	2	73900	510000	129000	1.8181045	71000
149000.00	10	160000	0	1	37000	268000	72100	2.0073029	36000
162287.00	10	160000	0	1	37000	268000	73100	2.1863031	33000
184511.60	11	176000	0	1	37000	289000	79100	2.4857092	32000
184766.00	11	176000	0	1	37000	289000	79100	2.4891364	32000
197260.00	22	352000	0	2	73900	570000	144000	2.6574535	54000
215000.00	15	240000	1	1	54100	397000	105000	2.8964438	36000
240030.00	16	256000	1	1	54100	418000	111000	3.2336437	34000
283998.00	17	272000	0	2	73900	469000	130000	3.8259732	34000

E.3 AERATION ROOM COST ANALYSIS

Notes for Table E-9

1. The field "AROOM" indicates facilities used in the model with an "*".

2. The field "EO_TOT" is the annual EO use at the facility.

3. The field "NUM_CELLS" is the number of aeration cells assigned to that facility.

4. The field "COST_CELLS" gives the cost of aeration cells.

5. The field "NUM_1000" is the number of 1,000 ft^3/min control units.

6. The field "NUM_3000" is the number of 3,000 ft^3/min control units.

7. The field "CAT_FOB" is the capital cost (FOB) of a catalytic oxidation control.

8. The field "TCC" gives the total capital cost for the facility.

9. The field "TAC" is the total annual control cost for the facility.

10. The field "ARRED" is the annual emission reduction (mg).

11. The field "CEFF" gives the cost effectiveness ($/Mg).

REFERENCES

1. Letter and attachments from Olson, C., Donaldson Company, Inc., to S. Srebro. MRI. March 23, 1989. Capital and operating costs of 1,000 ft^3/min EtO Abator™ catalytic oxidizer.

2. Telecon. Srebro, S., MRI, with C. Olson. Donaldson Company, Inc. April 4, 1989. Discussion about costs of EtO Abator™.

3. Telecon. Nicholson, R., MRI, with C. Olson. Donaldson, Company, Inc. May 12 and June 13, 1988. Costs of EtO Abators™.

4. Chemical Engineering. Economic Indicators. April 25, 1988. p. 9.

5. Chemical Engineering. Economic Indicators. June 1989. p. 224.

E.4 EXAMPLE FACILITY CALCULATIONS

TABLE E-10. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS[1]
(4th Quarter 1987 Dollars)

Item	Cost
A. CAPITAL COSTS[a]	
1. Installed equipment costs	
a. Acid/water scrubber[b]	98,900
b. Explosion-proof valves for scrubber[c]	N/A[c]
c. Chlorine filter house[d]	166
d. Purchased equipment costs, total	99,100
e. Installation of scrubber[e]	49,500
f. Installation of chlorine filters	80
g. Taxes: 5 percent of equipment cost	4,960
h. Freight: 5 percent of equipment cost	4,960
i. Vacuum pump[f]	0
j. Manifolding of chambers (includes check valve)[g]	463
k. Subtotal Capital Costs	159,000
l. Contingencies[h]	15,900
TOTAL CAPITAL INVESTMENT	175,000
B. ANNUAL COSTS[a]	
1. Direct operating costs	
a. Labor[i]	3,540
b. Materials	
50 percent H_2SO_4[j]	364
50 percent NaOH[k]	350
Chlorine filters[l]	
Taxes: 5 percent of materials cost	117
Freight: 5 percent of materials cost	42
c. Water[m]	42
d. Electricity[n]	0
e. Compressed air[o]	124
f. Disposal of ethylene glycol[p]	0
	4,040
2. Indirect operating costs	
a. Overhead: 0.60 x labor[40]	
b. Property tax, insurance, and administration[q]	2,120
c. Capital recovery costs[r]	7,000
	28,500
TOTAL ANNUAL COSTS	46,200
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (tons EO/yr)	6.8 (7.5)
2. Cost effectiveness, 1987, $/Mg ($/ton EO)	6,800 (6,200)

TABLE E-10. (continued)

[a]Costs rounded to three significant figures.
[b]Model 400 based on largest chamber size of 1,000 ft^3.
[c]Not applicable.
[d]One per tank at $41.50 each (four tanks--Model 400).
[e]Fifty percent of scrubber cost.
[f]One at $5,170. The cost of the first vacuum pump is included in the installation cost of the scrubber.
[g]See Table E-4. One chamber costed for a check valve at $463.
[h]Assumed to be 10 percent of subtotal capital costs to account for uncertainties in the capital cost estimates.
[i]Labor was calculated for 0.25 person-hours/shift, 3 shifts/day, 365 days/year for system inspection and 16 person-hours for each regeneration of the scrubber at $11.65/person-hour.
[j]The cost of acid is calculated, (UNC_FAC)÷(2,000)x(594)x($0.070)x1.15. (15 percent extra is for spillage.) (UNC_FAC) is equal to uncontrolled emissions (lb) from vent and drain at baseline.)
[k]The cost of caustic is calculated, No. drum = (UNC_FAC)÷(2,000)x (250)÷(350). No. drum = 5.4; therefore, unit cost = $0.0802. Total cost = (No.drums)x(700)x(0.0802)x1.15 (15 percent extra for spillage).
[l]Chlorine filter cost is (UNC_FAC)x(15)÷(2,000).
[m]Calculated as (scrubber model)x(2)x(UNC_FAC)/[(2,000)x(No. of tanks)]x(0.25/1,000).
[n]See preceeding notes for calculation methodology.
[o]The cost of 10 seconds of house-supplied compressed air per cycle was considered negligible.
[p]Disposal cost is (UNC_FAC)÷(2,000)x(4,845)x(0.110).
[q]Calculated as 4 percent of total capital costs.
[r]Calculated as (0.16275)x(total capital costs) for an interest rate of 10 percent and a 10-year recovery period.

TABLE E-11. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS TO CONTROL CHAMBER EXHAUST VENTS[2]
(4th Quarter 1987 Dollars)

Item	Cost
A. CAPITAL COSTS[a]	
1. Installed equipment costs	
a. Acid/water scrubber[b]	44,900
b. Chlorine filter house[c]	42
c. Purchased equipment costs, total[d]	44,900
d. Installation of chlorine filters[d]	20
e. Sales tax: 5 percent of equipment cost[d]	2,240
f. Freight: 5 percent of equipment cost[d]	2,240
g. Manifolding of vents[e]	8,410
TOTAL CAPITAL INVESTMENT[f]	117,000
B. ANNUAL COSTS[a]	
1. Direct operating costs	
a. Labor[g]	3,310
b. Materials	
(1) 50 percent H_2SO_4[h]	31
(2) 50 percent NaOH[i]	42
(3) Chlorine filters[j]	10
(4) Taxes: 5 percent of materials cost	4
(5) Freight: 5 percent of materials cost	4
c. Water[k]	0
d. Electricity[l]	82
e. Compressed air[m]	0
f. Disposal of ethylene glycol[n]	350
2. Indirect operating costs	
a. Overhead: 0.60 x labor	1,990
b. Property tax, insurance, and administration[o]	4,680
c. Capital recovery costs[p]	19,000
TOTAL ANNUAL COSTS	29,500
C. COST EFFECTIVENESS[a]	
1. Emission reduction, Mg EO/yr (ton EO/yr)	0.71 (0.78)
2. Cost effectiveness, 1987, $/Mg EO ($/ton EO)	30,000 (27,000)

TABLE E-11. (continued)

[a]Capital and annual costs rounded to three significant figures. Cost effectiveness rounded to two significant figures.
[b]Facility has four chambers. Therefore, costed for a 6,000 ft^3/min scrubber.
[c]One per tank at $41.50 each.
[d]Capital equipment cost.
[e]See Section E.5 for a detailed summary of manifolding costs.
[f]Capital costs were increased by a factor of 2.2 (except manifolding costs) to account for additional capital expenditures necessary to install the control. The total capital costs were calculated as (2.2 x [sum of items with superscript d]) + manifolding costs.
[g]Labor was calculated for 0.25 person-hours/shift, 3 shifts/day, 365 days/year for system inspection and 16 person-hours for each regeneration of the scrubber at $11.65/person-hour.
[h]The cost of acid is calculated, (UNC_RCE) ÷ (2,000) x (594) x ($0.070) x 1.15. (Extra 15 percent for spillage.) (UNC_RCE is equal to uncontrolled emissions (lb) from rear chamber exhaust vents.)
[i]The cost of caustic is calculated, No. drum = (UNC-RCE) ÷ (2,000) x (250) ÷ (350). No. drum = 0.6; therefore, unit cost = $0.110. Total cost = (No. drums) x (700) x ($0.11) x 1.15 (15 percent extra for spillage).
[j]Chlorine filter cost is (UNC_RCE/2,000) x 15.
[k]Calculated as (scrubber model) x (2) x (UNC_RCE/2,000) x (0.25/1,000).
[l]See preceeding notes for calculation methodology.
[m]The cost of 10 seconds of house-supplied compressed air per cycle was considered negligible.
[n]Disposal cost is (UNC_RCE) ÷ (2,000) x (4,845) x (0.110).
[o]Calculated as 4 percent of total capital investment.
[p]Calculated as (0.16275) x (total capital investment) (i.e., an interest rate of 10 percent and a 10-year recovery period).

TABLE E-12. CAPITAL AND ANNUAL COSTS OF GAS/SOLID REACTOR TO CONTROL AERATION UNITS AT AN EXAMPLE FACILITY[3]
(4TH QUARTER 1987 Dollars)

Item	Cost, $
A. CAPITAL COSTS	
1. Installed Equipment Costs	
a. Gas/solid reactor	17,100
b. Installation of gas/solid reactor[a]	5,130
c. Taxes: 5 percent of equipment cost	855
d. Freight: 5 percent of equipment cost	855
e. Aeration units, installed cost[b]	32,000
f. Manifolding of aeration units[c]	9,830
g. Subtotal capital costs	65,800
h. Contingencies[d]	9,870
TOTAL CAPITAL COSTS	75,700
B. ANNUAL COSTS	
1. Direct operating Costs	
a. Maintenance labor[e]	151
b. Maintenance materials[f]	76
c. Reactant replacement[g]	2,480
d. Labor for reactant replacement[h]	70
e. Electricity[i]	416
f. Disposal of reactant[j]	812
2. Indirect Operating Costs	
a. Overhead[k]	136
b. Property tax, insurance, and administration[l]	3,030
c. Capital recovery costs[m]	11,900
TOTAL ANNUAL COSTS	19,100
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (ton EO/yr)	0.176 (0.194)
2. Cost effectiveness, $/Mg EO ($ton EO)	110,000 (100,000)

TABLE E-12. (continued)

[a]Calculated as 30 percent of gas/solid reactor cost.

[b]Includes ductwork. Each aeration unit cost $16,000 installed. The example facility would require two aeration units.

[c]See Section E.5 for a detailed summary of manifolding costs.

[d]Assumed to be 15 percent of the subtotal capital costs to account for uncertainties in the capital cost estimates.

[e]Assumed 15 minutes per week (52 weeks per year) for a 1,000 ft^3/min system and 20 minutes per week for a 3,000 ft^3/min control system for system inspection and general maintenance. Labor rate ($11.65 per hour) was calculated as (323.8/218.8) x ($7.87 per hour).

[f]Maintenance materials were calculated as (0.5) x (maintenance labor).

[g]The maximum reactant life is 1.5 years but could be shorter depending on the amount of EO being controlled (in pounds). Assumed that control requires 4 pounds of reactant per ft^3/min of airflow and that each pound of reactant can control 0.3 lb of EO. If the pounds of EO through the control (in a 1 1/2-year period) exceed the maximum capacity of the unit, then the reactant life is calculated as follows: [({0.3 lb EO/lb reactant} x {4 lb reactant/ft^3/min of flow} x {flow rate, ft^3/min})/maximum capacity of the unit, in pounds of EO]*1.5 years. Reactant replacement costs were calculated as (flow rate, ft^3/min) x (4 lb reactant/ft^3/min of flow rate) x ($1/lb of reactant) x (340.8/412). Where 340.8/412 is the Chemical Engineering cost indice to convert from 1989 to 1987 dollars.[h]Each 1,000 ft^3/min control unit requires about 8 person hours to refill. Depending on the interval of reactant replacement, capital recovery factors were determined as [CRC = $i(i + 1)^n/(i + 1)^{n-1}$] where i = 0.1 (10 percent interest) and n = life (years). Labor costs were calculated as ($7.87 per hour) x (323.8/218.8) x (CRC).

[i]The 1,000 and 3,000 ft^3/min systems are equipped with 1.1 and 10 kW (1.5 and 13.5 horsepower) fans, respectively. Electricity costs were calculated based on 365 days per year at continuous (24 hour) operation and an electricity cost of $0.0432 kWh. Costs were calculated as (365 days per year)(24 hours per day)(fan power)($0.0432 kWh).

[j]Disposal costs were developed assuming the reactant would be recycled and that there would be no credit or charge for the reactant. Transportation costs were calculated assuming a distance of 1,500 miles at a charge of $0.15 per pound for less than 5,000 pounds and $0.12 per pound for a shipment greater than 5,000 pounds.

[k]Calculated as 60 percent of the sum of the maintenance labor and maintenance materials.

[l]Calculated as 4 percent of total capital costs.

[m]Assumed life of 10 years for gas/solid reactor oxidizer and aeration unit and an interest rate of 10 percent. Assumed a life of 20 years and a 10 percent interest rate for manifolding materials. Capital recovery cost was calculated as 0.16275/[(total capital costs)-(cost to change catalyst+labor to change catalyst+manifolding costs)] + (0.1175) x (manifolding costs) where 0.16275 and 0.1175 are the capital recovery factors for the catalytic oxidizer and manifolding, respectively.

TABLE E-13. CAPITAL AND ANNUALIZED COSTS OF CATALYTIC OXIDATION AT AN EXAMPLE FACILITY[3]
(4th Quarter 1987 Dollars)

Item	Cost, $
A. CAPITAL COSTS	
1. Installed Equipment Costs	
a. Catalytic oxidizer(s)	47,800
b. Installation of catalytic oxidizer[a]	7,170
c. Taxes: 5 percent of equipment cost	2,390
d. Freight: 5 percent of equipment cost	2,390
e. Aeration units, installed cost[b]	32,000
f. Manifolding of aeration units[c]	19,700
g. Subtotal capital costs	111,000
h. Contingencies[d]	16,700
TOTAL CAPITAL COSTS	128,000
B. ANNUAL COSTS	
1. Direct Operating Costs	
a. Maintenance labor[e]	1,060
b. Maintenance materials[f]	150
c. Catalyst replacement[g]	1,460
d. Labor for catalyst replacement[h]	15
e. Electricity[i]	13,900
f. Disposal of catalyst[j]	21
2. Indirect Operating Costs	
a. Overhead[k]	726
b. Property tax, insurance, and administration[l]	5,120
c. Capital recovery costs[m]	20,600
TOTAL ANNUAL COSTS	43,100
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (ton EO/yr)(0.194)	0.176 (0.194)
2. Cost effectiveness, $/Mg EO ($/ton EO)	240,000 (220,000)

TABLE E-13. (continued)

[a]Calculated as 15 percent of catalytic oxidation cost.

[b]Includes ductwork. Each aeration unit cost $16,000 installed. The example facility would require two aeration units.

[c]See Section E.5 for a detailed summary of manifolding costs.

[d]Assumed to be 15 percent of the subtotal capital costs to account for uncertainties in the capital cost estimates.

[e]Assumed 15 minutes per day (365 days per year) for system inspection and general maintenance of a 1,000 ft^3/min system and an additional 5 minutes for each step up in catalytic oxidizer size. Labor rate ($11.65 per hour) was calculated as (323.8/218.8)x($7.87/h).

[f]Assumed $150 a year (base cost) for 1,000 ft^3/min unit and an additional $50 a year for each step up in catalytic oxidizer size.

[g]The 1,000, 3,000, 6,000, 9,000, and 12,000 ft^3/min catalytic oxidizers have 4, 16, 32, 48, and 64 catalytic cells, respectively. Each cell costs approximately $1,240 to refill. Costs were annualized over a 4-year life at 10 percent interest using a capital recovery factor of 0.31547.

[h]Each cell requires about 1-person hour to refill. Refill labor costs were annualized over 4 years assuming a 10 percent interest rate using a capital recovery factor of 0.31547.

[i]The 1,000, 3,000, 6,000, 9,000, and 12,000 ft^3/min systems have 80, 120, 180, 230, and 290 kilowatt (kW) catalytic oxidizer preheaters, respectively. System designed for 70 percent heat recovery uses only 46 percent of rated kW. Electricity cost calculated as ($0.0432/kWh)x(kW of heater)x(0.46)x(24 hours per day)x(365 days per year). No costs were attributed to fan electrical consumption because the preheating electrical costs were considerably larger.

[j]Disposal costs calculated as [($80/400 lb)x(90 lb cell)x(No. of cells)]/4 years. Includes transportation to an industrial landfill calculated as $25 per 55-gallon drum (7.35 ft^3/drum). Density of catalyst is 1 g/cm^3 (62.4 lb/ft^3). Transportation equals [(90 lb/cell)x($25/drum)x(No. of cells)]/[(62.4 lb/ft^3)x(7.35 ft^3/drum) x(4 yr)]. All disposal costs were multiplied by (329.8/354.2) to correct to 1987 dollars.

[k]Calculated as 60 percent of the sum of the maintenance labor and maintenance materials.

[l]Calculated as 4 percent of total capital costs.

[m]Assumed life of 10 years for catalytic oxidizer and aeration unit and an interest rate of 10 percent. Assumed a life of 20 years and a 10-percent interest rate for manifolding materials. Capital recovery cost was calculated as 0.16275x[(total capital costs)-(cost to change catalyst + labor to change catalyst + manifolding costs)] + (0.1175)x(manifolding costs) where 0.16275 and 0.1175 are the capital recovery factors for the catalytic oxidizer and manifolding, respectively.

E.4 EXAMPLE FACILITY CALCULATIONS

REFERENCES

1. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Cost Effectiveness of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. March 21, 1991.

2. Memorandum. deOlloqui, V., and Srebro, S., to D. Markwordt. EPA/CPB. Costing of Control Alternatives for the Rear Chamber Exhaust Emissions. March 21, 1991.

3. Memorandum. Srebro, S., and deOlloqui, V., to D. Markwordt. EPA/CPB. Costing Methodology for the Control of Aeration Room Emissions. March 21, 1991.

E.5 MANIFOLDING COSTS

TABLE E-14. INCREMENTAL CAPITAL COSTS OF MANIFOLDING STERILIZATION CHAMBERS, 1987, $

	Cost 1987, $	Reference[1]
1. Opening in explosion-proof wall		
Cost	2[a c]	3-100, p. 12
Adjustable sheet metal sleeve		
Labor hours		
Concrete core drilling, 1-in. to 3-in. hole	4.4	3-100, p. 22
Adjustable sheet metal sleeve	0.75	3-100, p. 22
Total labor hours	5.15	
Labor costs at $18,91/labor hour	97[a]	3-0, p. 2
Overhead costs at $8.75/labor hour	45[b]	1.0, p. 5
2. Drill hole for pipe hangers		
Labor hours		
3/8 in. diameter hole through 1/2 in. thick steel beam, 20 holes	7.5	5-10, p. 16
Labor costs at $20.32/person-hour	153[a]	5-0, p. 1
Overhead costs at $15.78/person-hour	118[b]	1-0, p. 5
3. Piping		
Cost		
100 ft, 2 in. diameter, 40 standard carbon steel pipe	251[a c]	15-43, p. 4
90° elbows, 3 at $4.40	14[a c]	15-43, p.9
Tee with full-size outlet	15[a c]	15-43, p. 13
Swing check valve	367[a c]	15-43, p. 31
Bolts and gaskets, two sets at $7.08	15[a c]	15-72, p. 3
Pipe hangers, 1 carton of 50 hangers	147[a c]	15-76, p. 25
Total cost	808	
Labor hours to install		
Cut, three at 0.16 labor hours	0.48	15-77, p. 27
Bevel, three at 0.10 labor hours	0.30	15-77, p. 30
Pipe	8.3	15-43, p. 4
Field erection joint buttweld	2.9	15-43, p. 29
Penetration through one wall	1.7	15-43, p. 8
Elbows, three at 2.00 labor hours	6.0	15-43, p. 9
Tee	3.0	
Valve	1.1	15-43, p. 13
Boltup of valve, two sets at 1.35 labor hours	2.7	15-43, p. 31
Pipe hangers, 10 at 0.16 labor hours	1.6	15-72, p. 3
Total labor hours	28.0	15-76, p. 35
Labor costs at $21.47/labor hour	601[a]	15-0, p. 2
Overhead costs at $13.31/labor hour	373[b]	1-0, p. 5
4. Total installed cost for piping system		
Total direct costs	1,663[d]	
Total overhead costs	536[e]	
Administration	152[f]	1-0, p. 6
10 percent of total direct costs		
Taxes: 5 percent of equipment costs	33[g]	1-0, p. 6
Total indirect costs	721[h]	
Total installed cost	2,384[i]	

TABLE E-14. (continued)

	Cost 1987, $	Reference[1]
5. Total installed cost for new vacuum pump	5,170[j]	MRI report[2]
6. Total installed capital cost	7,554[k]	

[a]Direct cost.
[b]Overhead cost.
[c]Equipment cost.
[d]Total of costs with superscript a.
[e]Total of costs with superscript b.
[f]Administration = 0.10x(sum of costs with superscript a)
[g]Taxes = 0.05xsum of costs with superscript c.
[h]Total indirect costs = sum of costs with superscripts e, f, and g.
[i]Total installed cost = total direct costs (superscript d)+total indirect costs (superscript h).
[j]$5,000 (1986 $)x1.034 (see Section E.2).
[k]Equal to total installed cost for piping (superscript i)+total installed cost for new vacuum pump (superscript j).

TABLE E-15. DUCTWORK COSTS OF MANIFOLDING CHAMBER EXHAUST VENTS TO A SCRUBBER

Item	Cost, $, 1987	Reference[1,3]
Chamber exhaust vent to manifold[a]		
1. 15 ft 10-in. diameter, 1/8 in. thick carbon steel	210	Gard, p. 4-19
2. 90° elbow, 10-in. diameter	204	Gard, p. 4-22
3. Labor[b]	164	Richardson, 15-9 p. 2
Manifold		
1. 36 ft 41-in. diameter, 1/8 in. thick carbon steel	2,290	Gard, p. 4-19
2. Labor[b]	1,352	Richardson, 15-9 p. 2
Manifold to control unit		
1. 30 ft 24-in. diameter, 1.8 in. thick carbon steel	1,110	Gard, p. 4-19
2. 90° elbow, 24-in. diameter		
3. Tec, 24-in. diameter	580	Gard, p. 4-22
4. Labor[b]	192	Gard, p. 4-22
	769	Richardson, 15-9 p. 2

[a]Costs to duct chamber exhaust vent(s) to a manifold were calculated for each sterilizer at a facility. (It was assumed that ductwork costs for one of the sterilizers was included in the control device installation cost.)
[b]Labor costs developed as $3.51/ft^2 of ductwork.

TABLE E-16. DUCTWORK COSTS OF MANIFOLDING AERATION UNITS TO A GAS/SOLID REACTOR

Item	Cost, $, 1987	Reference[1,3]
Aeration room (AR) ductwork		
A. AR unit to manifold[a]		
1. 32 ft 15-in. diameter, 1/8 in. thick carbon steel	710	Gard, p. 4-19
2. 90° elbow, 15-in. diameter	326	Gard, p. 4-22
3. Labor[b]	481	Richardson, 15-9 p. 2
B. AR manifold		
1. 5 ft 41-in. diameter, 1/8 in. thick carbon steel	318	Gard, p. 4-19
2. Labor[b]	187	Richardson, 15-9 p. 2
C. Manifold to control unit		
1. 67 ft 24-in. diameter, 1/8 in. thick carbon steel	2,480	Gard, p. 4-19
2. 90° elbow, 24-in. diameter costed at $580/elbow	1,160	Gard, p. 4-22
3. Labor[b c]	2,140	Richardson, 15-9 p. 2

[a]These costs were developed for each aeration unit at a facility.
[b]Labor costs developed as $3.51/ft^2 of ductwork.
[c]Labor costs include the cost to concrete core drill (24 in. hole) the aeration room wall at $784.

E.5 MANIFOLDING COSTS

REFERENCES

1. Richardson Engineering Services, Inc. Process Plant Construction Estimating Standards. 1884.

2. Beall, C., Meeting Minutes: Damas Corp. and Johnson & Johnson. Midwest Research Institute. Raleigh, NC. April 30, 1986. 9 p.

3. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc., Niles, IL. Publication No. EPA-450/5-80-002. December 1978.

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E.6 COST INDICES

TABLE E-17. CHEMICAL ENGINEERING COST INDICES

	Cost indices	Conversion factor
Scrubbers	352.2 (1987)[a] 392.1 (1989)[b]	0.90
Chlorine filters	352.2 (1987)[c] 344.1 (1987)[d]	1.02
Chemicals	340.8 (1987)[e] 340.0 (1986)[f]	1.002
Operations and maintenance labor	323.8 (1987)[g] 218.8 (1988)[h]	1.48
Disposal of ethylene glycol	323.8 (1987)[i] 318.4 (1986)[j]	1.02
Gas/solid reactor or catalytic oxidizer	352.2 (1987)[k] 390.7 (1989)[l]	0.90
Reactant or catalyst replacement	340.8 (1987)[m] 412.0 (1989)[n]	0.83
Ductwork	323.8 (1987)[o] 218.8 (1978)[p]	1.48
Disposal of reactant or catalyst	329.8 (1987)[q] 354.2 (1989)[r]	0.93
Labor for installation of ductwork	323.8 (1987)[s] 322.7 (1984)[t]	1.00
Vacuum pumps	433.0 (1987)[u] 418.6 (1986)[v]	1.03

[a]Reference 1. CE Plant Cost Index, Equipment Machinery, Supports. October 1987 final.
[b]Reference 2. CE Plant Cost Index, Equipment. September 1989 final.
[c]Reference 1. Structural Supports and Miscellaneous. October 1987 final.
[d]Reference 3. Structural Supports and Miscellaneous. February 1986 final.
[e]Reference 4. Current Business Indicators. October 1987 latest.
[f]Reference 3. Current Business Indicators. February 1986 previous.
[g]Reference 1. CE Plant Cost Index, 1987 Annual Index.
[h]Reference 1. CE Plant Cost Index, 1978 Annual Index.
[i]Reference 1. CE Plant Cost Index, 1987 Annual Index.
[j]Reference 1. CE Plant Cost Index, 1986 Annual Index.
[k]Reference 1. CE Plant Cost Index, Equipment, Machinery, Supports. October 1987 final.
[l]Reference 5. CE Plant Cost Index. Equipment, March 1989 final.
[m]Reference 6. Current Business Indicators, Producer Prices, Industrial Chemicals, October 1987 (latest).
[n]Reference 5. Current Business Indicators, Producer Prices, Industrial Chemicals, March 1989.
[o]Reference 5. CE Plant Cost Index, 1987 Annual Index.

TABLE E-17. (continued)

[p]Reference 3. CE Plant Cost Index, 1978 Annual Index.
[q]Reference 1. CE Plant Cost Index, October 1987 final.
[r]Reference 3. CE Plant Cost Index, March 1989 final.
[s]Reference 3. CE Plant Cost Index, 1987 Annual Index.
[t]Reference 3. CE Plant Cost Index, 1984 Annual Index.
[u]Reference 4. CE Plant Cost Index, October 1987 final.
[v]Reference 3. CE Plant Cost Index, February 1986 final.

E.6 COST INDICES

REFERENCES

1. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. April 25, 1988. p. 9.

2. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. December 1989. p. 186.

3. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. June 23, 1986. p. 7.

4. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. December 7, 1987. p. 7.

5. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. June 1989. p. 224.

TECHNICAL REPORT DATA
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16. ABSTRACT

National emission standard to control emissions of ethylene oxide from new and existing sterilization/fumigation operations are being proposed under Section 112 of the Clean Air Act. This document contains information on the background and authority, regulatory alternatives considered, and environmental and economic impacts of the regulatory alternatives.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Air pollution Ethylene oxide Pollution control National emission standards Industrial processes Hazardous air pollutants Sterilization industry Fumigation industry	Air pollution control Ethylene oxide Stationary sources	13B

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
AIR QUALITY PLANNING
AND STANDARDS

February 23, 2021

MEMORANDUM

SUBJECT: Use of Stand-Alone Timers for Volatile Organic Compound (VOC) Sample Collection in Canisters

FROM: Greg Noah, QA Team Lead
Air Quality Assessment Divison, Ambient Air Monitoring Group

TO: EPA Regional Air Monitoring Contacts

EPA has received reports of issues with the use of stand-alone timers used for VOC sub-ambient sample collection. The issues involve potential leaks in the timer and/or sample flow controller that allow the sample canisters to drop to ambient pressure (0"Hg) during sampling and results in the invalidation of the sample. The invalidation requirement is consistent with direction in the National Air Toxics Trends Station Technical Assistance Document, Revision 3, Section 4.2.3.2.2 located here: https://www3.epa.gov/ttn/amtic/files/ambient/airtox/NATTS%20TAD%20Revision%203_FINAL%20October%202016.pdf.

The most common sampling method for VOCs is to collect ambient air in canisters for subsequent analysis using EPA method TO-15/TO-15A. Two types of automated "all-in-one" sampling methods exist for VOC sampling. The first method is pressurized sampling where a mechanism pumps ambient air into the canister and automatically stops sampling at a user-defined time. The second method is sub-ambient sampling where the canister begins sampling under a vacuum and air is metered into a canister using a sampling device, again, stopping at a user specified time. Both sampler types are expensive, robust, electrically powered and must be operated within a shelter that is protected from the weather. The stand-alone timer is a cheaper option that is sometimes used in instances where the more robust samplers are cost prohibitive or other resources are not available. These timers are more affordable, battery powered, weatherproof and are easy to program. To set up a sample, a flow controller device is fitted to the top of the timer, and this assembly is then attached to the top of the sample canister. The apparatus is then placed on a stand outdoors where the timer is programmed to open and close at a user designed interval.

Historically, these timers have presented issues when used in VOC studies. In the School Air Toxics Monitoring Initiative conducted in 2009, the timers developed leaks within the timer unit itself and sampled air from within the timer enclosure. This resulted in qualification or

invalidation of some samples. Recently, ethylene oxide sampling studies involving timers have yielded similar issues resulting in the invalidation of data where final canister pressures fell to ambient pressure. In addition, temperature extremes experienced during these studies are suspected of impacting the functionality of the system.

There are several reasons why the stand-alone timer used with a flow control device may leak.

- Adding a timer creates more connections that can become loose and leak,
    - Timer to canister
    - Timer to flow controller
- Fittings in the flow controller assembly can become loose and leak,
- Leaks can occur within the timer unit itself,
- Contraction and expansion around the seals within the timer may create leaks in temperature extremes,
- Functionality of the timers degrade with low battery life.

If resources dictate that using stand-alone timers are the best option, EPA recommends the monitoring organization use experienced staff to conduct the sampling activities and exercise extreme caution and oversight. Due to the potential issues noted above, the following guidance should be considered prior to and during the study.

- Follow all directions in the vendor operating manual.
- Upon each sampling event, ensure all fittings (canister to timer, timer to flow controller, and flow controller fittings, particulate filter) are tight. Some fittings require an extra quarter turn after the fitting is finger tight. Consult tightening guidance of the fitting vendor.
- Leak test the sampling apparatus (canister, timer, and flow controller) every sampling run (procedure can be found in TO-15A).
- Leak check timer every 10 runs.
- Replace the batteries frequently.
- Conduct a flow check on the flow controller to ensure that vacuum (4 to 11 inches of Hg) will remain in the can following the sampling duration.
- Immediately report samples that end the sampling run at ambient pressure (0 inches of Hg) to the QA staff for corrective action.
- Train the operator to conduct the sampling and retrieval procedure properly and to be cognizant of issues, and potential issues, in the sampling system.

Following the above recommendations will not guarantee a successful sampling event, but it will greatly improve the success of collecting a valid sample. For questions, please contact me at noah.greg@epa.gov.

cc: Richard Wayland, AQAD Division Director
Kristen Benedict, AAMG Group Leader

Xi (Doris) Chen, AAMG Air Toxics Methods Lead

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
RESEARCH TRIANGLE PARK, NC 27711

May 7, 2021

MEMORANDUM

SUBJECT: Effect of Canister Type on Background Ethylene Oxide Concentrations

TO: Richard Wayland, Director
Air Quality Assessment Division, Office of Air Quality Planning and Standards

FROM: Lara Phelps, Director LARA PHELPS Digitally signed by LARA PHELPS Date: 2021.05.07 14:12:07 -04'00'
Air Methods and Characterization Division, Center for Environmental Measurement and Modeling

The U.S. Environmental Protection Agency (EPA) National Air Toxics Trends Stations (NATTS) network and other state and local air monitoring agencies currently use EPA Methods TO-15 and TO-15A to quantify ethylene oxide (EtO) concentrations in ambient air. Recently, questions have been raised among the ambient air monitoring community regarding potential bias in ambient EtO measurements when using certain types of stainless-steel sample containers. Preliminary study results show this likely to be the case.

Researchers in the Office of Research and Development (ORD) have begun a study to investigate background EtO concentrations that may be observed in different types of specially prepared stainless-steel canisters typically used for TO-15/TO-15A sampling and analysis. Initial results indicate that silicon-ceramic lined canisters may be suitable for ambient EtO monitoring after sufficient canister qualification, whereas electropolished canisters may not be suitable. This determination is based on the elevated concentrations of EtO observed in humidified air samples stored in electropolished canisters as compared to the minimal concentrations observed in humidified air samples stored in silicon-ceramic coated canisters over a one-month storage period.

To make this assessment, ORD acquired a limited number of new commercially available stainless-steel canisters specifically manufactured for the purpose of ambient sampling and analysis of volatile organic compounds. Containers obtained for this study included both silicon-ceramic coated canisters from two vendors and electropolished canisters from one vendor. The canisters were initially cleaned using a canister cleaning method involving 20 cycles of pressurization/evacuation heated to ~70°C using humidified zero air, leak checked, and pressurized with humidified zero air following TO-15A guidelines for initial canister qualification. The laboratory-generated samples were analyzed by preconcentration/gas chromatography-mass spectrometry within one week and again after 4 – 5 weeks to evaluate changes in background EtO concentrations after typical laboratory holding periods.

Initial one-week results showed EtO concentrations in the samples stored in the silicon ceramic-lined canisters were below the method detection limit (MDL) for all samples, whereas EtO was measured at

detectable concentrations in all of the samples stored in electropolished canisters. After the 4 – 5 week holding period, the background EtO concentrations observed in the silicon-ceramic canisters were below the MDL for the majority of the samples. However, the EtO concentrations in the electropolished canisters had increased over the 4 – 5 week hold time by a factor of 7 to 10 times from the initial one-week values corresponding to EtO concentrations substantially higher than typical ambient EtO concentrations.

While results generated from this research effort are considered preliminary, these early findings indicate electropolished canisters may not be suitable for ambient EtO monitoring as they may contribute an unacceptably high positive EtO bias in ambient samples for sample holding periods longer than a few days. The silicon-ceramic coated canisters from the two vendors demonstrated better performance with lower EtO background concentrations overall. Regardless of canister type, it is recommended laboratories perform canister validation procedures outlined in TO-15A to confirm background EtO concentrations in specific canisters are within acceptable limits for typical laboratory sample hold times. ORD plans to continue this research effort to gain a better understanding of these ambient EtO interference issues and provide technical guidance on optimized methods to accurately measure EtO in ambient air.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Office of Air Quality Planning and Standards

Air Quality Assessment Division

Ambient Air Monitoring Group

Technical Note: The Ethylene Oxide (EtO) Canister Effect

5/25/2021

The chemical mechanism of EtO formation and growth in a subset of canisters remains unclear and merits further investigation. The U.S. Environmental Protection Agency (EPA)'s Office of Air Quality Planning and Standards (OAQPS) is currently working collaboratively with the Office of Research and Development (ORD) and our national contract lab, as well as canister manufacturers, to better understand, mitigate, and resolve these canister EtO issues.

Evaluation of current measurement method TO-15, using canisters as the sampling media and Gas Chromatography/Mass Spectrometry (GC/MS) as the analytical instrument for EtO, has revealed positive sampling bias introduced by certain canisters to various degrees (see explainer document and EtO technical webinar slides here https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/epas-work-understand-background-levels-ethylene-oxide; https://www.epa.gov/sites/production/files/2021-05/documents/eto-technical-webinar-041521-w-qandas.pdf).

For those canisters with above detection level EtO concentrations, a continued formation and growth of EtO in the canisters (the EtO canister effect) was found in two sets of studies over time (within typical laboratory sample holding times) with humid air as the sample matrix. While examining for the EtO canister effect with different types of canisters, it was discovered that the canister inner surface lining characteristics play an important role in the EtO canister effect. Based on a cleanliness study recently conducted by EPA's ORD on small number of brand new canisters from multiple vendors (https://www.epa.gov/sites/production/files/2021-05/documents/ord-eto-canister-background-memo-05072021.pdf), canisters with a silicon-ceramic lined inner surface appear to be less affected by the EtO canister effect than those passivated with an electropolished inner surface for typical laboratory sample holding times (~30 days). In addition, further studies examining the EtO canister effect by our national contract lab for a variety of canister types (i.e., canister interior surfaces passivated with silicon-ceramic, electropolished and discontinued SUMMA linings) have revealed that even within the same type of canisters, some individual canisters exhibited distinctive characteristics not consistent with that particular canister type. Also, canister age and how thorough the canisters were cleaned before use were a factor in determining the extent of detectable EtO concentrations. Based on current understanding, the observed EtO

canister effect will generally diminish to some extent over time with multiple and repeated cleanings.

Further, certain aspects (e.g., canister blank certification) in method TO-15 might not be sufficient in identifying problematic canisters which are not appropriate for low concentration EtO sampling. However, the newly released TO-15A[1] method has updated requirements which are more relevant by using humidified zero air rather than nitrogen for canister zero certifications, as well as a more stringent cleanliness criterion (≤0.02 ppbv per target VOC when a canister is filled to standard ambient pressure (101.3 kPa absolute or 14.7 psia)). Most importantly, appropriate and sufficient canister cleaning and canister blank certification processes will be necessary before any canisters should be put in use for ambient EtO sampling. Such processes will allow for a better understanding of representative EtO concentrations in ambient air using the canister-based GC/MS measurement technique.

[1] Determination of Volatile Organic Compounds (VOCs) in Air Collected in Specially Prepared Canisters and Analyzed by Gas Chromatography–Mass Spectrometry (GC-MS) https://www.epa.gov/sites/production/files/2019-12/documents/to-15a_vocs.pdf

Air Toxics Risk Assessment Reference Library

Volume 1

Technical Resource Manual

U.S. Environmental Protection Agency
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PART I

BACKGROUND

Chapter 1 Introduction

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1.1 Introduction

The mission of the United States Environmental Protection Agency (EPA) is to protect human health and to safeguard the natural environment – air, water, and land – upon which life depends.[1] Following this mission, the Agency has implemented a variety of laws and programs that require and encourage the safe use and management of toxic chemicals. Many of these programs focus on understanding the consequences of releasing chemicals to the air, land, and water and working to reduce those releases when they pose too great a risk (see Glossary for definition of risk in this Reference Library). This manual describes the programs and technical tools that EPA uses to evaluate and address chemicals that are released to the air from many different types of sources, and which have the potential to harm people and the environment.

The potential impacts of chemicals released to the air depend on a number of factors, including the quantity of chemicals in the air, how the chemicals move and transform in the environment, the length of time people or the environment is exposed, and the toxic nature of the chemicals. The human health effects of exposure to air pollutants can range from no response, responses that are relatively minor and reversible (such as mild eye irritation), responses that are more serious and debilitating (such as aggravation of asthma) and, in some cases, fatal responses. Air pollution also can cause negative impacts on the environment, including distress and death in plants and animals, as well as damage to buildings and important cultural sites.

In the mid-20th century, Congress recognized the potential for air pollution to cause these kinds of problems and responded by enacting the Clean Air Act (CAA). Since that time, this Act, as amended, has provided the primary authority that EPA uses to develop programs for protecting people and the environment from the harmful effects of air pollution across the United States.

A key component of the current version of the CAA (most recently amended by the 1990 CAA Amendments) is the requirement that EPA significantly reduce emissions to the air of chemicals that are known or suspected to cause serious health problems, such as cancer or birth defects. As a starting point in this effort, the Act explicitly identifies 188 **hazardous air pollutants (HAPs)**[a] for regulation. This group of chemicals is also commonly referred to as the HAPs, **toxic air pollutants** or, simply, **air toxics**. (The CAA also covers another important group of chemicals, known as **criteria air pollutants**; these are discussed in Chapter 2.)

Many different types of sources can release air toxics. These sources include stationary facilities that release large quantities of HAPs to the air (known as **major sources**); stationary facilities that release smaller amounts of HAPs to the air (known as **area sources**); on-road and nonroad **mobile sources** (such as cars, trucks, and construction equipment) that release HAPs to the air; **indoor sources** of air toxics (such as paint and cleaning products); and **natural sources** of air toxics (such as volcanoes). Chapter 4 provides a detailed description of how EPA identifies and, in the case of anthropogenic (manmade) sources, regulates each of the various types of sources of air toxics.

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[a]Since the original Act, which listed 189 chemicals, one chemical (caprolactam) has been delisted, leaving 188 HAPs. EPA is also in the process of considering proposals to delist methyl ethyl ketone (MEK and ethylene glycol butyl ether (EGBE)). EPA has the authority to add and delete chemicals from the original list based on specified criteria [CAA Section 112(b)(3)].

1.2 The Special Concerns of Urban Areas

In urban areas, toxic air pollutants are of particular concern because people and sources of emissions are concentrated in the same geographic area. Since most people live in urban areas, this proximity leads to the potential for large numbers of people to be exposed to numerous air pollutants. While some of these urban chemical exposures tend to be fairly similar across the country (e.g., ambient air concentrations of benzene from petroleum use tend to be similar across the lower 48 states), studies also indicate that the concentrations of air toxics in many urban (and some nonurban) areas can vary significantly from one location to the next (e.g., concentrations in areas with petroleum refineries may be higher than in areas that do not have petroleum refineries). The sources of urban emissions tend to be relatively small in size but large in number, such as gas stations or mobile sources. In addition, these emissions are typically found at ground level where people are more likely to be exposed to them.

Urban air toxics also have a potential to elevate health risks among particular urban sub-populations, including children, the elderly, and persons with existing illnesses. In addition, the prevalence of minority and low-income communities in urban industrial and commercial areas, where concentrations of air toxics may be greatest, increases the likelihood of elevated exposures among these subpopulations.

Considering the large number of people potentially at risk from air toxics exposures, Congress directed in the 1990 CAA amendments that elevated outdoor (also called **ambient**) concentrations of air toxics in large urban areas be substantially reduced. In response to this mandate, EPA developed an **Integrated Urban Air Toxics Strategy**. This Urban Strategy, which was published in the *Federal Register* on July 19, 1999,[2] has since become EPA's **Air Toxics Strategy (The Strategy)** and is part of the overall national effort to reduce air toxics. The Strategy attempts to address all the significant stationary, mobile, and indoor sources necessary to achieve protection of public health and the environment. The specific goals of the Strategy are to:

- Attain a 75 percent reduction in incidence of cancer attributable to exposure to HAPs emitted by stationary sources;

- Attain a substantial reduction in public health risks posed by HAP emissions from area sources; and

- Address disproportionate impacts of air toxics hazards across urban areas.

The Strategy identifies four main areas of action to help achieve these goals:

- **Develop regulations addressing sources of air toxics at the national and local levels**. Pursuant to this effort, the Agency will continue its work to develop rules that require reductions in air toxics emissions from stationary facilities (such as manufacturing plants, electric power plants, gas stations, and dry cleaners), as well as from cars, trucks, and other mobile sources and their fuels. EPA has historically developed and implemented many such standards over the years, and the Strategy indicates the need for additional standards to reduce risks in urban areas.

- **Initiate local and community-based projects to address specific multi-media pollutants (e.g., mercury) and cumulative risks within urban areas**. The CAA requires EPA to "encourage and support area-wide strategies developed by the state or local air pollution control agencies" to address air toxics in urban areas. EPA is developing tools (such as this Reference Library) and is working with communities to assess and reduce risks at the community level.

  The Strategy also recognizes the need to assess the risks from exposures to indoor air toxics and to develop non-regulatory, voluntary programs to address those risks. The Strategy also points out that air pollutants may move into other environmental media such as soil and water resulting in multimedia (i.e., more than just air) concerns. EPA is engaged in a number of activities that recognize the ability of many air toxics to deposit out of the air and bioaccumulate in biota consumed by humans and ecological receptors (e.g., deposition of mercury in watersheds, with subsequent uptake by fish).

  In risk assessment, the term "receptor" generally refers to an individual person or ecological component that is potentially exposed to a stressor (air toxic). In modeling, the term sometime refers to the location where impacts are predicted.

- **Conduct air toxics assessments to identify areas of concern, prioritize efforts to reduce risks, and track progress**. The Strategy identifies a variety of national-level assessment activities that will help EPA identify urban areas of particular concern, characterize the risks that air toxics pose, and track the progress toward meeting overall air toxics program goals. EPA is implementing the National Air Toxics Assessment (NATA) to address this goal. NATA includes:
  - Expanding air toxics monitoring;
  - Improving and periodically updating emissions inventories;
  - Assessing national- and local-scale air quality by using multimedia and exposure modeling;
  - Continuing to research the exposures to, and health effects of, toxic chemicals in ambient and indoor air; and
  - Using and improving exposure and assessment tools.

  These activities will help EPA and other stakeholders[(b)] better understand air toxics risks, as well as risk reductions associated with emissions control standards and other initiatives aimed at reducing emissions. A particularly high-profile aspect of NATA has been the national-scale assessment of 1996 emissions that produced predictions of county-level estimates of air toxics concentrations and calculated risks for a subset of HAPs that EPA believes pose most of the urban area risk. For additional information this particular analysis, see EPA's *The National-Scale Air Toxics Assessment*.[(3)] The national scale assessment of 1999 emissions is currently being performed and will be released in 2004 (see Chapter 2).

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[b]This reference manual uses the term "stakeholder" broadly to include all parties with a potential interest in a given air toxics risk assessment, including regulators, the regulated community, community partners, and individual members of the public.

- **Perform education and outreach**. Given the scientific complexity inherent in air toxics issues, EPA recognizes that the success of the overall air toxics program depends on the public's understanding of the nature of air toxics risks and the activities that can help reduce those risks. To further this understanding, EPA will support education and outreach efforts at the national level and through its state, local, and tribal (S/L/T) partners (e.g., government, industry, community). This reference manual, for example, is an outgrowth of this educational/outreach effort.

For additional information on the Integrated Urban Strategy see EPA's *Air Toxics Strategy: Overview*[4].

1.3 Promoting Localized Assessment

While substantial reductions have been achieved through federal standards, EPA is evaluating the need for additional emissions controls at the national level. However, since the mix of sources and pollutants in specific geographic areas can be quite variable, one element of an effective approach for reducing any remaining unacceptable risks is to understand the cumulative impacts at the local level, target the problem areas, and tailor risk reduction strategies to the local circumstances in those areas.

To encourage reductions of air toxics emissions at the local community level, EPA Headquarters and Regional Offices are working collaboratively with S/L/T and community partners. This team effort has focused on education/information exchanges, identification and assessment of pollution prevention and control options, and promotion of voluntary measures and innovative solutions to assess and address community air pollution problems.

While EPA has the authority to issue standards to address certain air toxics risks, in many cases these risks may be more appropriately and more effectively addressed at the S/L/T level, rather than at the federal level. Specifically, S/L/T air agencies may wish to address issues that are of concern on a state-wide, area-wide, community-wide, or individual neighborhood basis, and for areas in the immediate vicinities of specific air toxics sources. Some S/L/T governments are already addressing some of these issues; others are just beginning to develop their own programs.

1.4 The Risk-Based Approach

While there are several methodologies to assess potential health impacts of air toxics on populations at the local level, the risk-based approach is perhaps the most effective.

The methodology described here, called **risk assessment,** is the process for evaluating:

- The sources of air toxics released to the environment;
- How the released chemicals move and change in the environment;
- Who may be exposed to the chemicals and at what levels;
- How exposures may occur;
- The toxic effects of the chemicals in question and how potent; and
- How likely it is that the potentially exposed people will experience harm because of the exposures.

This manual also discusses the ecological risk assessment process, which assesses the impact of air toxics on ecological receptors such as aquatic organisms and terrestrial mammals.

This kind of information can be extremely helpful to decision makers as they try to balance the competing concerns of protecting public health, fostering economic development, and evaluating issues of fairness and equity, among others. Specifically, risk assessment can provide:

- A predictive estimate of the potential health risks posed by air toxics, which may help determine the need for action;
- A basis for determining the levels of chemicals that can be released to the air without posing unacceptable risks to public health and the environment;
- A basis for comparing potential health impacts of various pollution reduction alternatives;
- A consistent process for evaluating and documenting threats to public health and the environment from toxic air pollution; and
- A basis for comparing risks from various exposure scenarios (e.g., the risk from breathing contaminated air compared to the risk from eating contaminated food).

Performing an air toxics risk assessment is often challenging. Risk assessments can be resource and time-intensive, depending on the specific questions being asked and the level of detail needed for informed decision making. Risk assessments usually require input from a number of scientists and engineers with a variety of skills (e.g., chemistry, toxicology, statistics, modeling, meteorology, monitoring). Decision makers may also need to acquire new skills in order to understand and use the risk assessment results. Finally, although they are based on science, risk assessments often rely on the best judgment of the analysts in the face of various uncertainties.

There has not been, up to this point, a unified and comprehensive reference manual on the methods and tools that are currently available to perform air toxics risk assessments *per se*. This document is EPA's attempt to fill that void.

1.5 The Purpose of this Reference Manual

The primary purpose of this reference manual (Volume 1) is to provide, in one single place, descriptions of the major methods and technical tools that are commonly used to perform air toxics risk assessments. Specifically, the manual attempts to cover all the common basic technical approaches that are used to evaluate: how people in a particular place (e.g., a city or neighborhood) may be exposed; what chemicals they may be exposed to and at what levels; how toxic those chemicals are; and how likely it is that the exposures may result in adverse health outcomes. Topics include uncertainty and variability, basic toxicology and dose-response relationships, air toxics monitoring and modeling, emissions inventory development, and risk characterization. This manual also discusses approaches for using the results of a risk assessment in the risk management decision-making process. Links to more detailed references on each subject are presented, along with EPA contacts. Additionally, EPA's Fate, Exposure, and Risk Analysis (FERA) web site (www.epa.gov/ttn/fera) provides up-to-date tools for air toxics risk assessment, including computer models, databases, and other information used by EPA and others for air pollutant human exposure modeling, multimedia modeling, and risk.

To provide readers with a broad perspective on the potential impacts of air toxics (in addition to information on the risk assessment process), this manual also includes a discussion of a

complementary process called a **public health assessment** (PHA). One of the objectives of a PHA is to evaluate whether existing cases of illness in a community may possibly have resulted from past exposures to particular toxins (based on epidemiological principles). This process is routinely carried out at Superfund sites by the Agency for Toxic Substances and Disease Registry (ATSDR) in addition to EPA's Superfund risk assessment process. PHAs often involve the use of capabilities beyond those required for risk assessment, including medical skills. S/L/T air agencies generally will not perform such assessments themselves; however, because questions about current or past illnesses and deaths in communities often arise during the risk assessment process, information about the PHA process is offered to help S/L/T air agencies and other stakeholders understand the rudiments of the process and whom to contact for more information and help.

1.6 The Layout of this Reference Manual

This reference manual is divided into six Parts, each of which are divided further into three or more chapters. Chapters are numbered consecutively. A number of Appendices provide more detailed reference materials.

- **Part I (Background)** provides a general introduction to air toxics risk assessment and is divided into four chapters.
  - Chapter 1 (this chapter) provides an introduction to the manual.
  - Chapter 2 begins with an overview of the CAA as well as major regulations, programs, and initiatives that relate to air toxics risk reduction.
  - Chapter 3 provides an overview of risk assessment and the risk-based decision making framework, including an introduction to tiered approaches to risk assessment.
  - Chapter 4 identifies the set of chemical pollutants that are the focus of this manual and describes the general categories of air toxics sources and the primary emissions inventories (which contain information on the nature and magnitude of emissions released from various sources).

- **Part II (Human Health Risk Assessment: Inhalation)** provides a discussion of the methods and tools used to evaluate risks to human health via the inhalation pathway. It is divided into nine chapters.
  - Chapter 5 provides an overview of the inhalation risk assessment process, discusses the initial planning and scoping process that needs to be completed before the risk assessment begins, and describes the **exposure assessment**, which will usually comprise the bulk of the effort for most air toxics risk assessments.
  - Chapter 6 describes the problem formulation phase which results in the development of the conceptual model and analysis plan for the risk assessment.
  - Chapter 7 describes how to develop an emissions inventory for the risk assessment.
  - Chapter 8 discusses the factors that affect the movement and, in some cases, chemical transformation of chemicals in the atmosphere following release (i.e., the fate and transport of chemicals in the atmosphere).
  - Chapter 9 provides an overview of the use of computer modeling to predict the movement, fate, and transport of air toxics in the atmosphere. It also describes the major computer models that are commonly used for this purpose.
  - Chapter 10 provides an overview of monitoring methods that are commonly used to measure ambient concentrations of air toxics in the atmosphere.

- Chapter 11 provides information for estimating exposure concentrations for inhalation analyses, including exposure modeling.
- Chapter 12 provides an overview of **toxicity assessment** for air toxics.
- Chapter 13 provides information for completing the **risk characterization**, including uncertainty analysis and how to present the results of the risk assessment.

- **Part III (Human Health Risk Assessment: Multipathway)** provides a discussion of the methods and tools used to evaluate risks to human health when air toxics that are highly persistent or bioaccumulative are present in emissions. The focus of the multipathway risk assessment is to evaluate the potential exposures associated with ingesting soil, food, and water that has become contaminated with these chemicals after deposition from the atmosphere to surfaces, such as soils and surface waters. This Part is divided into nine chapters.
  - Chapter 14 provides an overview of the multipathway risk assessment process, discusses the initial planning and scoping process that needs to be completed before the risk assessment begins, and describes the multipathway **exposure assessment**.
  - Chapter 15 describes problem formulation for the multipathway risk assessment.
  - Chapter 16 describes how to develop an emissions inventory for the multipathway risk assessment.
  - Chapter 17 discusses the factors that affect the movement and, in some cases, chemical transformation of air toxics in soil, water, sediment, and biota.
  - Chapter 18 provides an overview of the computer modeling used to predict the movement, fate, and transport of toxics in soil, water, sediment, and biota and describes the major multimedia computer models commonly used by risk assessors.
  - Chapter 19 provides an overview of monitoring methods used to measure ambient concentrations of air toxics in soil, water, sediment, and biota.
  - Chapter 20 provides a summary of the process and assumptions used to estimate chemical intake rates – the key measure of exposure used to assess ingestion risks – including exposure modeling.
  - Chapter 21 provides an overview of the toxicity assessment for air toxics that are persistent and which may also have a high potential to bioaccumulate in food chains.
  - Chapter 22 provides information on how to complete the risk characterization for the multipathway risk assessment, including uncertainty analysis and how to present the results of the risk assessment.

- **Part IV (Ecological Risk Assessment)** provides an overview of the methods and tools used to evaluate risks to ecological receptors (e.g., birds, mammals, plants, and ecological communities) due to exposure to air toxics. This Part is divided into four chapters.
  - Chapter 23 provides an overview of the ecological risk assessment process and discusses the initial planning and scoping process that needs to be completed before the risk assessment begins.
  - Chapter 24 provides information on characterizing exposure for the ecological risk assessment.
  - Chapter 25 provides information on characterizing ecological effects, including development of the stressor-response profile.
  - Chapter 26 provides information on how to complete the risk characterization for the ecological risk assessment, including the analysis of uncertainty, and how to present the results of the ecological risk assessment.

- **Part V (Risk-Based Decision Making)** discusses the process by which the information from the risk assessment can be used to inform risk management decisions and two important aspects of that process. This Part is divided into three chapters.
  - Chapter 27 provides an overview of the risk management process, including the types of decisions that may need to be made and how the risk assessment informs the decision-making process.
  - Chapter 28 provides an overview of the importance of stakeholder involvement in the risk assessment and management process and provides information for developing and implementing a stakeholder involvement plan.
  - Chapter 29 provides information for developing and implementing a risk communication strategy for helping members of the community and the media understand the risk assessment results and how they are being used in the decision-making process.

- **Part VI (Special Topics)** provides an overview of three tools or procedures that may be used as part of performing or reporting a risk assessment.
  - Chapter 30 provides an overview of the process by which public health agencies may evaluate the public health implications posed by the emissions from air toxic sources in a community. The public health assessment, if performed, is a complementary process to risk assessment.
  - Chapter 31 discusses probabilistic risk assessment, which is aimed at describing risks as a distribution (or range) of potential outcomes.
  - Chapter 32 provides an overview of the use of Geographical Information System (GIS) tools in the process of conducting risk assessments and reporting results.

- The **Glossary** defines key terms and acronyms.

- **Appendix A** provides a listing of all HAPs along with their status as a Toxics Release Inventory (TRI) chemical, a Section 112(k) high priority urban toxic, and a Mobile Source Air Toxic.

- **Appendix B** provides a guide to the agencies and organizations that oversee air toxics regulations.

- **Appendix C** provides recommended dose-response values for cancer and noncancer effects for all HAPs.

- **Appendix D** presents the decision process by which the persistent, bioaccumulative HAP compounds (PB-HAPs) were selected.

- **Appendix E** provides an overview of all CAA designated air toxics Source Categories, including the most common HAPs in emissions, typical industries, and applicable maximum achievable control technology (MACT) standards.

- **Appendix F** provides a list of all of the specific pollutants and compound groups included in the 1999 National Emissions Inventory (NEI) along with their Chemical Abstract Services (CAS) numbers.

- **Appendix G** provides an overview of meteorology as it relates to the movement of air toxics in the atmosphere. This appendix also provides information on sources of meteorological data for modeling air toxics dispersal and transport.

- **Appendix H** discusses the process of evaluating and reducing a monitoring data set (e.g., air, water, soil sample results) into a grouping of data that are useable for exposure evaluation.

- **Appendix I** provides a general overview of how a reduced monitoring data set (developed by the methods in Appendix H) may be used to estimate exposure concentrations.

- **Appendix J** provides an overview of available air toxics monitoring methods.

- **Appendix K** provides the equations for calculating the concentrations of PB-HAPs in non-air media (e.g., soil, food, water).

1.7 The Relationship of this Manual to Volumes 2 and 3

This manual is the first volume of a three-volume set. **Volume 1: Technical Resource Manual** discusses the overall air toxics risk assessment process and the basic technical tools needed to perform these analyses. The manual addresses both human health and ecological analyses. It also provides a basic overview of the process of managing and communicating risk assessment results. Other evaluations (such as the public health assessment process) are described to give risk assessors, risk managers, and other stakeholders a more holistic understanding of the many issues that may come into play when evaluating the potential impact of air toxics on human health and the environment.

Volume 2: Facility-Specific Assessment builds on the technical tools described in Volume 1 by providing an example set of tools and procedures that may be used for source-specific or facility-specific risk assessments, including tiered approaches to source- or facility-specific risk analysis.

Volume 3: Community-Level Assessment builds on the information presented in Volume 1 to describe to communities how they can evaluate and reduce air toxics risks at the local level. The volume will include information on screening level and more detailed analytical approaches, how to balance the need for assessment versus the need for action, and how to identify and prioritize risk reduction options and measure success. Since community concerns and issues are often not related solely to air toxics, the document will also present readily available information on additional multimedia risk factors that may affect communities and strategies to reduce those risks. The document will provide additional, focused information on stakeholder involvement, communicating information in a community-based setting, and resources and methodologies that may play a role in the overall process. Note that EPA's Office of Pollution Prevention and Toxics has also developed a "Community Air Screening How To Manual" that will be available in 2004 and will be discussed in Volume 3 (Volume 3 will be available in late 2004).

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Chapter 2 Clean Air Act Requirements and Programs to Regulate Air Toxics

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2.1 Introduction

In a general sense, an air pollutant is any substance introduced into the air by human activities (currently, approximately 75,000 industrial chemicals are produced or imported into the United States,[a] and science knows many millions more). Some air pollutants may take the form of solid particles, liquid droplets, or gases. Many different types of air pollutants can injure health and/or harm the environment (see Common Air Pollutants box).

Common Air Pollutants

acid aerosols
asbestos
carbon monoxide (CO)
carbonyl compounds
ground level ozone
metals
nitrogen oxides (NO_x)
particulate matter (PM)
propellants
radon
refrigerants
semivolatile organic compounds
sulfur dioxide (SO_2)
volatile organic compounds

In early versions of the Clean Air Act (CAA), Congress identified six criteria air pollutants for regulation. In addition to these pollutants, the1990 CAA Amendments focused EPA's efforts on another group of pollutants, the 188 Hazardous Air Pollutants (**HAPs**).[b] Additionally, EPA has identified 21 mobile source air toxics, 20 of which are also HAPs and the other one is "diesel particulate matter and diesel exhaust organic gases" (see Chapter 4).

The group of six criteria air pollutants occur commonly throughout the U.S. and are derived from numerous and diverse mobile and stationary sources. EPA has set National Ambient Air Quality Standards (NAAQS) for these pollutants based on health and welfare-related criteria (see Section 2.4.1 and http://www.epa.gov/ttn/naaqs/). No such national ambient air quality standards currently exist for HAPs, although regulatory programs are in place to address emissions of HAPs. In addition, air pollutants from indoor sources are of concern (with many of the chemicals emitted indoors overlapping with the criteria and HAP lists). EPA, however does not currently regulate indoor air.

A Note on Terminology

The terms "**air toxics**" and "**toxic air pollutants**" are often used interchangeably with "**hazardous air pollutants**" (which is a Clean Air Act phrase specific to the 188 pollutants that are the focal point of section 112 of the Act – see http://www.epa.gov/ttn/atw/188polls.html). For the purposes of this reference library, however, the term "air toxics" is used in the more general sense to refer generally to any air pollutant (other than criteria pollutants) that has the potential to cause adverse impacts to human health or the environment.

Criteria air pollutants are six common air pollutants determined to be hazardous to human health and for which EPA has established National Ambient Air Quality Standards (NAAQS). The six criteria air pollutants are carbon monoxide, lead, nitrogen dioxide, ozone, sulfur dioxide, and particulate matter.

The CAA is the primary federal law that regulates air emissions of HAPs. The Act applies to a number of different types of sources; these include small and large stationary facilities such as factories and neighborhood dry cleaners, as well as mobile sources such as cars and trucks. The original CAA was passed in 1963 and has been

[a] TSCA Chemical Substance Inventory, http://www.epa.gov/opptintr/newchems/invntory.htm

[b] CAA section 112(b)(1) lists 189 HAPs, but since the original Act, one chemical (caprolactam) has been delisted, leaving 188 HAPs (61 FR 30816, June 18, 1996).

amended since that time on a number of occasions, most recently in 1990. Congress intended the 1990 amendments to resolve unaddressed or insufficiently addressed air pollution problems such as acid rain, ground-level ozone, and stratospheric ozone depletion. The 1990 amendments also dramatically affected how EPA was to approach the issue of air toxics. For example, previous versions of the Act required EPA itself to identify pollutants as HAPs one-by-one and to set health-based standards for each. Given the problems that arose in working to implement this approach, Congress restructured the approach for air toxics in the 1990 amendments. The discussion below describes this current approach.

Specifically, this chapter provides an overview of the CAA requirements that are specific to HAPs, with emphasis on **stationary sources**, **mobile sources**, and **indoor sources** of HAPs. The chapter also provides insight into other aspects of air quality that play a role in understanding the air toxics problem. The chapter concludes with a brief description of some of the important studies EPA was required to perform under the Act to better understand the nature of the air toxics problem. The full text of the Act can be accessed at http://www.epa.gov/oar/caa. EPA has also developed a plain English guide to the Act that can be accessed at http://www.epa.gov/oar/oaqps/peg_caa/pegcaain.html.

2.2 HAPs and their Sources: Stationary, Mobile, and Indoor Sources

2.2.1 Hazardous Air Pollutants (HAPs)

Hazardous air pollutants (HAPs) are those 188 listed pollutants and groups of pollutants[c] that EPA knows or suspects cause cancer or other serious human health effects, such as reproductive effects or birth defects, or adverse environmental effects (Appendix A presents the full list).[1] Examples of HAPs include benzene, which is found in gasoline; perchloroethlyene, which is emitted by most dry cleaning facilities; methylene chloride, which is used as a solvent and paint stripper by a number of industries; dioxin; asbestos; toluene; and compounds of metals such as cadmium, mercury, chromium, and lead. Congress has given EPA the authority to add and subtract chemicals from that list, following established criteria [CAA Section 112(b)(3)]. According to summary data compiled by EPA, an estimated 5.1 million tons of HAPs were released from stationary and mobile sources in the U.S. in 1999.

Major Source – Any source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year (tpy) or more of any hazardous air pollutant or 25 tpy or more of any combination of hazardous air pollutants [CAA section 112(a)(1)].

Area Source – any stationary source of hazardous air pollutants that is not a major source ... not includ[ing] motor vehicles or nonroad vehicles subject to regulation under title II [CAA section 112(a)(2)].

People exposed to HAPs at sufficient concentrations and for a sufficient duration of time may have an increased chance of developing cancer or experiencing other serious health effects. These health effects can include damage to the immune system, as well as neurological,

[c] CAA section 112(b)(1) lists 189 HAPs, but since the original Act, one chemical (caprolactam) has been delisted, leaving 188 HAPs (61 FR 30816, June 18, 1996)

reproductive (e.g., reduced fertility), developmental, respiratory, and other health effects. In addition to exposure from breathing air toxics, some HAPs such as mercury compounds can deposit onto soils or surface waters, where they can be taken up by plants and animals (see Chapter 4). Like humans, ecological systems may experience adverse health problems if exposed to sufficient quantities of HAPs over time (ecological risk assessment is discussed in Part IV of this reference manual).

People may be exposed to HAPs in many ways, including:

- Breathing contaminated air;
- Eating contaminated food products, such as fish from contaminated waters; meat, milk, or eggs from animals that fed on contaminated plants; and fruits and vegetables grown in contaminated soil on which HAPs have been deposited;
- Drinking water contaminated by HAPs;
- Ingesting contaminated soil. Young children are especially vulnerable because they often ingest soil from their hands or from objects they place in their mouths; and
- Touching (making skin contact with) contaminated soil, dust, or water (for example, during recreational use of contaminated water bodies).

Anthropogenic sources of HAPs include stationary sources (e.g., factories, refineries, power plants), mobile sources (e.g., cars, trucks, buses), and indoor sources (e.g., some building materials and cleaning solvents). Some HAPs are also released from natural sources such as volcanoes.

The Urban Air Toxics

In 1999, EPA identified a group of 33 HAPs (the *Urban Air Toxics*) as those most important to health risks in urban areas (see Section 1.1).

acetaldehyde	coke oven emissions	manganese compounds
acrolein	dioxin	mercury compounds
acrylonitrile	1, 2-dibromoethane	methylene chloride[(b)]
arsenic comounds	propylene dichloride	nickel compounds
benzene	1, 3-dichloropropene	polychlorinated biphenyls (PCBs)
beryllium compounds	ethylene dichloride[(a)]	polycyclic organic mater (POM)
1,3-butadiene	ethyene oxide	quinoline
cadmium compounds	formaldehyde	1, 1, 2, 2-tetrachlorethane
carbon tetrachloride	hexachlorobenzene	tetrachloroethylene[(c)]
chloroform	hydrazine	trichloroethylene
chromium compounds	lead compounds	vinyl chloride

[(a)] also represented as 1,2-dichloroethane
[(b)] also represented as dichloromethane
[(c)] also represented as perchloroethylene

2.2.2 Stationary Sources: The Pre-1990 CAA "Risk-Only" Approach

Prior to 1990, the CAA directed EPA to regulate toxic air pollutants from stationary sources based on the risks each pollutant posed to human health. Specifically, the Act directed EPA to:

- Identify all pollutants that caused "serious and irreversible illness or death," and
- Develop standards to reduce emissions of these pollutants to levels that provided an "ample margin of safety" for the public.

In other words, EPA was tasked with identifying the chemicals to be considered HAPs and setting standards for chemical emissions that would not only be "safe," but would be safe with an "ample margin" to the public. (A discussion of what the term "ample margin of safety" means is presented in Chapter 27. A discussion as how to interpret risk levels such as "one in a million" is provided in Chapter 13.) EPA turned to a method called "risk assessment" in performing this task because it provided the tools necessary to evaluate the potential risks posed by hazardous chemicals released to the air.[(d)]

While attempting to understand and control air toxics during the 1970s and 1980s, EPA became involved in many legal, scientific, and policy debates over which pollutants to regulate and how stringently to regulate them. Much of the debate focused on what kinds of risk assessment methods to use, what assumptions in the process were appropriate, the amount of data needed to justify regulation, questions about the costs to industry and benefits to human health and the environment, and decisions about "how safe is safe" (see additional discussion in Chapter 3).

While EPA and the scientific community gained valuable knowledge about risk assessment methods during this time, the chemical-by-chemical regulatory approach – an approach based solely on risk – proved difficult. In fact, between 1970 and 1990 EPA regulated only seven pollutants (asbestos, benzene, beryllium, inorganic arsenic, mercury, radionuclides, and vinyl chloride) in this manner. Standards for sources of HAPs, known as the **National Emissions Standards for Hazardous Air Pollutants** or **NESHAPs**, cut annual air toxics emissions by an estimated 125,000 tons. However, the process did not work quickly enough to address pressing air pollution concerns.

2.2.3 Stationary Sources and the 1990 Clean Air Act Amendments: A "Technology First, Then Risk" Approach

Realizing the shortcomings of the "chemical-by-chemical" risk-based decision framework for stationary sources and acknowledging the gaps in scientific and analytical information, Congress adopted a new strategy in 1990. Specifically, Congress revised section 112 of the Act to mandate a more practical, phased approach to reducing emissions of toxic air pollutants.

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[d]People have been assessing risk in various ways for thousands of years, so in one sense, "risk assessment" is an ancient practice. However, methods to quantitatively assess risk for specific applications are a more recent development. As noted above, the methods necessary to assess the risks posed by air toxics are an even more recent development and are the subject of this discussion.

2.2.3.1 Step 1: The Technology-based Approach

This new approach has two components. In the first phase, EPA identifies categories of stationary sources that emit large amounts of HAPs and then develops pollution reduction regulations – called **Maximum Achievable Control Technology** or **MACT** standard - for those sources.[e] The MACT standards adopted by EPA are *technology-based* (not risk-based), which means EPA requires emission reductions based on an evaluation of the emission reductions that the best-performing similar sources are already achieving.

Specifically, when developing a MACT standard for a particular source category, EPA looks at the level of emissions already being achieved by the best-performing similar sources through clean processes, control devices, work practices, or other methods. The CAA specifies baselines (often referred to as the "MACT floors") for the new standards. At a minimum, a MACT standard must achieve, throughout the industry, a level of emissions control that is at least equivalent to the MACT floor. EPA can establish a more stringent standard after considering cost, non-air quality and environmental impacts, and energy requirements (section 112(d)(2) of the CAA).

The MACT floors specified in the CAA are different for existing sources and new sources. For existing sources, the MACT floor must equal the average emissions limitations achieved by the best-performing 12 percent of sources in that source category, if there are 30 or more existing sources. If there are fewer than 30 existing sources, then the MACT floor must equal the average emissions limitation achieved by the best-performing five sources in the category. For new sources, the MACT floor must equal the level of emissions control achieved in practice by the best-controlled similar source.

EPA has issued MACT standards for a variety of industrial source categories, including chemical plants, oil refineries, aerospace manufacturers, and steel mills, and smaller sources, such as dry cleaners, commercial sterilizers, secondary lead smelters, and chromium electroplating facilities. EPA has also issued standards pursuant to section 129 of the Clean Air Act to control emissions of certain toxic pollutants from solid waste combustion facilities. A comprehensive list of final MACT rules and regulations for the MACT program can be found at http://www.epa.gov/ttn/atw/mactfnl.html. EPA's proposed timetable for finalizing the remaining standards is available at http://www.epa.gov/ttn/atw/mactprop.html. When fully implemented, all of these standards will reduce air toxics emissions by several million tons per year – more than 10 times the reductions achieved prior to 1990.

2.2.3.2 Step 2: The Risk-based Approach

In the second phase of the process, EPA reviews the technology-based MACT standards to ensure that these standards have adequately reduced risk within an "ample margin of safety." In this second assessment, the Agency must adopt additional standards to address any significant risks remaining (also called **residual risks**) after the first phase implementation of the technology-based standards (section 112(f)(2)(A) of the CAA). This time lag between the

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[e] MACT standards are also considered NESHAPs.

technology and risk-based phases allows EPA to evaluate the best way to use risk assessment as a tool for assessing residual risks (see Chapter 3).

Within eight years after promulgation of MACT standards for each category or subcategory of sources, EPA must promulgate standards for such category or subcategory if the MACT standard for the category or subcategory does not protect public health with an ample margin of safety or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect (section 112(f)(2)(A)). In 1999, EPA reported to Congress on its residual risk assessment framework and included a discussion of its methods, data, and tools.[2]

EPA has begun to assess residual risk for several source categories, including coke ovens, dry cleaning, gasoline distribution Stage I, commercial ethylene oxide sterilizers, halogenated solvent cleaning, industrial cooling towers, and magnetic tape manufacturing.

2.2.4 Mobile Sources of Air Toxics Rule

Mobile sources is a term used to describe a wide variety of vehicles, engines, and equipment that generate air pollution and that move, or can be moved, from place to place. Mobile sources pollute the air through combustion and fuel evaporation. These emissions contribute greatly to air pollution nationwide and are the primary cause of air pollution in many urban areas. EPA has identified 21 mobile source air toxics (MSATs) (see box below). Twenty of these are also listed as HAPs in CAA section 112(b); the remaining one (diesel particulate matter and diesel exhaust organic gases) is a mixture that includes many HAPs.[3] The two major divisions or types of mobile sources include:

- **On-road** (highway) sources include vehicles used on roads for transportation of passengers or freight. These include passenger cars, light-duty trucks (pickup trucks, minivans, passenger vans, and sport-utility vehicles), heavy-duty vehicles, and motorcycles. On-road vehicles may be fueled with gasoline, diesel fuel, or alternative fuels such as alcohol or natural gas.

- **Nonroad** (off-road) sources include vehicles, engines, and equipment used for construction, agriculture, transportation, recreation, lawn and garden care, and many other purposes. These include equipment and vehicles fueled with diesel fuel, gasoline, propane, or natural gas. Mobile sources include boats, aircraft, and locomotives. Not all mobile sources are "self-propelled." They can include portable generators, air compressors, chainsaws, trimmers, and shredders.

EPA uses an integrated approach (including regulations) to reduce pollution from mobile sources. From better engine design to better transit options, EPA's approach addresses:

- Vehicles, engines, and equipment;
- The fuels they use; and
- The people who operate them.

Mobile Source Air Toxics Listed in 2001 Rule[3]

- acetaldehyde
- acrolein
- arsenic compounds[a]
- benzene
- 1,3-butadiene
- chromium compounds[a]
- diesel particulate matter and diesel exhaust organic gases (DPM + DEOG)
- dioxin/furans[b]
- ethylbenzene
- formaldehyde
- n-hexane
- lead compounds[a]
- manganese compounds[a]
- mercury compounds[a]
- methyl tertiary butyl ether (MTBE)
- naphthalene
- nickel compounds[a]
- polycyclic organic matter (POM)[c]
- styrene
- toluene
- xylene

[a] Although the different metal compounds may differ in their toxicity, the on-road mobile source inventory contains emissions estimates for total metal compounds (i.e., the sum of all forms).
[b] This entry refers to two large groups of chlorinated compounds. In assessing their cancer risks, their quantitative potencies are usually derived from that of the most toxic, 2,3,7,8-tetrachlorodibenzodioxin.
[c] Polycyclic organic matter includes organic compounds with more than one benzene ring, and which have a boiling point greater than or equal to 100 degrees Celsius. A group of seven polynuclear aromatic hydrocarbons, which have been identified by EPA as probable human carcinogens (benz(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, 7,12-dimethylbenz(a)anthracene, and indeno(1,2,3-cd)pyrene) are used here as surrogates for the larger group of POM compounds.

This approach includes national engine and fuel standards, as well as state requirements (e.g., engine maintenance, traffic flow/roadway design) established to enable attainment of the NAAQS for the criteria pollutants. The approach also involves extensive collaboration among EPA, state local and tribal (S/L/T) governments, transportation planners, individual citizens, and vehicle, engine, and fuel manufacturers and has been responsible for greatly reducing mobile source air pollution during the last 30 years.

In addition to achieving air toxics emissions reductions as a result of actions aimed at reductions in criteria pollutants, the 1990 CAA Amendments contain provisions specific to air toxics. These amendments direct EPA to address emissions of air toxics from motor vehicles and their fuels. Specifically, section 202(l) of the Clean Air Act instructs EPA to:

- Study the need for and feasibility of controlling emissions of toxic air pollutants associated with motor vehicles and their fuels. This section identifies benzene, 1,3-butadiene, and formaldehyde for particular consideration. EPA completed this study in 1993 and updated it in 1999.

- Set standards for HAPs from motor vehicles, their fuels, or both. Those standards are to be promulgated under section 202(a) or section 211(c) of the Act and must address at least benzene and formaldehyde. EPA is to base these standards on available technology, taking into account existing standards; costs, noise, energy, and safety factors; and lead time. EPA promulgated a rulemaking in accordance with CAA section 202(l) on March 29, 2001 (66 FR 17230).

The many vehicle and fuel changes in the last 25 years have greatly reduced air toxics emissions from highway vehicles. For example, the removal of lead from gasoline has essentially eliminated on-road mobile source emissions of this highly toxic substance in the United States. In addition, results of recent modeling indicate that current and planned programs will reduce emissions of mobile source air toxics by about one million tons (about 35 percent) between 1996 and 2007; on-highway emissions of benzene, formaldehyde, 1,3-butadiene, and acetaldehyde by 67 to 76 percent between 1990 and 2020; and on-highway diesel particulate matter by 94 percent between 1990 and 2020.[4] New cars using reformulated gasolines are capable of emitting more than 90 percent less air toxics on a per-mile basis than the uncontrolled models of 1970; new trucks and buses are designed to emit less than half the air toxics of their 1970 counterparts. Overall air toxics emissions will continue to decrease as older vehicles leave the fleets and as new regulatory programs take effect. However, the number of vehicles on the road and the number of miles they travel is continuing to grow. Without additional controls, growth in vehicle travel will offset progress in reducing air toxics.

Rulemakings and Voluntary Efforts to Reduce MSATs and other Air Pollutants

- Tier 2 gasoline/sulfur rulemaking (http://www.epa.gov/otaq/tr2home.htm)
- Reducing nonroad diesel emissions (http://www.epa.gov/nonroad/)
- Voluntary diesel retrofit program (http://www.epa.gov/otaq/retrofit)
- Best Workplaces for Commuters (http://www.commuterchoice.gov)
- Clean School Bus USA (http://www.epa.gov/cleanschoolbus.
- It All Adds Up to Cleaner Air (http://www.italladdsup.gov)

2.2.5 Indoor Air and Indoor Air Toxics

Indoor pollution sources that release gases or particles into the air are the primary cause of indoor air quality problems in homes and other buildings. Inadequate ventilation can increase indoor pollutant levels by not bringing in enough outdoor air to dilute emissions from indoor sources and by not carrying indoor air pollutants out of the building. High temperature and humidity levels can also increase concentrations of some pollutants.

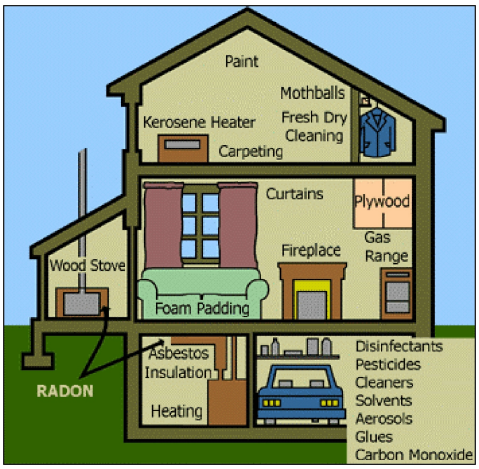
The importance of indoor air exposures to the total risk from air toxics is a relatively new finding. The contribution of indoor sources was not really recognized until the early 1980s when EPA performed the Total Exposure Assessment Methodology (TEAM) studies, which showed that the indoor concentrations of some air toxics can be significantly higher than outdoor concentrations. Since that time, numerous studies have confirmed that finding. In addition, the fact that Americans spend about 90 percent of their times indoors makes these exposures even more important

2.2.5.1 Potential Sources of Indoor Air Toxics

There are many potential sources of indoor air toxics in any home or building. These sources include combustion sources such as oil, gas, kerosene, coal, wood, and tobacco products; building materials and furnishings as diverse as deteriorated, asbestos-containing insulation, and cabinetry or furniture made of certain pressed wood products; products for household cleaning and maintenance (e.g., pesticides), personal care, or hobbies; and outdoor sources such as radon and other air pollution that penetrate into the indoor space.

Sources of Indoor Air Toxics

- Indoor air can become contaminated from numerous sources.
- Indoor air can have significantly higher concentrations of air toxics than outdoor air.
- EPA currently does not regulate indoor sources of air toxics.



The relative importance of any single source depends on how much of a given pollutant it emits and how hazardous those emissions are. In some cases, factors such as the age of the source and whether it is properly maintained are significant. For example, an improperly adjusted gas stove can emit significantly more carbon monoxide than one that is properly adjusted.

Some sources, such as building materials, furnishings, and household products like air fresheners, release pollutants more or less continuously (usually at a decreasing rate with age). Other sources, related to activities carried out in the home, release pollutants intermittently. These include smoking, the use of unvented or malfunctioning stoves, furnaces, or space heaters, the use of solvents in cleaning and hobby activities, the use of paint strippers in redecorating activities, and the use of cleaning products and pesticides in housekeeping. High pollutant concentrations can remain in the air for long periods after some of these activities.

How Does Outdoor Air Enter a House?

Outdoor air enters and leaves a house by: infiltration, natural ventilation, and mechanical ventilation. In a process known as infiltration, outdoor air flows into the house through openings, joints, and cracks in walls, floors, and ceilings, and around windows and doors. In natural ventilation, air moves through opened windows and doors. Air movement associated with infiltration and natural ventilation is caused by air temperature differences between indoors and outdoors and by wind. Finally, there are a number of mechanical ventilation devices, from outdoor-vented fans that intermittently remove air from a single room, such as bathrooms and kitchens, to air handling systems that use fans and duct work to continuously remove indoor air and distribute filtered and conditioned outdoor air to strategic points throughout the house. The rate at which outdoor air replaces indoor air is described as the air exchange rate. When there is little infiltration, natural ventilation, or mechanical ventilation, the air exchange rate is low, and pollutant levels can increase.

2.2.5.2 Indoor Air Toxics

Although EPA does not regulate indoor air pollution levels, it does take a proactive approach. The Agency provides a broad range of information about indoor air-related

risks, as well as the steps to reduce them, through the use of public awareness campaigns, guidance document dissemination, training course delivery, the operation of several linked hotlines and clearinghouses, and other outreach efforts. Useful resources on indoor air quality from the Agency are also available online.[5][6] EPA's activities to reduce exposures to indoor air toxics are many and include publishing guidelines about radon testing and result interpretation; persuading parents and caregivers of young children not to smoke indoors; and providing information to homeowners, school administrators, and office managers on the proper use of products and materials indoors, including appropriate maintenance and ventilation.

In 2001, EPA issued the Healthy Buildings, Healthy People (HBHP) report, a vision for indoor environmental quality in the 21st century.[7] The report covers three general areas: (1) why human health indoors deserves the scrutiny, concern, and action of policy makers; (2) a vision statement of EPA's vision, goals, broad strategies, and guiding principles to address indoor air quality issues; and (3) potential actions that EPA or others may pursue. The report also provides an overview of current indoor environmental program priorities in various offices within EPA and examines the roles of the Agency's partners in indoor environmental protection, including Federal, S/L/T organizations, and stakeholders.

EPA's objective is to realize major human health gains over the next 50 years by upgrading indoor environments. The Agency has set five goals and strategies to accomplish this objective:

- Achieve major health gains and improve professional education;
- Foster a revolution in the design of new and renovated buildings;
- Stimulate nationwide action to enhance health in existing structures;
- Create and use innovative products, materials, and technologies; and
- Promote health-conscious individual behavior and consumer awareness.

In addition to providing information on actions and strategies that can be taken to protect people indoors, EPA's vision acknowledges the important role individuals play in protecting their own health and the health of those around them.

EPA's specific goals to reduce the health risks from indoor air for 2005 include:

- 700,000 homes with high radon levels will be mitigated and 1 million homes with radon-resistant construction techniques will be constructed;
- The proportion of households in which children ages six and under are regularly exposed to smoking will be reduced from 27 percent in 1994 to 15 percent;
- Five percent of office buildings will be managed with indoor air quality practices consistent with EPA's *Building Air Quality* guidance;[8]
- Fifteen percent of the nation's schools will adopt good indoor air quality practices consistent with EPA's *Indoor Air Quality Tools for Schools* guidance;[9]
- One million children with asthma will have reduced exposure to indoor asthma triggers; and
- 200,000 low-income adults with asthma and 2.5 million people with asthma overall, will have reduced exposures to indoor asthma triggers.

Additional information on EPA's indoor air programs can be found EPA's Indoor Air Toxics web site.[5]

2.2.5.3 Health Risks and Indoor Pollutants

The health risks from a few indoor air toxics (e.g., radon, environmental tobacco smoke, benzene, lead, and asbestos) are well known and have been the subject of risk assessments both within and outside EPA. EPA's best estimate of annual lung cancer deaths from radon is currently about 21,000 (with an uncertainty range of 8,000 to 45,000). Environmental tobacco smoke is estimated to cause an additional 3,000 lung cancer deaths in non-smokers each year. EPA estimates that environmental tobacco smoke may also significantly aggravate symptoms of asthma for 200,000 children and may affect as many as 1,000,000 children to some extent. A California report estimates that environmental tobacco smoke causes 9,700 to 18,600 cases of low birth weight in infants each year and 35,000 to 62,000 cardiovascular deaths among non-smokers.[10]

To prioritize activities for other chemicals typically found in indoor air, EPA's Office of Radiation and Indoor Air (ORIA) is sponsoring a screening-level, risk-based analysis, which is currently in draft form and being revised. Some of the chemicals that may be of concern in indoor air, based on the draft ranking, are provided in the box to the right. However, it should be noted that the final results of this analysis may be significantly different. It should also be noted that, because monitoring data were only available for 112 chemicals and only 59 chemicals could be ranked, many chemicals found indoors might rank higher, given more complete information.

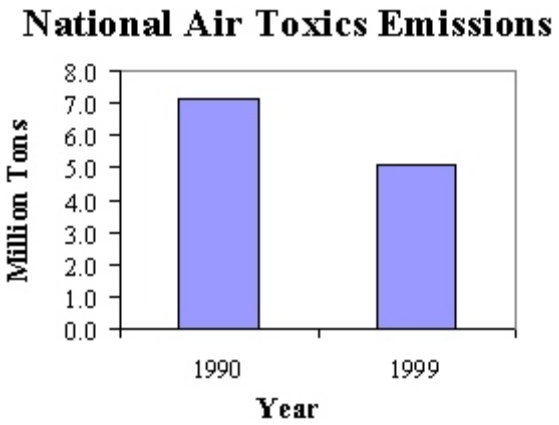
Some Pollutants of Potential Concern Indoors

- Formaldehyde
- Heptachlor
- 1,4-Dichlorobenzene
- Aldrin
- Chloroform
- Dieldrin
- Benzene
- Chlordane
- Tetrachloroethylene
- Acetaldehyde
- Trichloroethylene
- Dichlorvos
- Methylene chloride
- Lindane

Both acute and chronic cancer and noncancer health effects were addressed in the analysis, which focused on inhalation exposure only. Ten monitoring studies provided 213 concentration records for 112 air toxics including metals, aldehydes, volatile organic compounds (VOCs), and semivolatile organic compounds (SVOCs). Studied microenvironments included office buildings, residences, and schools. The general methodology used in the analysis echoed that used by the stationary source program to choose a list of urban HAPs for the Integrated Urban Air Toxics Strategy (64 FR 38706).

The study also estimated the indoor source contribution to indoor concentrations by subtracting associated outdoor concentrations from indoor concentrations. The listed pollutants were found to have large indoor source components. Note, however, that four of the listed pollutants (i.e., heptachlor, aldrin, dieldrin, and chlordane) are pesticides that are no longer in use but may continue to be of concern due to their persistence in the environment and the presence of unused and uncollected stocks.[11]

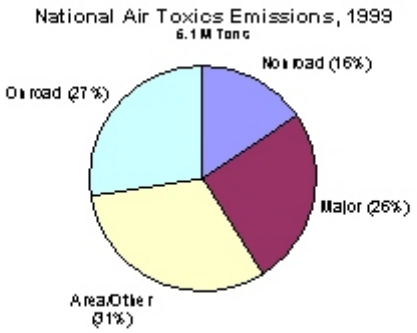
2.3 Progress in Understanding and Reducing Toxic Air Pollution



While monitoring data is critical to understanding and reducing toxic air pollution, EPA and S/L/T governments do not currently maintain as extensive a nationwide monitoring network for outdoor concentrations of air toxics as they do for many of the other pollutants (such as ozone and particulate matter). And, while EPA and S/L/T regulatory agencies do collect monitoring data for a number of toxic air pollutants, both the chemicals monitored and the geographic coverage of the monitors vary among individual S/L/T partners. EPA is working with these regulatory partners to build upon the existing monitoring sites to create a national outdoor monitoring network for a number of toxic air pollutants. The Agency's goal is to improve the scientific and technical competency of existing outdoor air monitoring networks in order to be more responsive to the public and the scientific and health communities; in this way, EPA can accommodate future needs in the face of scarce resources.

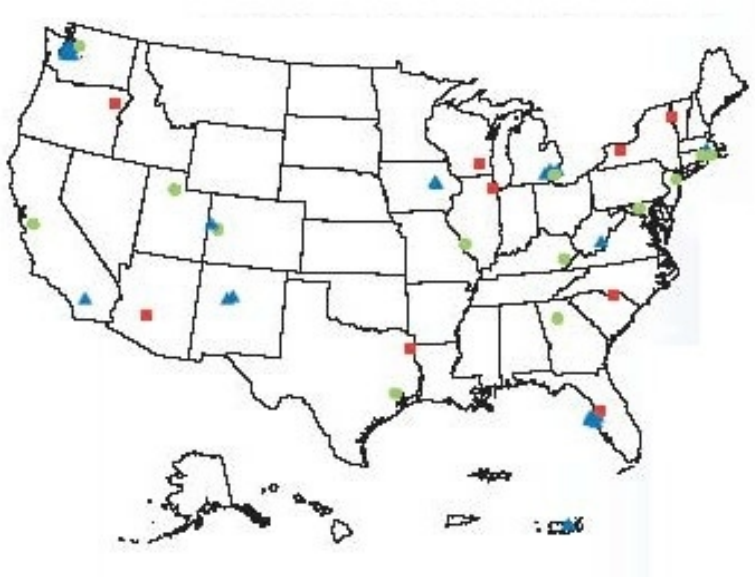
2.3.1 Trends

Monitoring data that are available can help air pollution control agencies track local trends in toxic air pollutants around the country. EPA began a pilot city monitoring project in 2001 with the intention to help answer several important national network design questions (e.g., sampling and analysis precision, sources of variability, and minimum quantitation levels). Based on the results of this year-long study and an analysis of historical monitoring data, the Agency is establishing a network of 22-city National Air Toxics Trends Sites (NATTS) that will help develop national trends for several pollutants of concern. For the latest information on national air toxics monitoring, see www.epa.gov/ttn/amtic/airtxfil.html.

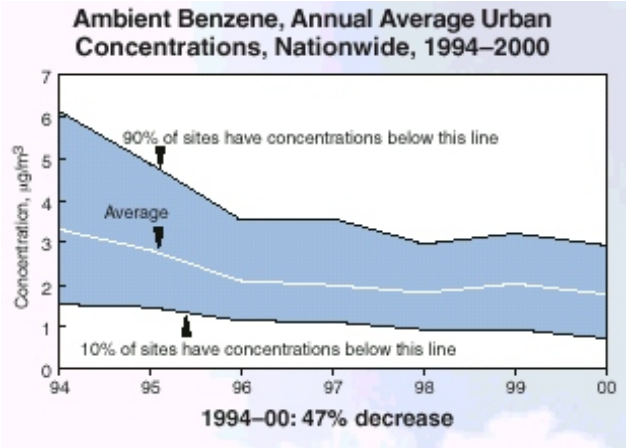


As shown in this pie chart, based on 1999 estimates (the most recent year of available data in the National Emissions Inventory (NEI) for air toxics), the emissions of HAPs are relatively equally divided between four types of sources: on road, non road, major, and area/other sources. However, this distribution varies from city to city.

Based on the data in the NEI, estimates of nationwide outdoor air toxics emissions have dropped approximately 29 percent between baseline (1990-1993) and 1999. Thirty-three of these air toxics (the Urban Air Toxics), which are considered to pose the greatest threat to public health in most urban areas, have similarly dropped 31 percent. Although changes in how EPA compiled the national inventory over time may account for some differences, EPA and S/L/T regulations, as well as voluntary reductions by industry have also achieved large reductions in air toxic emissions.

National Air Toxics Trends Stations (NAATS) Sites		
		
January 2003 Startup ●	**January 2004 Startup** ■	**Pilot Programs** ▲
Providence, RI Roxbury, MA New York, NY Washington, DC Decatur (Atlanta), GA Hazard, KY** Detroit, MI Deer Park (Houston), TX St. Louis, MO Bountiful, UT Grand Junction, CO** San Jose, CA Seattle, WA	Chittenden County, VT** Rochester, NY Tampa, FL Chesterfield, SC** Chicago, IL Mayville, WI Harrison County, TX** Phoenix, AZ La Grande, OR**	Barcelona/San Juan, PR Providence, RI Keeney Knob, WV Tampa, FL Detroit, MI Rio Rancho, NM Cedar Rapids, IA San Jacinto, CA Grand Junction, CO Seattle, WA ** rural site
Source: EPA's *Latest Findings on National Air Quality*[12]		

Trends for individual air toxics vary from pollutant to pollutant. Benzene, the most widely monitored toxic air pollutant, is emitted from cars, trucks, oil refineries, and chemical processes. The graph at right shows measurements of benzene taken from 95 urban monitoring sites around the country. These urban areas generally have higher levels of benzene than other areas of the country. These site measurements show, on average, a 47 percent drop in benzene levels from 1994 to 2000 (see adjacent graph). During this period,



EPA phased in new (so-called "tier 1") car emission standards, implemented the federal reformulated gasoline program in several parts of the country, and required reductions in emissions of benzene and other HAPs from oil refineries and chemical manufacturers. EPA estimates that, nationwide, benzene emissions from all sources dropped 20 percent from 1990 to 1996.

2.3.2 NATA National Scale Assessment

As part of its National Air Toxics Assessment (NATA)[f] activities, EPA has developed a national-scale risk characterization for 33 toxic air pollutants (Exhibit 2-1), based on 1996 emissions data. This set of pollutants is similar to the list of 33 Urban Air Toxics except that diesel particulate matter is included and dioxin is not. EPA used computer modeling of the 1996 NEI air toxics data as the basis for developing health risk estimates. The goal of the national-scale assessment risk characterization is to identify those air toxics which may be of potential concern in terms of contribution to population risk. The results are being used to, among other things, set priorities for the collection of additional air toxics data (e.g., emissions data and ambient monitoring data). EPA plans to update the national scale assessment every three years.

A number of important limitations and uncertainties are associated with the national scale assessment (see Summary of Limitations, Variability, and Uncertainty in the 1996 National-Scale Air Toxics Assessment box). Nonetheless, the results provide important information for priority setting. For example, the following map shows the distribution of relative predicted cancer risk attributed to exposures to outdoor sources of air toxics across the continental United States as estimated by the national-scale assessment. The highest ranking 20 percent of counties in terms of risk (622 counties) contain almost three-fourths of the U.S. population. Three air toxics (chromium, benzene, and formaldehyde) appear to pose the greatest nationwide carcinogenic risk. This map does not include the potential risk from diesel exhaust emissions because the existing health data were not deemed sufficient to develop a numerical estimate of cancer risk for this pollutant. However, exposure to diesel exhaust is widespread, and EPA has concluded that diesel exhaust is a likely human carcinogen and ranks it with the other substances that the national-scale assessment suggests pose the greatest relative risk. One toxic air pollutant, acrolein, is estimated to pose the highest potential nationwide for chronic adverse effects other than cancer. For more information about NATA activities, see www.epa.gov/ttn/atw/nata.

This technical assessment represents an important step toward characterizing air toxics nationwide. It is designed to help identify general patterns in air toxics exposure and risk across the country, but is not recommended as a tool to characterize or compare risk at local levels (e.g., to compare risks from one part of a city to another). More localized assessments, including monitoring and modeling, provide a more appropriate way to accurately characterize local-scale risk.

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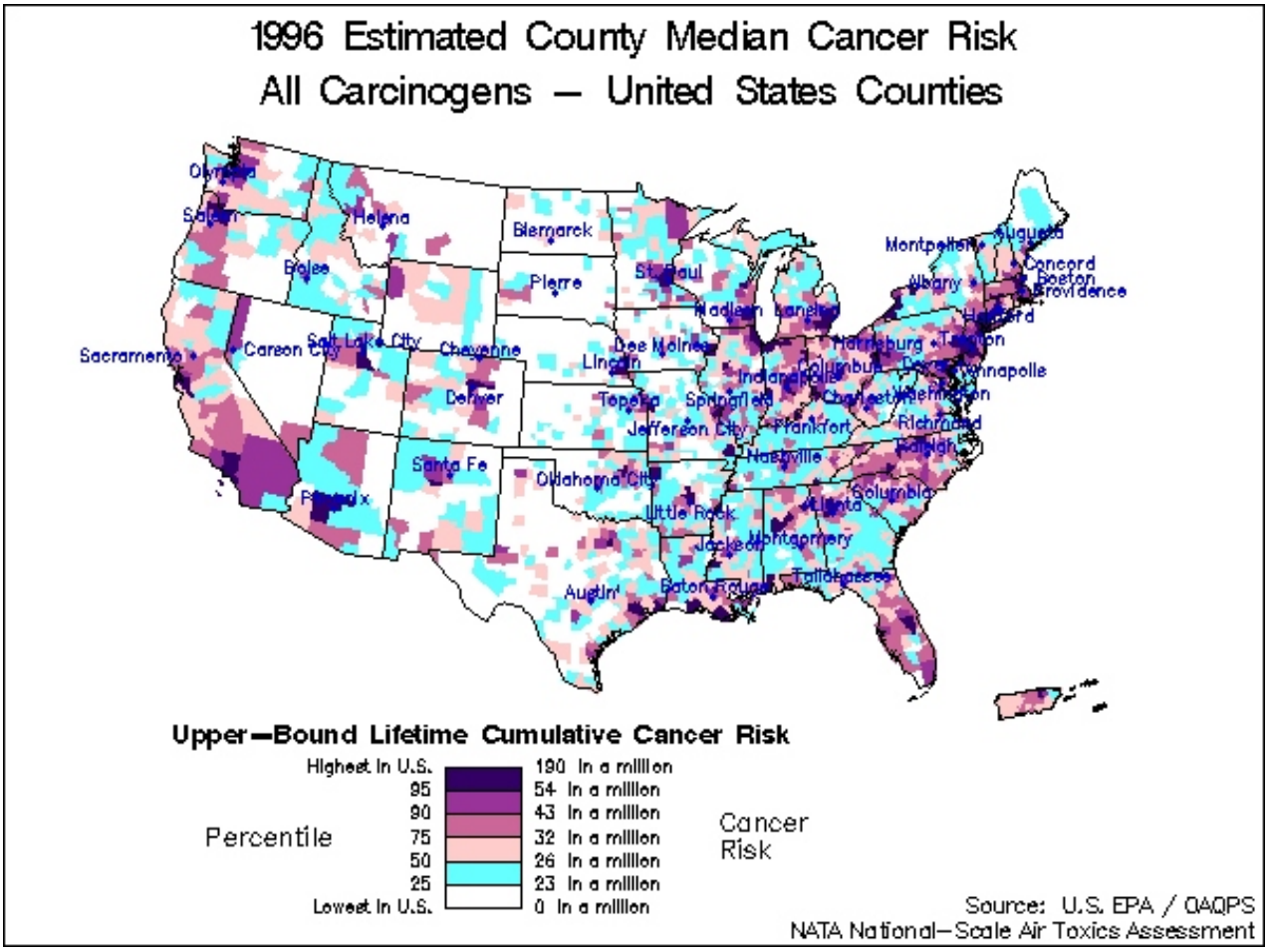
[f] NATA is EPA's ongoing comprehensive evaluation of air toxics in the U.S. These activities include expansion of air toxics monitoring, improving and periodically updating emission inventories, improving national- and local-scale modeling, continuing research on health effects and exposures to both ambient and indoor air, and improving assessment tools (http://www.epa.gov/ttn/atw/nata/index.html).

Exhibit 2-1. The 33 Pollutants Included in the National-Scale Air Toxics Assessment		
acetaldehyde	coke oven emissions	mercury compounds
acrolein	1,3-dichloropropene	methylene chloride
acrylonitrile	diesel particulate matter	nickel compounds
arsenic compounds	ethylene dibromide	perchlorothylene
benzene	ethylene dichloride	polychlorinated biphenyls (PCBs)
beryllium compounds	ethylene oxide	polycyclic organic matter (POM)[a]
1,3-butadiene	formaldehyde	propylene dichloride
cadmium compounds	hexachlorobenzene	quinoline
carbon tetrachloride	hydrazine	1,1,2,2-tetrachloroethane
chloroform	lead compounds	trichloroethylene
chromium compounds	manganese compounds	vinyl chloride

[a]Also represented as 7-PAH
EPA plans eventually to include all 188 HAPs in the NATA national-scale assessment
Source: http://www.epa.gov/ttn/atw/nata/34poll.html



Summary of Limitations, Variability, and Uncertainty in the 1996 National-Scale Air Toxics Assessment[a]

- **Limitations**. The NATA results provide macro-level data on emissions, ambient air concentrations, exposures, and risks across broad geographic areas (such as counties, states and the nation) at a moment in time. As such, they help the EPA identify specific air toxics compounds, and specific source sectors such as stationary sources or mobile sources, which generally produce the highest exposures and risks in the country. But the results are also based on assumptions and methods that limit the range of questions that can be answered reliably. The data cannot be used to identify exposures and risks for specific individuals, or even to identify exposures and risks in small geographic regions such as a specific census tract. Also, these data are not appropriate for determining impacts close to particular facilities. These limitations, or caveats, must always be kept in mind when interpreting the results, and the results should be used only to address questions for which the assessment methods are suited.

- **Variability**. Emissions, air concentrations, exposures and risks are not the same throughout the U.S., and are not the same for every person. Some geographic areas have higher concentrations than others; there are some periods of time when the concentration is higher at a given location than at other times. Some individuals have an exposure and/or risk below the national average, while others have an exposure and/or risk above the national average. It is necessary, therefore, to have some idea of how the ambient air toxics concentrations, exposures, and risks vary throughout the U.S. Such a process is called a variability analysis.

- **Uncertainty**. EPA seeks to protect health with reasonable confidence. Scientific estimates of air concentrations, exposures, and risks, however, always involve simplifying assumptions that make the assessment possible given available information and resources. These assumptions introduce uncertainties into the results, since there is never complete confidence that the assumptions are entirely correct. It is necessary to understand the size of these uncertainties, the level of confidence that can be placed in any statement related to the assessment, and how this confidence affects the ability to make reasoned decisions. Such a process is called an uncertainty analysis.

[a]More detailed discussion of specific limitations, variability, and uncertainty associated with the 1996 national-scale assessment is provided in three individual pages accessed by links from http://www.epa.gov/ttn/atw/nata/natsalim2.html.

2.4 Other Air Pollutants of Potential Concern

As previously noted, there are many other air pollutants that may be harmful to public health and the environment and, for some of these chemicals, other programs may already be in place to help control them. This section discusses several groups of air pollutants, some of which overlap with the list of 188 HAPs.

2.4.1 Criteria Air Pollutants

Pursuant to the CAA, EPA has set standards, also known as **National Ambient Air Quality Standards (NAAQS)**, for six **criteria pollutants** (Exhibit 2-2). The Clean Air Act requires these standards to be set at levels that protect public health with an adequate margin of safety and without consideration of cost. These standards serve two important purposes: first, they provide information to the public about whether the air in their community is healthful; and second, they

present state and local governments with the targets they must meet to achieve clean air. EPA requires that each state containing areas that do not attain the standards develop a written plan for cleaning the air in those areas. The plans developed are called state implementation plans (SIPs). Through these plans, the states outline efforts that they will make to try to correct the levels of air pollution and bring their areas back into attainment.

Exhibit 2-2. National Ambient Air Quality Standards (NAAQS)

Pollutant	Standard Value*		Standard Type
Carbon Monoxide (CO)			
8-hour Average	9 ppm	(10 mg/m^3)	Primary
1-hour Average	35 ppm	(40 mg/m^3)	Primary
Nitrogen Dioxide (NO_2)			
Annual Arithmetic Mean	0.053 ppm	(100 µg/m^3)	Primary & Secondary
Ozone (O_3)			
1-hour Average	0.12 ppm	(235 µg/m^3)	Primary & Secondary
8-hour Average	0.08 ppm	(157 µg/m^3)	Primary & Secondary
Lead (Pb)			
Quarterly Average	1.5 µg/m^3		Primary & Secondary
Particulate (PM_{10}) *Particles with diameters of 10 micrometers or less*			
Annual Arithmetic Mean	50 µg/m^3		Primary & Secondary
24-hour Average	150 µg/m^3		Primary & Secondary
Particulate ($PM_{2.5}$) *Particles with diameters of 2.5 micrometers or less*			
Annual Arithmetic Mean	15 µg/m^3		Primary & Secondary
24-hour Average	65 µg/m^3		Primary & Secondary
Sulfur Dioxide (SO_2)			
Annual Arithmetic Mean	0.030 ppm	(80 µg/m^3)	Primary
24-hour Average	0.140 ppm	(365 µg/m^3)	Primary
3-hour Average	0.500 ppm	(1300 µg/m^3)	Secondary

* Parenthetical value is an approximately equivalent concentration

Four of these pollutants (CO, Pb, NO_2, and SO_2) result primarily through direct emissions from a variety of sources. PM results from direct emissions, but is also commonly formed from emissions of nitrogen oxides (NO_x), sulfur oxides (SO_x), ammonia, organic compounds, and other gases in the atmosphere. Sources of fine particles ($PM_{2.5}$) include many types of combustion activities (e.g., motor vehicles, power plants, wood burning) and certain industrial processes. Ozone is not directly emitted from sources, but is formed when NO_x and VOCs react in the presence of sunlight.

Exposure to the criteria pollutants is associated with numerous effects on human health, including increased respiratory symptoms, hospitalization for heart or lung diseases, and even premature death. The CAA established two types of NAAQS for the criteria pollutants:

- **Primary standards** are designed to establish limits to protect public health, including the health of sensitive populations such as asthmatics, children, and the elderly.

- **Secondary standards** set limits to protect public welfare, including protection against visibility impairment and adverse effects on crops, vegetation, and building materials.

Many of the health effects associated with the criteria pollutants can happen within a few hours or days after breathing polluted air. Thus, EPA has developed an index, called the Air Quality Index or AQI, for reporting daily air quality. The AQI can be thought of as a yardstick that runs from 0 to 500. The higher the AQI value, the greater the level of air pollution and the greater the health danger. For example, an AQI value of 50 represents good air quality and little potential to affect public health, while an AQI value over 300 represents hazardous air quality. Most States now provide this information to their citizens on either their own website or through the EPA's AirNow website (http://www.epa.gov/airnow/where/).

Air Quality Index

Air Quality Index (AQI) Values	Levels of Health Concern	Colors
0 to 50	Good	Green
51 to 100	Moderate	Yellow
101 to 150	Unhealthy for sensitive groups	Orange
151 to 200	Unhealthy	Red
201 to 300	Very Unhealthy	Purple
301 to 500	Hazardous	Maroon

Despite the progress made in the last 30 years, millions of people live in counties in which monitoring data show unhealthy air for one or more of the six criteria pollutants. EPA's most recent evaluation of air pollution trends for these six pollutants can be found at http://www.epa.gov/airtrends/. General information on the criteria pollutants can be found at http://www.epa.gov/air/urbanair/6poll.html.

2.4.2 Chemicals on the Toxics Release Inventory

In 1984, a cloud of methyl isocyanate released from an accident at a pesticide plant in Bhopal, India, killed thousands of people. Shortly thereafter, there was a serious chemical release at a sister plant in West Virginia. These incidents underscored the needs of industrial workers and communities for more complete information on hazardous materials. Public interest and environmental organizations around the country increased demands for information on toxic chemicals being released "beyond the fence line" – outside of the facility. In response, Congress enacted the Emergency Planning and Community Right-to-Know Act (EPCRA) in 1986. Shortly thereafter, the CAA Amendments of 1990 required EPA to publish regulations and guidance for chemical accident prevention at facilities using extremely hazardous substances (see box below).

Risk Management Planning: Accidental Release Prevention

The CAA Amendments of 1990 required EPA to publish regulations and guidance for chemical accident prevention at facilities using extremely hazardous substances. The Risk Management Program Rule was written to implement section 112(r) of these amendments. The rule, which built upon existing industry codes and standards, requires companies of all sizes that use certain flammable and toxic substances to develop a Risk Management Program, which includes a(n):

- Hazard assessment that details the potential effects of an accidental release, an accident history of the last five years, and an evaluation of worst-case and alternative accidental releases;
- Prevention program that includes safety precautions and maintenance, monitoring, and employee training measures; and
- Emergency response program that spells out emergency health care, employee training measures, and procedures for informing the public and response agencies (e.g., the fire department) should an accident occur.

A summary of each facility's risk management program (known as a "Risk Management Plan" or "RMP") was to be submitted to EPA by 1999 and must be revised and resubmitted every five years.

The List of Regulated Substances under section 112(r) of the Clean Air Act is found in 40 CFR Part 68 and lists the regulated substances, including their synonyms, and threshold quantities (in pounds) to help facilities assess if they are subject to the RMP rule or the general duty clause (see http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr68_00.html). Note that pursuant to section 112(r), threshold quantities for RMPs, are of *amounts stored on site* and not emissions. Additional information on the Risk Management Program can be found at: http://yosemite.epa.gov/oswer/ceppoweb.nsf/content/RMPS.htm

EPCRA's primary purpose is to inform communities and citizens of chemical hazards in their areas. Sections 311 and 312 of EPCRA require businesses to report the locations and quantities of chemicals stored on-site as a means of helping communities prepare for chemical spills and similar emergencies. EPCRA section 313 requires EPA and the states to annually collect data on releases and transfers of listed toxic chemicals from certain industrial facilities, and make the data available to the public in the Toxics Release Inventory (TRI). In 1990, Congress passed the Pollution Prevention Act which required that additional data on waste management and source reduction activities also be reported in the TRI. One of the goals of the TRI is to empower citizens, through information, to hold companies and local governments accountable for the management of toxic chemicals.

The TRI program has expanded significantly since its inception in 1987. The Agency has issued rules to roughly double the number of chemicals that the TRI includes to over 650. The TRI has added seven new industry sectors, expanding coverage significantly beyond manufacturing industries. Most recently, the Agency has reduced the reporting thresholds for certain persistent, bioaccumulative, and toxic (PBT) chemicals (discussed in Chapter 4) in order to provide additional information to the public on these chemicals. A full list of the TRI chemicals, along with information on accessing the database and health and environmental effects information, can be found at http://www.epa.gov/tri/.

2.4.3 Toxic Chemicals that Persist and Which Also May Bioaccumulate

Toxic chemicals that persist and which also may bioaccumulate are compounds that can build up in the food chain to levels that are harmful to human and ecosystem health. Such chemicals, commonly called PBT chemicals, may be associated with a range of adverse human health effects, including effects on the nervous system, reproductive and developmental problems, cancer, and genetic impacts. EPA's challenge in reducing risks from these chemicals stems from the pollutant's ability to transfer easily between air, water, and land; to linger for generations in people and the environment; and in some cases to travel long distances. A number of "lists" of these chemicals have been developed through international and EPA efforts (see Chapter 4).

Over the years, much work has been done to reduce the risk associated with these chemicals. However, the nation still finds PBT chemicals in the air, water, land, and, as a result, food. For example, the total number of advisories for eating contaminated fish in the United States increased by 93 percent from 1993 to 2002.[13] Although there are advisories for a total of 39 chemical contaminants, most advisories involve five primary contaminants: mercury, PCBs, dioxins, DDT, and chlordane. Almost 75 percent of the advisories have been issued at least in part because of mercury contamination. The 2,800 advisories issued in 2002 represent approximately 33 percent of the nation's total lake acreage and over 15 percent of the nation's total river miles.

Until the late 1990s, EPA actions to reduce emissions of toxic chemicals that persist and which also may bioaccumulate have been separate regulatory activities aimed at pollutant releases to individual environmental media (air, water, or land). In 1998, EPA developed a **PBT Strategy** to better coordinate these actions and to assure, for example, that regulations removing a pollutant from the air do not inadvertently result in transferring it to the land or water (http://www.epa.gov/opptintr/pbt/). The main goals of the strategy are to:

- Develop and implement national action plans to reduce priority PBT pollutants, utilizing the full range of EPA tools;
- Continue to screen and select more priority PBT pollutants for action;
- Prevent new PBTs from entering the marketplace; and
- Measure progress of these actions against the Government Performance and Results Act (GPRA) goals and national commitments.

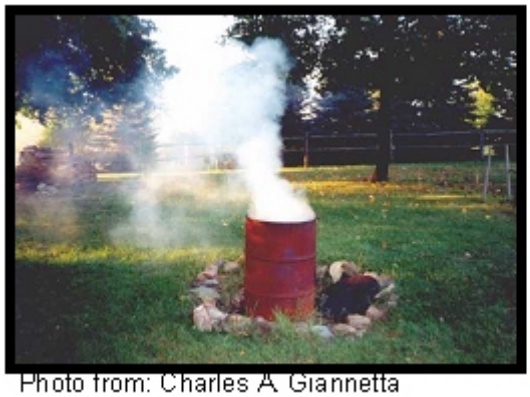
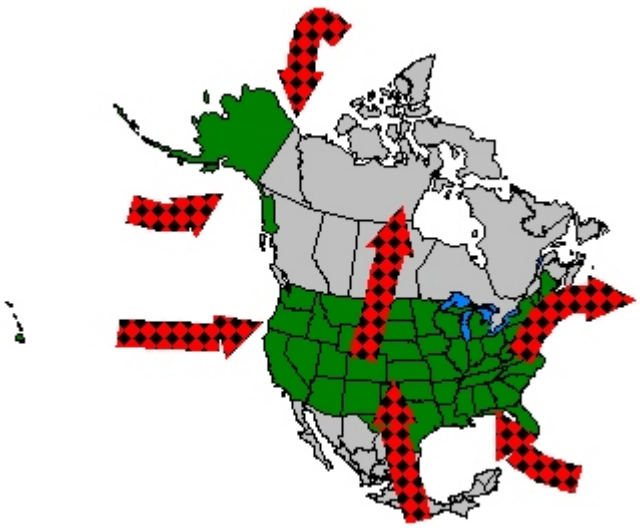


Photo from: Charles A. Giannetta

The Agency-wide strategy enables EPA to harness all of its tools – voluntary, regulatory, international, enforcement, compliance, and research – and direct them at a set of priority pollutants of common concern to all EPA program offices. Implementing the strategy will require time and the coordination of many EPA offices as well as other stakeholders, such as industry, other governmental groups, and the international community.

International Transport of Air Pollutants

There is the potential for toxic chemicals that persist and which also may bioaccumulate to be transported from long distances to contaminate distant regions of the globe. An investigation by EPA Region 5 has shown the possibility of long-range transport of certain of these chemicals (identified in an international treaty as "persistent organic pollutants," or POPs – see Chapter 4) which were used in Central America prior to the 1980s to impact the Great Lakes. This is due to several phenomena. The semi-volatility of many POPs, allows them to be volatilized from warmer regions of the globe and redeposited in cooler regions in higher latitudes. Additionally, meteorological patterns during certain times of year can transport air masses and pollutants from the Central American region though the central U.S. into the northern states. Air masses from Central America have an unobstructed path to the Great Lakes (e.g. no physical barriers such as mountain ranges). Satellite photos show the transport of smoke from Central American fires in May of 1998 up through the Great Lakes Region.



This figure illustrates the mean wind flow at 1500 meters of altitude during the months of June, July and August from 1985 to 1996. Although these patterns can be disrupted by climatological events such as El Niño, it is clear that POPs released in the southern areas of this hemisphere can impact areas of the U.S. Studies have shown that long range transport from many regions of the globe is a significant source of POP chemicals to the Great Lakes and that mitigation efforts are going to be needed both in the U.S. and globally to address potential sources. The study of Central American sources has shown that this region is a potential contributor to POPs contamination in the Great Lakes, due to the fact that these chemicals degrade very slowly, and there still exist areas of high contamination and stockpiles of these chemicals that are no longer in use in Cental America.

For more information on International Issues & U.S. Air Quality, see EPA's Air Trends website at http://www.epa.gov/airtrends/international.html

2.4.4 Overlaps and Differences Between Chemical "Lists"

The various lists of chemicals discussed above (e.g., HAPs, criteria air pollutants, TRI chemicals) do not always treat groups of chemicals (or chemical precursors/reaction products) in the same manner. Some examples of the ways in which these lists overlap or differ include:

- "Glycol ethers" are defined differently for the TRI and as HAPs (see box below);
- Ozone is formed by the interaction of NO_X, VOCs, and sunlight. Some of the HAPs are VOCs that may contribute to ozone formation;
- "Particulate matter" that is regulated as a criteria pollutant can be comprised of any number of individual chemicals and may contain various HAPs.

Glycol Ethers in the TRI and as HAPs

The TRI includes certain glycol ethers R-(OCH2CH2)n -OR' where:
n = 1, 2, or 3
R = alkyl C7 or less; phenyl or alkyl substituted phenyl
R' = H, or alkyl C7 or less
OR' consisting of carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.

The list of HAPs includes mono- and di- ethers of ethylene glycol, diethylene glycol, and triethylene glycol R-(OCH2CH2)n -OR' where:
n = 1, 2, or 3
R = alkyl or aryl groups
R' = R, H, or groups which, when removed, yield glycol ethers with the structure: R-(OCH2CH)n-OH.
Polymers (surfactant alcohol ethoxylates and their derivatives)are excluded from the glycol category.

It is important to keep these overlaps and differences in mind since they can have important legal, policy, and other practical implications when studying air toxics impact or developing risk reduction alternatives for a particular location. The reader should also remember that the differences among chemical "lists" are based mostly on legal and regulatory considerations, not necessarily on toxicologic properties.

2.5 Reports to Congress on Air Toxics Issues

The CAA requires EPA to study and produce reports on several specific topics relevant to our understanding of air toxics and the risks they pose to human health. These studies have been critical to our understanding of important air toxics sources and how certain chemicals move through and impact our environment. A synopsis of several of these studies is presented below. Links to all of the various reports can be found at http://www.epa.gov/ttn/oarpg/t3rc.html.

2.5.1 Air Toxics Deposition to the Great Waters

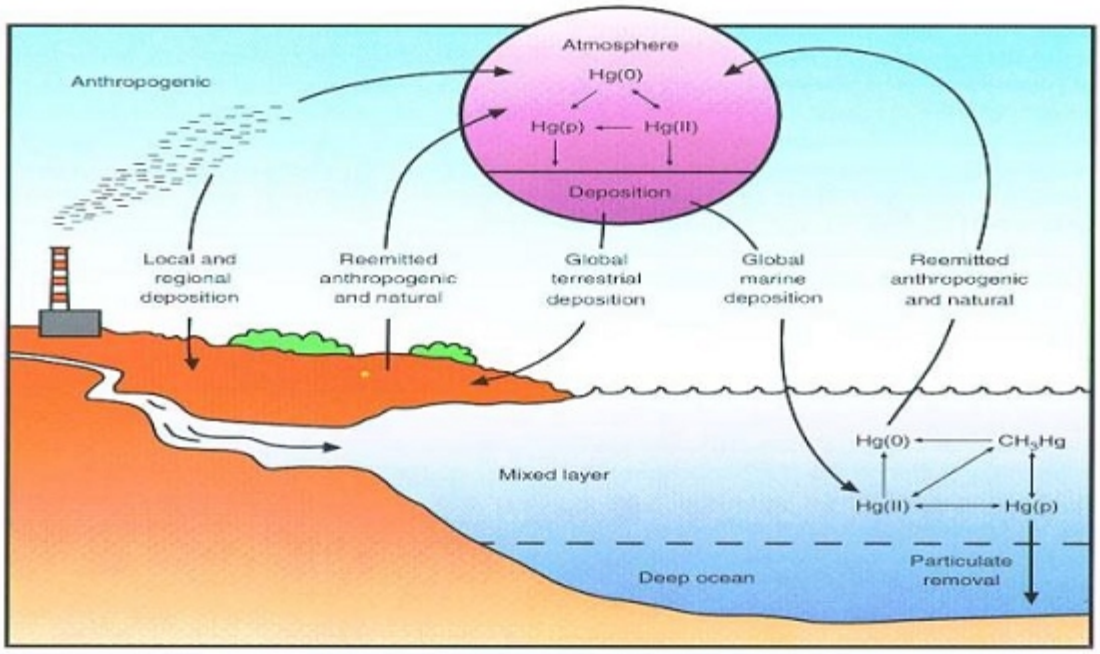
Pursuant to section 112(m) of the CAA, EPA, in conjunction with the National Oceanic and Atmospheric Administration (NOAA), has issued three reports to Congress on the deposition of air toxics and the resulting effects on the Great Lakes, Chesapeake Bay, Lake Champlain, and certain other coastal waters, collectively known as the **Great Waters**. In addition to EPA and NOAA, other international, national, regional, and local organizations also contribute to the body of science relevant to the Great Waters program and are engaged in activities that seek to reduce sources and quantities of pollution to the Great Waters. These activities focus on 15 **pollutants of concern**, including certain pesticides, metal compounds, chlorinated organic compounds, and nitrogen compounds. These pollutants enter the air in a variety of ways, including direct emission from industries and natural sources, and "re-emission" from soil and water. The Agency selected pollutants of concern due to their persistence, potential to bioaccumulate, and/or potential for adverse impacts to the Great Waters. Some of these pollutants are also likely **endocrine disruptors**, meaning they may interfere with the action of hormones in wildlife and humans. EPA will work to increase public awareness of risks of exposure to Great Waters pollutants as well as continue to support the development of modeling tools that address the transport and fate of pollutants in ecosystems and characterize risk, including research to clarify mechanisms of mercury methylation so as to better predict and manage ecosystems at risk. The most recent Great Waters Report to Congress is available at http://www.epa.gov/airprogm/oar/oaqps/gr8water/.

2.5.2 Mercury Study Report to Congress

Mercury compounds are one of the 188 HAPs. They are of concern because they persist in the environment, and bioaccumulate in food, and are associated with serious health and environmental effects, including neurological impacts in infants. Coal-fired electric utility plants are the largest air emission sources of mercury in the U.S. (responsible for approximately 40 percent of 1999 emissions). Resultant mercury concentrations in air are usually low and of little direct concern. However, when mercury enters surface waters, biological processes transform it to a highly toxic form that accumulates in fish, which can result in large exposures to fish consumers (including people). (See following graphic.)

EPA prepared the 1997 Mercury Study as a Report to Congress pursuant to the requirements of section 112(n)(1)(B) of the CAA to provide an assessment of the magnitude of U.S. mercury emissions by source, the health and environmental implications of those emissions, and the availability and cost of control technologies. As the state-of-the-science for mercury is continuously and rapidly evolving, this Report represents a "snapshot" of our understanding of mercury. This Report does not quantify the risk from mercury exposure because of scientific uncertainty in a number of important areas. The Report identifies areas where further research is needed to provide a quantitative risk assessment. The full Report can be accessed at http://www.epa.gov/ttn/atw/112nmerc/mercury.html.

Mercury Cycling in the Environment



2.5.3 Utility Report to Congress

Section 112(n)(1)(A) of the 1990 CAA Amendments required EPA to conduct a study of the public health impacts of emissions of air toxics from electric utilities that burn fossil fuel. Utility emissions include 67 HAPs, including arsenic compounds, nickel compounds, chromium compounds, radionuclides, and mercury compounds. EPA has presented the results of these studies in two key documents, a 1998 Report to Congress and a 1999 analysis of emissions reduction options. The key findings of the report to Congress include:

- **Air Toxics Emissions of Concern**. The report indicates that, although uncertainties in the analysis exist, on balance, mercury from coal-fired utilities is the hazardous air pollutant of greatest potential public health concern. Three other air toxics are identified, for which there are some potential concerns and uncertainties that may need further study: dioxins, arsenic, and nickel.

- **Risk Assessment of Exposure Pathways Other Than Inhalation**. The assessment determined that exposures due to non-inhalation routes (i.e., dermal, ingestion) are by far the most important routes of exposure for mercury and dioxins. For arsenic and radionuclides, both inhalation and ingestion appear to be important exposure routes. However, there are uncertainties and limitations in the data that indicate a need for further evaluation to more fully characterize the public health impacts of these pollutant emissions from utilities.

- **Inhalation Exposure Assessment**. The modeling assessment suggests that a substantial fraction of the utility emissions are dispersed well beyond the local area due to the nature of the emissions (mostly fine particulate substances) and the height of the tall stacks. Assessment of inhalation exposure for the 67 air toxics emitted by utilities indicate that the cancer risk from inhalation exposure is estimated to be less than one in a million for the majority of utility plants, with a few plants perhaps with slightly greater risks. Further research and evaluation may be needed to more comprehensively assess the inhalation cancer risks.

- **Mercury**. The results of the investigation indicate that mercury from coal-fired utilities is the air pollutant of greatest potential concern to public health from utilities. Coal-fired utilities are estimated to emit about one-third (52 tons) of U.S. anthropogenic (manmade) mercury emissions per year. The risk assessment indicates that ingestion of contaminated fish is the most important route of exposure to mercury. The modeling assessment, in conjunction with available scientific data, provides evidence for a plausible link between emissions of mercury from utilities and the methylmercury found in soil, water, air, and fish. Consequently, mercury emissions from coal-fired utilities may contribute to the potential exposures to mercury through consumption of contaminated fish. However, there remain uncertainties about the extent of impacts directly attributable to mercury emissions from utilities.

- **Alternative Control Strategies**. There are numerous potential alternative control technologies and strategies for air toxics control, although the feasibility and effectiveness of potential control technologies vary.

2.5.4 Residual Risk Report to Congress

The Residual Risk Report to Congress responds to section 112(f)(1) of the Clean Air Act, which requires EPA to investigate and report to Congress on a variety of topics pertaining to the assessment of residual risks associated with air toxics emissions from stationary sources remaining after the implementation of technology based standards per section 112(d) (i.e., MACT standards).[(g)]

While the main purpose of the Report is to describe the methods and the framework that EPA will use to make residual risk determinations, the Report also discusses, in general terms, the available methods of reducing residual risks - including pollution prevention, add-on controls, and voluntary approaches - and factors relevant to costs of these methods; the current state of knowledge regarding health effects of air toxics on humans; and EPA's current methods for collecting and assessing health effects data.

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[g]As touched on in Section 2.2.3.2, section 112(f) of the CAA requires the Agency to consider the need for additional standards following regulation under section 112(d) to protect public health and the environment. Section 112(f) of the CAA specifies that such residual risk standards "provide an ample margin of safety to protect public health." Section 112(f) also requires EPA to determine whether residual risk standards are necessary to prevent "an adverse environmental effect" taking into consideration "costs, energy, safety, and other relevant factors" in deciding what level is protective.

While developed in response to Clean Air Act provisions particular to "residual risk," the report describes methodologies intended for EPA's use more broadly in assessing risk from toxic air pollutants. The Report does not specify a particular method for conducting risk assessments, stressing that EPA has the flexibility to use current techniques along with new methods as they are developed. The full report is available at http://www.epa.gov/ttncaaa1/t3/reports/risk_rep.pdf.

Specifically, the *Residual Risk Report to Congress*[2] identifies two objectives for residual risk activities:

- Assess any risks remaining after MACT standard compliance; and
- Set standards for the identified source categories, if additional HAP emission reductions are necessary to provide an ample margin of safety to protect public health or, taking into account cost, energy, safety, and other relevant factors, to prevent an adverse environmental effect.

2.5.5 Integrated Urban Strategy Report to Congress

The Strategy addresses the need to reduce emissions of air toxics in urban areas and looks collectively at large and small industrial and commercial operations, as well as mobile sources of pollution. The Strategy also includes plans for improving current understanding of the health risks posed by toxics in urban areas. This Report to Congress provides the following: a more detailed examination of the methodologies used for selecting the 33 initial urban air toxics identified in the Strategy; a summary of recent risk assessments conducted in several urban areas; and a detailed discussion of research needs to achieve the goals outlined in the Strategy. These needs were identified in the following areas: exposure assessment, health effects, dose-response assessment, risk assessment, risk characterization, and risk management. The report is available at http://www.epa.gov/ttnatw01/urban/natprpt.pdf.

2.5.6 Other Reports

Finally, EPA prepared two other reports that were called for in the Clean Air Act (http://www.epa.gov/ttn/atw/112npg.html).

First, section 112(n)(5) of the CAA required EPA to assess the public health hazards associated with emissions of hydrogen sulfide from oil and gas extraction. This report, *Hydrogen Sulfide Air Emissions Associated with the Extraction of Oil and Natural Gas* (EPA-453/R-93-045), is available from the National Technical Information Services (NTIS) as publication number PB94-131224.

Second, section 112(n)(6) of the CAA required EPA to assess the public health hazards associated with emissions of hydrofluoric acid in areas that do not have comprehensive health and safety regulations addressing hydrofluoric acid. The *Hydrogen Fluoride Study: Report to Congress* (EPA 550-R-93-001) was published in September 1993 and is available from NTIS as publication number PB 94-121308.

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Chapter 3 EPA's Risk Assessment Process for Air Toxics: History and Overview

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3.1 Introduction

This chapter provides the historical backdrop to the air toxics risk assessment process that is in use at EPA today. It examines the overall framework of the risk assessment process and how the various elements of the process relate to one another, including resource and timing considerations. Subsequent chapters of this reference manual describe each of the specific elements of the risk assessment process in detail.

3.2 A Short History of the Development of Human Health Risk Assessment and Risk Management Approaches for Air Toxics

Risk assessment is not new. However, only recently have some attempted to formalize the process into a coherent framework. This section briefly describes the chronology and important events in the development of those risk assessment methodologies outlined in this document.

3.2.1 The 1983 National Academy of Sciences Report

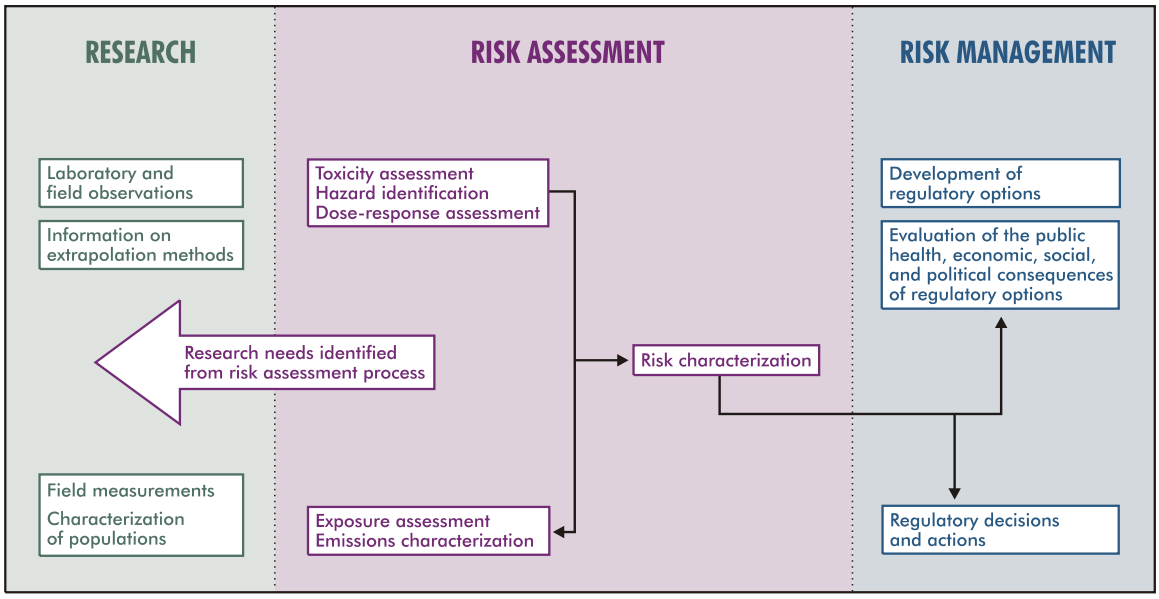
In the 1980s, the emerging practice of federal-level risk assessment spurred Congress to commission a report from the National Research Council (NRC) of the National Academy of Sciences (NAS) on how the process was being used. The result was the landmark 1983 study entitled *Risk Assessment in the Federal Government: Managing the Process*.[1] The document is often referred to as "The Red Book" because of its distinctive red cover. The Red Book acknowledged that regulatory agencies have differing statutory obligations that require some flexibility in both the risk assessment and risk management processes. The Red Book also clarified what risk assessment and risk management are by giving them the definitions that are still commonly used today (see Exhibit 3-1):

Purpose of the 1983 NRC Report

- Assess the merits of separating the analytic functions of developing risk assessments from the regulatory functions of making policy decisions.
- Consider the feasibility of designating a single organization to do risk assessments for all regulatory agencies.
- Consider the feasibility of developing uniform risk assessment guidelines for use by all regulatory agencies.

- "We use **risk assessment** to mean the characterization of the potential adverse health effects of human exposures to environmental hazards" (p. 18).
- "The Committee uses the term **risk management** to describe the process of evaluating alternative regulatory actions and selecting among them" (p. 18).

Exhibit 3-1. Risk Assessment and Risk Management Paradigm



Source: Adapted from the 1983 "Red Book"

The Red Book did not recommend "bright line analysis" because it gives too much weight to risk numbers that are, by their very nature, uncertain. The NRC also made two important recommendations regarding the risk assessment and risk management processes used by federal agencies:

- First, the scientific finding and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.
- Second, uniform guidelines should be developed for use by federal regulatory agencies in the risk assessment process.

Bright Line Analysis

"Bright line analysis" is the process of comparing a risk assessment result (the estimated numerical value of risk) to a preestablished acceptable level of risk (the "bright line") and making risk management decisions solely on whether the estimated risk is above or below the acceptable level. The NRC emphasized that risk assessment results are only one component of the risk management decision process and that assessment results should not be the only information risk managers consider.

The Red Book had a significant impact on risk assessment and management processes throughout the federal government, and it continues to be an influential reference at EPA. For example, in response to its recommendations, EPA established the Risk Assessment Council (RAC) and began publishing Agency-wide risk assessment guidelines (see Section 3.1.4 below). (Note that the recommendation to develop uniform risk assessment guidelines for use by all regulatory agencies did not happen – each agency is still free to develop their own approaches and guidelines.)

3.2.2 The 1994 National Research Council Report

Recognizing the growing importance of quantitative risk assessment in the regulatory process, Congress in section 112(o) of the Clean Air Act (CAA) amendments required EPA to enter into a contract with the NRC to evaluate the risk assessment methods EPA was using at the time. The NRC's 1994 report, *Science and Judgment in Risk Assessment*,[2] was prepared by the NRC's Committee on Risk Assessment of Hazardous Air Pollutants in the Board on Environmental Studies and Toxicology. In a sense, the "Blue Book" was a follow-up to the 1983 Red Book, but with a specific emphasis on EPA's scientific methods.

Purpose of the 1994 NRC Report

Congress asked the NRC to answer the following questions:

- Given that quantitative risk assessment is essential for EPA's implementation of the CAA, is EPA conducting risk assessments in the best possible manner?
- Has EPA developed mechanisms for keeping its risk assessment procedures current in the face of new developments in science?
- Are adequate risk-related data being collected to permit EPA to carry out its mandates?
- What, if anything, should be done to improve EPA's development and use of risk assessments?

The NRC committee observed that several themes were common to all elements of the risk assessment process and noted that these themes were usually the focal points for criticisms of individual risk assessments:

- The use of default assumptions;
- Available data;
- Uncertainty and variability;
- Assessment of multiple chemical exposures, multiple routes of exposure, the potential for multiple adverse effects; and
- Steps taken to validate the methodologies used throughout the risk assessment process.

In the Blue Book, the NRC updated the risk assessment/risk management paradigm and presented several recommendations for increasing the effectiveness and accuracy of EPA's risk assessment and risk management process, particularly as it pertained to air toxics:

- EPA should generally retain its conservative, default-based approach to risk assessment for screening analysis in standard-setting.
- EPA should use iterative approaches that incorporate improvements in both the models and data used in each successive iteration of analysis. For example, EPA should start with relatively inexpensive screening techniques and move to a more resource-intensive level of data-gathering, model construction, and model application as the particular situation warrants. This method avoids costly case-by-case evaluations of individual chemicals at every facility in every source category.

- EPA should explicitly identify each use of a default option in a risk assessment, should clearly state the scientific and policy basis for each default option, and should consider attempting to give greater formality to its criteria for departure from default options.
- EPA should establish regulatory priorities based on initial assessments of each chemical's possible impact on human health and welfare.
- EPA should present not only point estimates of risk, but also the sources and magnitudes of uncertainty associated with these estimates.

EPA has progressively worked to adopt the report's recommendations as it transitions the Agency into the risk-based phase of the CAA legislative strategy for HAPs.

3.2.3 The CRARM

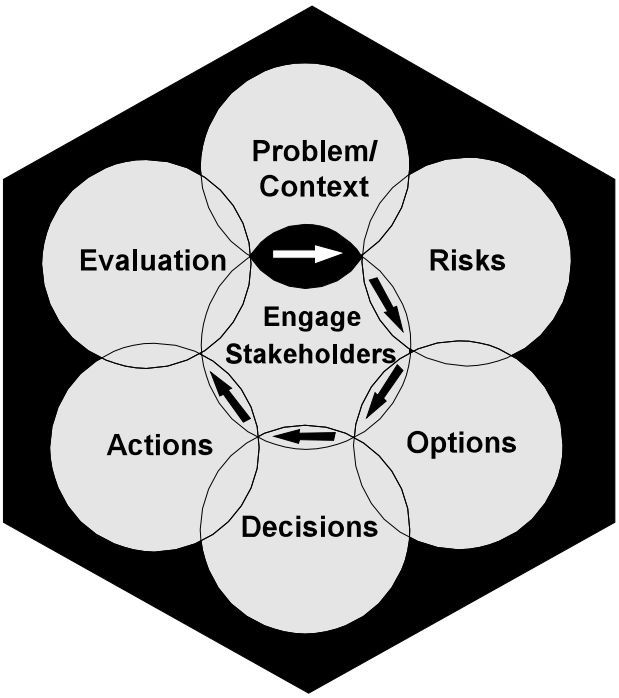
Section 303 of the 1990 CAA Amendments mandated the formation of a Presidential Commission on Risk Assessment and Risk Management (CRARM) in response to unresolved questions about EPA's approach to assessing public health risks remaining after implementation of the maximum achievable control technology (MACT) program (i.e., technology based control). CRARM released its report, *Risk Assessment and Risk Management in Regulatory Decision-Making*, or the White Book, in two volumes in 1997. Volume I focuses on the framework for environmental health risk management. Volume II addresses a variety of technical issues related to risk assessment and risk management, including a common metric for assessment of cancer and other effects, management of residual risks from air toxics, comparative risk, decision criteria, uncertainty analysis, and recommendations to specific agencies.[3]

Purpose of the 1997 White Book

Investigate "the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic health effects which may result from exposure to hazardous substances."

The CRARM developed a risk management framework that fosters an integrated approach to addressing complex, real-world issues that affect multiple environmental media and involve exposures to mixtures of chemicals (Exhibit 3-2). Note that risk assessment (here "risk") is one of several steps in risk management. The framework aims to encourage integrated approaches to environmental risk management.

Exhibit 3-2. The CRARM Framework for Risk Management



The central element of the framework is encouraging stakeholder participation throughout the six stages of risk management. In addition, the framework intends to be iterative – if appropriate, risk assessors can redefine and reassess the risk problem as they develop new data. Another key principle of the framework is that risk management should explicitly consider the comprehensive, real-world context of a risk problem and not limit the context to one that considers only one type of risk associated with a single chemical in a single environmental medium. The CRARM made several additional recommendations:

- **Conduct Comparative Risk Assessment**. Federal agencies should try a comparative risk analysis approach on an experimental or demonstration basis to seek consensus on priorities for managing environmental risks. The results of such efforts should influence agency resource allocation.

- **Harmonize Cancer and Non-Cancer Methodologies**. Assessment techniques for carcinogens and non-carcinogens should be harmonized. This would aid in risk communication, risk management decisions, and comparative risk assessment.

- **Devise Realistic Exposure Scenarios**. Risk management decisions should be based on realistic exposure scenarios, rather than on the hypothetical **maximum exposed individual** (MEI). Distributions of the varied exposures within a population should be evaluated with

explicit attention to specific segments of the population (e.g., individuals with unusually high exposures, infants, children, pregnant women, low-income groups, and minority communities with exposures influenced by social or cultural practices).

- **Place Cost-Benefit Analysis in its Appropriate Context**. Economic analysis is a relevant consideration in risk management decisions, but should not be the overriding factor in a decision. Explicit descriptions of assumptions, data sources, sources of uncertainty, and costs across society should be presented in parallel with descriptions associated with risk assessments.

- **Ensure Interagency Consistency**. Agencies should coordinate their risk assessment methods and assumptions unless there is a specific statutory requirement that allows for different choices. Scientific disagreements should be explained.

- **Conduct Tiered Residual Risk Assessments**. EPA should implement a tiered approach to managing residual risks after implementation of the CAA's technology-based (MACT) standards.

Similar to the recommendations outlined in the Blue Book, EPA has continued to modify its risk assessment guidelines and approaches in response to these recommendations. Other documents, such as the National Research Council's 1996 document entitled *Understanding Risk: Information Decisions in a Democratic Society*,[(4)] also play a role in informing the continued development of the risk assessment and risk management process.[(a)]

3.2.4 Development of Human Health Risk Assessment at EPA

EPA has conducted human health risk assessments since its inception in 1970. EPA built on this early experience while confronting potential hazards associated with pesticide use. For example, after considering available human and non-human toxicity data, EPA restricted domestic use of DDT and other pesticides, in part due to their cancer risks.

Fundamental References for Air Toxics Risk Assessment

(1) Air Toxics Risk Assessment Reference Library, three volumes

(2) The NAS Red and Blue Books

(3) CRARM White Book

(4) EPA Guidelines for Risk Assessment Series

(Full citations are at the end of this chapter.)

EPA acknowledged that such risk-based regulations needed an appropriate scientific basis and began collecting cancer toxicity information on pesticides through administrative hearings and testimony. Summary documents from these hearings became known as the "Cancer Principles." Criticism of these documents, which many inadvertently perceived to be formal Agency cancer risk assessment policy, led the Agency to develop interim guidelines in 1976. Three years later, the

[a] *Understanding Risk* "...illustrates that making risks understandable to the public involves more than translating scientific knowledge. The volume also draws conclusions about what society should expect from risk characterization and offers guidelines and principles for informing the wide variety of risk decisions that face our increasingly technological society." (See http://books.nap.edu/catalog/5138.html.)

Interagency Regulatory Liaison Group (a conglomeration of several federal agencies, including EPA) published additional cancer risk assessment guidelines. Concurrently, EPA used cancer risk assessment techniques in its toxic chemicals regulation under the 1976 Toxic Substances Control Act. By the end of EPA's first decade in existence, the Agency used risk assessment techniques to develop water quality criteria protective of human health.

Throughout the 1980s, EPA increasingly utilized risk assessment to evaluate the potential for chemicals to cause non-cancer health effects in addition to cancer risks. During the 1980s, the Agency used cancer risk assessment techniques in the development of national emission standards for air toxics such as vinyl chloride and benzene.

As EPA increased its use of risk assessment throughout the 1980s, the Agency's inconsistent approach to risk assessment became apparent, largely due to a lack of standard guidance on the topic. To correct this problem, the Agency undertook administrative reforms and published several key guidelines and other policy documents.

First, the Agency published *Risk Assessment and Management: Framework for Decision Making.*[5] EPA intended this reference manual to conform EPA practices with NRC Red Book recommendations and to help the Agency make better and more rapid decisions about environmental toxic chemical problems.

Next, in 1986, EPA established the *Risk Assessment Council* (RAC) to oversee virtually all aspects of the Agency's risk assessment process. EPA appointed Senior Agency officials with experience and responsibilities in the area of science policy and risk assessment to the RAC. This group established EPA's fundamental policies for conducting risk assessments and evaluating risk information. These officials also oversaw the activities of the Risk Assessment Forum.

EPA Risk Assessment Forum

The Risk Assessment Forum is a standing committee of senior EPA scientists established to promote Agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate Agency risk assessment guidance. To fulfill this purpose, the Forum assembles Agency risk assessment experts in a formal process to study and report on issues from an Agency-wide scientific perspective. Major Forum guidance documents are developed in accordance with the Agency's regulatory and policy development process and become Agency policy upon approval by the Administrator or the Deputy Administrator. Risk Assessment Forum products include: risk assessment guidelines, technical panel reports on special risk assessment issues, and peer consultation and peer review workshops addressing controversial risk assessment topics (http://cfpub.epa.gov/ncea/raf/index.cfm).

Subsequently, EPA began publishing an influential series of Agency-wide guidelines in the *Federal Register* identifying the recommended methods for assessing human health risks from environmental pollution. EPA did not intend for these guidelines, which cover both cancer risks and non-cancer hazards, to be static, and the Agency has revised the guidelines as new information and methods become available (for example, EPA began a process in 1996 to revise and update its guidelines for carcinogenicity).

EPA established the Science Policy Council (SPC) in 1993 with a broader mission and as a replacement for the RAC; specifically, the SPC aims to integrate policies that guide Agency decision-makers in their use of scientific and technical information. To accomplish this goal, the SPC works to implement and ensure the success of selected initiatives that external advisory bodies (such as the National Research Council and the Science Advisory Board, as well as others such as the Congress, industry and environmental groups, and Agency staff), recommend. In this way, the SPC provides guidance for selected EPA regulatory and enforcement policies and decisions. The 1995 Guidance for Risk Characterization was an important part of the SPC's risk characterization program. Standing groups such as the Risk Assessment Forum, a Steering Committee, and interim working groups continue to support the SPC. For more information on the SPC, see http://www.epa.gov/osp/spc/2about.htm.

EPA Human Health Risk Assessment Guidelines[a]

Carcinogenicity
- 1999 Draft Revised Guidelines for Carcinogen Risk Assessment[b]
- 1986 Guidelines for Carcinogen Risk Assessment

Chemical mixtures
- 2000 Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures
- 1986 Guidelines for the Health Risk Assessment of Chemical Mixtures

Developmental toxicity
- 1991 Guidelines for Developmental Toxicity Risk Assessment

Exposure assessment
- 1992 Guidelines for Exposure Assessment

Mutagenicity
- 1986 Guidelines for Mutagenicity Risk Assessment

Neurotoxicity
- 1998 Guidelines for Neurotoxicity Risk Assessment

Probabilistic analysis
- 1997 Guiding Principles for Monte Carlo Analysis

Reproductive toxicity
- 1996 Guidelines for Reproductive Toxicity Risk Assessment

Risk characterization
- 2000 Handbook for Risk Characterization
- 1997 Guidance on Cumulative Risk Assessment. Part 1, Planning and Scoping
- 1995 Guidance for Risk Characterization

(a) A current list is available at http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55907.
(b) These guidelines are interim final drafts. Check above website for a final version.

Another important group within EPA with a risk assessment focus is the National Center for Environmental Assessment (NCEA). NCEA is a major component of the EPA's Office of Research and Development and acts as EPA's national resource center for human health and ecological risk assessment. NCEA conducts risk assessments, carries out research to improve the state-of-the-science of risk assessment, and provides guidance and support to risk assessors. Many of the critical Agency documents on risk assessment science and policy, as well as risk related databases such as the Integrated Risk Information System (IRIS), can be accessed through the NCEA website (www.epa.gov/ncea).

EPA's use and development of human health risk assessment continued to grow through the 1980s and 1990s with establishment of the IRIS toxicity database, the Agency's repository of chemical-specific toxicity data. IRIS is a critical resource for risk assessors because the database contains toxicity information that reflects a consensus among EPA program offices about a chemical's toxic properties.

EPA's Office of Solid Waste and Emergency Response's Superfund Program also has developed a series of very detailed guidance documents to help risk assessors understand the actual nuts-and-bolts of performing human and ecological risk assessments under the Superfund program. These "how to" documents are called the ***Risk Assessment Guidance for Superfund*** series, or the RAGS series for short. RAGS provides in-depth discussions and guidance for risk assessors to use in their day-to-day work and is an important reference for those working in the field of risk assessment.[b] A full set of RAGS documents is available online.[6]

Risk Assessor. The individual or team of individuals who organizes and analyzes air toxics data, develops exposure and risk calculations, and prepares the human health risk assessment reports. Risk assessors for air toxics can be industry, EPA, an S/L/T air agency, or contractor personnel. The larger **risk assessment team** will often be made up of people with a variety of expertise, including health scientists, monitoring or modeling personnel, and laboratory analysts.

Risk Manager. The individual or group of individuals who serve as the primary decision maker(s) for an area subject to the risk analysis process. The risk managers may base their decisions about the need for risk reduction on a variety of data, including the results of the risk assessment, economic considerations, technical feasibility of risk reduction options, community acceptance, and a number of other factors.

3.3 Air Toxics Human Health Risk Assessment: Overview of the Process

The reports and guidance documents discussed above tend to distill the risk assessment process down to the following five questions:

- Who is exposed to environmental pollutants?
- What pollutants are they exposed to?
- How are they exposed?
- How toxic are the chemicals they are exposed to?
- What is the likelihood that harm will occur because of the exposures?

The role of the risk assessor is to answer these questions. The main product of the risk assessment is a set of qualitative and quantitative statements about the likelihood that people will experience adverse health outcomes because of the exposures. The statements also should discuss how certain the assessor is about these statements. **Risk managers** then use the risk assessment results and other relevant information (including the cost or technical feasibility of resolving a problem) to decide what (if anything) should be done to reduce risk.

[b] Although the information provided in RAGS is primarily geared towards Superfund sites, some of these procedures are generally relevant and compatible to risk assessments developed by other Program Offices, including the Office of Air and Radiation. As such, the information provided in RAGS was taken into consideration in the development of this reference library.

The following sections briefly describe the overall risk assessment process for releases of air toxics to the ambient air. Subsequent chapters of this reference manual revisit each of these subjects in detail and provide contacts and references for more information.

3.3.1 Air Toxics Risk Assessment: What Is the Question?

The overall purpose of a human health air toxics risk assessment is to attempt to understand public health risks potentially associated with exposures to particular pollutants emitted into the air from sources of interest. Exhibit 3-3 presents a simple illustration of the overall real-world process that is investigated through the use of risk assessment.

As Exhibit 3-3 illustrates, air toxics risk assessments usually focuses, at a minimum, on the inhalation of contaminated air. However, for a small subset of air toxics (discussed in Chapter 4), the risk assessment also may need to address ingestion of or dermal contact with soils, water, or food that have become contaminated with chemicals that have deposited out of the air. (Dermal exposures are included here for completeness, but usually they are less of a risk factor for air toxics than ingestion or inhalation exposures.)

The following simple mathematical formula describes the basis for human health risk assessment. Specifically, the likelihood that injury or disease may occur from exposure to air toxics can be described as a function of two separate, but related, things – an estimate of exposure to a chemical and an estimate of the toxic properties of the chemical:

$$\text{Potential for Injury or Disease (i.e., the “Risk”)} = f\ (\text{metric of exposure, metric of toxicity})^{(c)} \qquad \text{(Equation 3-1)}$$

Two key principles emerge from this formula and Exhibit 3-3:

- **There is no risk if there is no exposure**. If a person has no chance of coming in contact with an air toxic, the risk posed to that person is zero.
- **The level of risk associated with an exposure depends on the toxic properties of the chemical**. These properties determine whether the exposure is of great or little concern. Some chemicals can cause severe health effects (even death) when a person receives exposure even to extremely small quantities at a single point in time. Conversely, other chemicals cause essentially no effect even after repeated exposure to high levels over long periods of time.

The general Equation 3-1 is important to understand and keep in mind since the exact equations used to develop risk estimates are derived from it. In other words, the risk equations that will be detailed in later chapters all include both a estimate of exposure and an estimate of toxicity.

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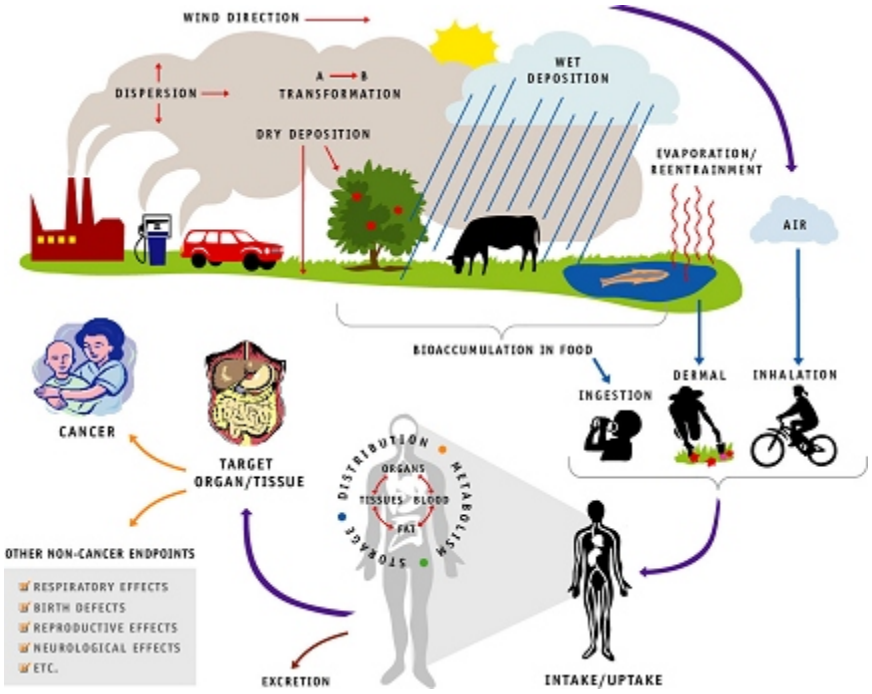
[c] The symbol “*f*” means “is a function of”

Exhibit 3-3. Generic Conceptual Model of How Air Toxics Releases May Result in Injury or Disease



Starting at the upper left hand side of this diagram, air toxics are released from one or more sources (e.g., factories, cars/trucks, small businesses, forest fires) to the air and begin to disperse by the wind away from the point of release. Once released, the chemical may remain airborne; convert into a different substance; and/or deposit out of the air onto soils, water, or plants. People may be exposed to air toxics by breathing contaminated air (inhalation) or through ingestion of chemicals that can accumulate in soils, sediments, and foods (the latter process is called **bioaccumulation)**. People also can be exposed to deposited chemicals via skin (dermal) contact, however, this tends to be a less important risk factor than ingestion or inhalation. Inhalation, ingestion, and dermal absorption are called the **routes of exposure**.

This description of what happens to an air toxic once it is released into the air is called **fate and transport** analysis. "Transport" evaluates how an air toxic physically moves (i.e., is transported) through the environment. "Fate" describes what ultimately happens to the chemical after it is released to the air (i.e., what is the "fate" of the chemical in the environment). The results of a fate and transport analysis is an estimate of the concentration of the air toxic in the air, soil, water, and/or food at the point where it is contacted by a person. The **exposure assessment** is the process of evaluating how human contact with the contaminated media occurs.

In the case of an air pathway analysis, the metric representing the inhalation exposure is called the **exposure concentration** (EC). For example, if benzene is released from a factory and blows into a nearby neighborhood where people breath it, the EC is the concentration of benzene in the air that they breath.

Once an exposure occurs, the air toxics can enter the body and exert an effect at the point of entry (the "portal of entry") or move via the bloodstream to other target organs or tissues. The action of a pollutant on a target organ can result in a variety of harmful effects, including cancer, respiratory effects, birth defects, and reproductive and neurological disorders. An overall risk assessment process evaluates what people are exposed to, how the exposure occurs, and, when combined with information about the toxic properties of the chemicals in question, estimates the likelihood that the exposure will result in injury or disease.

Air toxics risk assessments commonly look at two types of exposures and their associated toxic outcomes:

- Repeated or extended exposure to relatively low concentrations of air toxics over long periods of time (**chronic exposures**) that may result in **chronic health effects** (e.g., diseases like cancer or recurring respiratory ailments); and
- Infrequent exposure to relatively high concentrations of air toxics over short periods of time (**acute exposures**) that may result in the expression of either near term **acute health effects** (which can range from mild effects, such as reversible eye irritation, to extreme effects, such as loss of consciousness or sudden death), or long term effects (chronic effects).

3.3.2 Air Toxics Risk Assessment: The Process

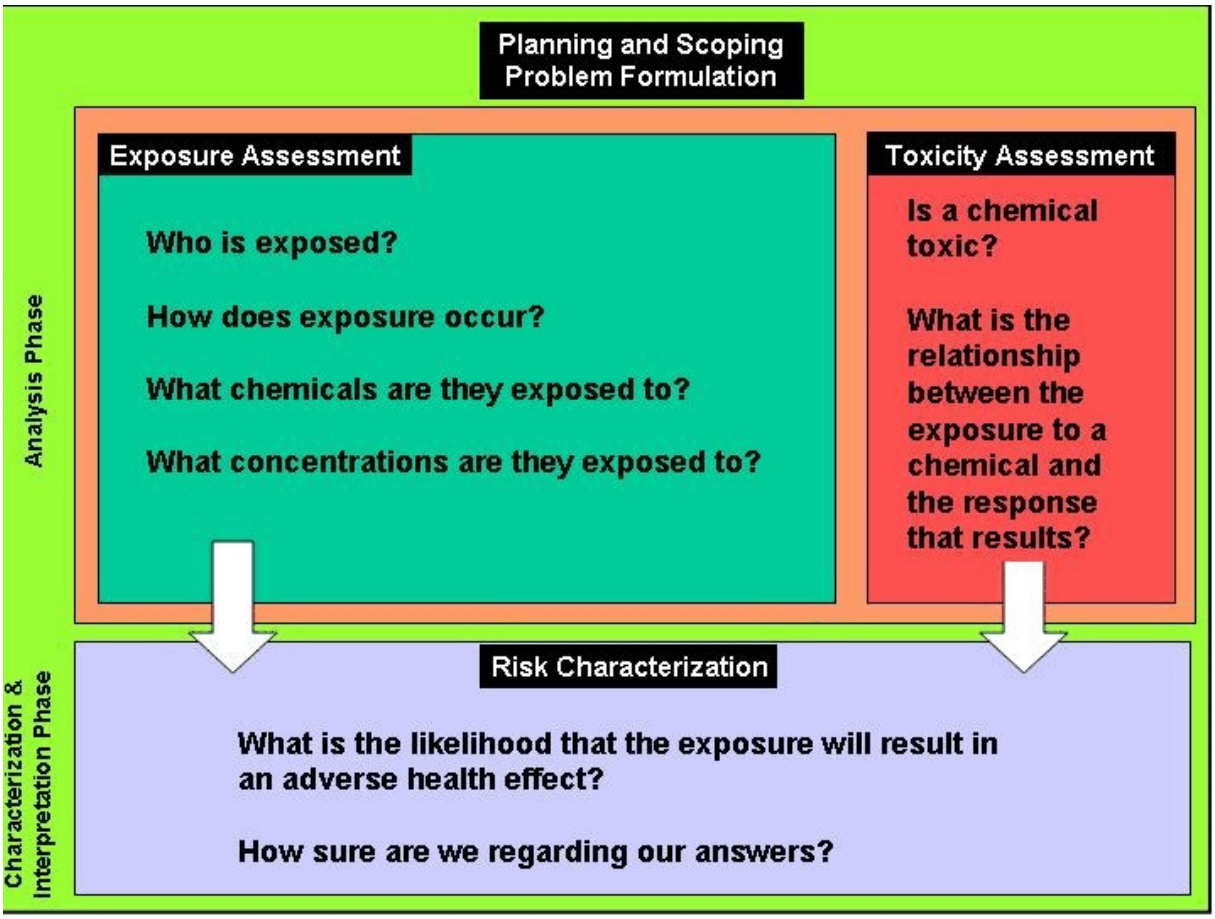
The illustration and narrative overview in the previous section (Exhibit 3-3) describes what may happen when toxic chemicals are released to the air and how those releases can result in adverse health outcomes in people. This picture and narrative description comprise a **conceptual model** of how releases of air toxics may pose risks to people. It is a conceptual model because it provides a picture (or "model") of our "concept" of what may happen in the real world when toxic chemicals are released to the air. The conceptual model provides a starting point for estimating risks posed by those releases. However, in addition to a conceptual model (in this case, a simple picture), there is a need for a defined process to quantify relationships among the conceptual model components in order to generate numeric risk estimates. Exhibit 3-4 outlines the major steps in the process that EPA uses to perform a risk assessment:

- Planning, scoping, and problem formulation;
- Analysis, which includes exposure assessment and toxicity assessment; and
- Risk characterization.

With the addition of an explicit planning and scoping step (which should always be done for any systematic investigation), Exhibit 3-4 encompasses the same features as espoused by the National Academies in the Red and Blue books described previously. The National Academies' process has been redrawn in Exhibit 3-4 to better clarify how the risk assessment is actually done in the air toxics arena.

It is useful to think of this figure as a "roadmap" to how air toxics risk assessments are performed. The roadmap breaks air toxics risk assessment down into four manageable elements, each of which are described briefly below and in detail in subsequent chapters. Note, however, that all of these steps are inter-related and usually require refinement throughout the risk assessment process. A helpful starting place is to think of these as "separate steps."

Exhibit 3-4. The General Air Toxics Risk Assessment Process



3.3.2.1 Planning, Scoping, and Problem Formulation

Any human health risk assessment should begin with **planning and scoping**. Properly planning and scoping the risk assessment at the beginning of the project is critical to the success of the overall effort. Good planning and scoping clearly articulates the assessment questions; states the quantity and quality of data needed to answer those questions; provides in-depth discussion of how assessors will do the analysis; outlines timing and resource considerations, as well as product and documentation requirements; and identifies who will participate in the overall process from start to finish and what their roles will be. Poor planning and scoping will almost certainly lead to an assessment that does not answer the correct questions, does not provide a supportable basis for risk management decision-making, and wastes significant amounts of time, resources, and good will. The planning and scoping process needs to recognize, to the extent possible, important data gaps and uncertainties and the measures needed to address these problems. Where the extent of data gaps and their potential impacts on the risk assessment are not fully understood, the planning process may be iterative, with decision points specified during the analytical phase (see below) that are contingent on the results of data gathering efforts or sensitivity/uncertainty analyses.

During **problem formulation**, the planning and scoping team generally makes initial decisions about the scope of the risk assessment (e.g., size of the study area, what emission sources and chemicals are to be considered); the appropriate level of detail and documentation; trade-offs between depth and breadth in the analysis; quality assurance and quality control requirements; analytical approaches to be used (modeling vs. monitoring); and the staff and monetary resources to commit. Problem formulation results in two important products: the conceptual model and the analysis plan.

- The **study-specific conceptual model** is similar to the generic conceptual model (Exhibit 3-3); however, for an actual assessment the conceptual model explicitly identifies the physical boundaries of the study area; the potential emission sources and air toxics they are emitting that the risk assessment will consider; the location and composition of potentially exposed populations; the fate/transport mechanisms by which those populations may be exposed; the routes of exposures that may be occurring; and the expected health outcomes to be evaluated. The study-specific conceptual model is developed as both a picture and a written description of how air toxics emissions may be affecting the study area. As the assessment moves forward, the assessment team members will use the model as a guide, but they also routinely refine the model as they learn more about the study area. For example, the initial study-specific conceptual model may include a deposition element. If subsequent modeling or monitoring suggests this fate and transport mechanism is unimportant, the assessors will revise the conceptual model.
- The **analysis plan** will guide the remainder of the assessment. It lays out in detail how the elements of the conceptual model are going to be studied. In developing the analysis plan, it is important to include provisions for tiered or iterative analyses, as discussed in Sections 3.2.3 and 3.3.5.

3.3.2.2 Analysis Phase

The analysis phase is the process in which analysts apply risk assessment approaches to evaluate the problem at hand. It consists of two main components: exposure assessment and toxicity assessment.

An **exposure assessment** is conducted to characterize the potentially exposed population, the chemicals of potential concern, identify exposure pathways and routes of exposure, and estimate the exposure. This includes estimating or measuring concentrations of air toxics in the environment and evaluating how nearby populations interact with the contaminated media.

In the exposure assessment, the risk assessment team will refine the initial conceptual model by providing detailed information about the study area (e.g., physical description, meteorology, source locations and detailed characteristics, population demographics and locations, the

What is "Study-Specific?"

Air toxics risk assessments can be designed to evaluate a wide range of air toxics release scenarios. For example, a risk assessment might look at the impact of one emission point at a factory on a nearby population or it might look at the combined impact of hundreds of sources on a large urban area.

This reference manual uses the term "study-specific" to mean the specific geographic area and populations under study, along with the emission sources included in the scope of the study.

exposure pathways under study). The exposure assessment also is the analytic step in which the magnitude, frequency, and duration of human exposures are quantified. For example, one of the main outcomes of an air toxics exposure assessment is an estimate of the concentration of air toxics in the air at the point where human contact occurs (the EC). Assessors usually estimate this value with either a computer program (a **model**) or by physically taking samples of air and measuring air toxics concentrations in a laboratory (a **monitor**). When there are concerns about exposure pathways other than inhalation, assessors may use different models or monitoring strategies to estimate or measure concentrations of air toxics in soil, water, or foods.

The **toxicity assessment** component of the risk assessment process considers: (1) the types of adverse health effects associated with exposure to the chemicals in question, and (2) the relationship between the amount of exposure and resulting response. Toxicity assessment for air toxics generally consists of two steps:

- **Hazard identification** is the process of determining whether exposure to a chemical can cause an adverse health effect (e.g., cancer, birth defect, etc.), as well as the nature and strength of the evidence of causation and circumstances in which these effects occur (e.g., inhalation/ingestion, repeated exposure over a long period/single exposure over a short period, etc,).
- **Dose-response assessment** is the process of quantitatively characterizing the relationship between the dose of the contaminant and the incidence of adverse health effects in the exposed population. As information on dose at the site in the body where the response occurs is rarely available, various factors and models are used to predict the dose metric from estimates of exposure (the inhalation exposure concentration or oral intake). From this quantitative dose-response relationship, toxicity values are derived for use in risk characterization.[(d)] Most toxicity assessments are based on studies in which toxicologists expose animals to chemicals in a laboratory and extrapolate the results to humans. For some chemicals, information from actual human exposures is available (usually from workplace exposure studies).

Although air toxics risk assessors need to understand the underlying scientific basis and uncertainties associated with toxicity values, they will usually rely on toxicity values already developed and available in the literature. A list of default screening level toxicity values that EPA recommends for the 188 HAPs is in Appendix C. The most up-to-date list is at http://www.epa.gov/ttn/atw/toxsource/summary.html.

3.3.2.3 Risk Characterization

The **risk characterization** summarizes and combines outputs of the exposure and toxicity assessments to characterize risk, both in quantitative (numerical) expressions and qualitative (descriptive) statements. Chemical-specific exposure-response information is mathematically combined with modeled or monitored contaminant levels and other information regarding how exposure occurs to give numbers that represent the likelihood that the exposure may cause an

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[d]Toxicity values are numerical expressions of the relationship between a given level of exposure to an air toxic and adverse health impacts. The two most common toxicity values for inhalation exposures are the upper-bound inhalation unit risk estimates (IURs) for cancer effects and reference concentrations (RfCs) for non-cancer effects (which include uncertainty factors). Chapter 12 provides a more detailed discussion of toxicity values.

adverse health outcome. Per the Agency's *Policy for Risk Characterization*,[7] this likelihood is evaluated both with regard to a "central tendency" of exposure estimates and "high end" estimates. The risk characterization also includes a thorough **uncertainty analysis** for each step of the entire risk assessment process in order to provide the risk manager with an understanding of which elements of the assessment are most uncertain, the magnitude and direction of the effect (higher or lower) that the various uncertainties have on the risk estimates and in some cases, a quantitative analysis of uncertainty. Often the uncertainty analysis is a narrative that reflects the assessor's best professional judgment. Other analyses, however, may require a more quantitative approach to evaluating uncertainty.

The product of the risk assessment is a written report that provides all of the analyses performed to assess exposure, identify toxicity values, characterize risk, and assess and present uncertainty. It is critical that the risk assessment only provide the factual basis of why the assessment was done, how it was done, what the answers are, and the uncertainties associated with those answers. That is not to say that the risk assessment should not provide an analysis of differing scientific opinions on any number of the elements of the risk assessment. It does, however, preclude the assessment from discussing items more appropriately considered under risk management (e.g., cost or technical feasibility of mitigation alternatives). The presentation also must be clear and provide enough details so future readers will find the overall assessment process, including critical assumptions, to be fully transparent.

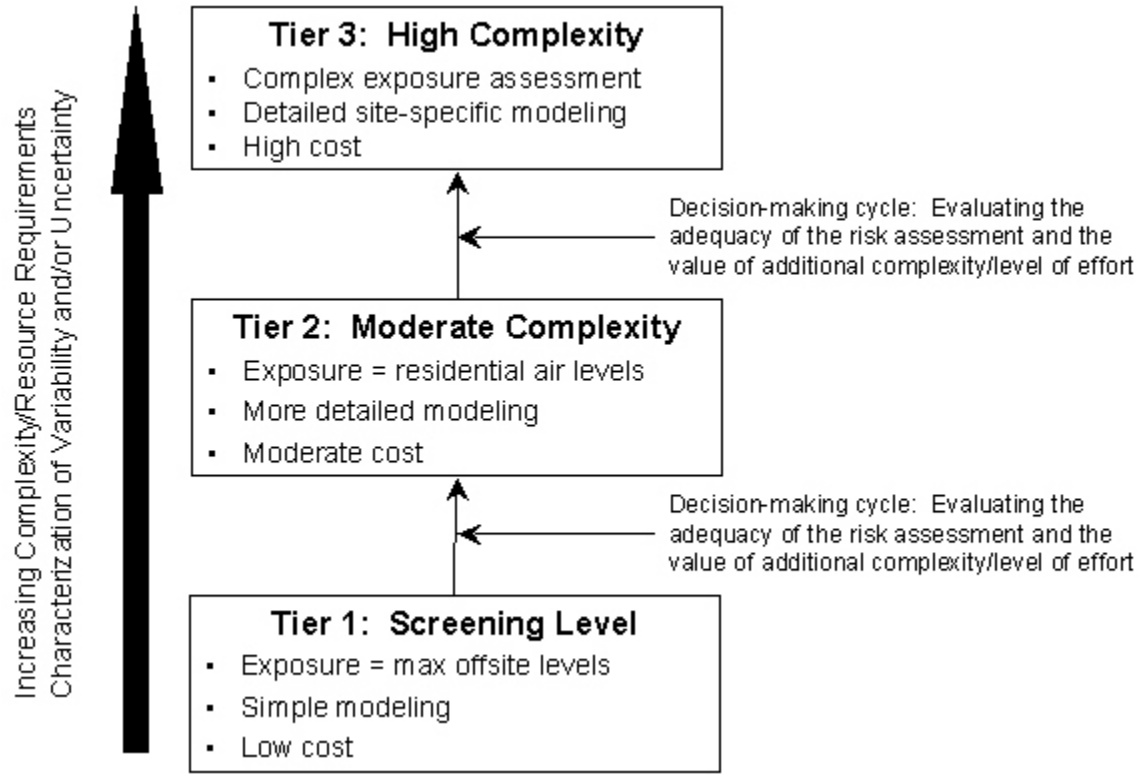
3.3.3 Tiered Assessment Approaches

Various EPA guidance documents and the Air Program's *Residual Risk Report to Congress* have recommended tiered approaches to risk assessments.[8] A tiered approach is a process for a systematic, informed progression from a relatively simple to a more complex risk assessment approach. Essentially, the approach begins with an analysis that includes few study-specific data and many conservative assumptions. This process generally results in a very conservative answer (and is likely to be fairly uncertain), but may demonstrate, with relatively little effort, that the sources being assessed pose insignificant risk. If such an approach indicates that the risk appears to be relatively high, assessors pursue a higher tier of analysis to determine if the risk is a realistic concern or an artifact of the lower tier's conservative assumptions. The higher level of analysis reflects increasing complexity and, in many cases, will require more time and resources. Higher tiers also reflect increasing characterization of variability and/or uncertainty in the risk estimate, which may be important for making risk management decisions.

Exhibit 3-5 illustrates a generalized representation of the tiered risk assessment concept. Central to the concept of the tiered approach is an iterative process of evaluation, deliberation, data collection, work planning, and communication aimed at deciding:

- Whether or not the risk assessment, in its current state, is sufficient to support the risk management decision(s); and
- If the assessment is determined to be insufficient, whether or not progression to a higher tier of complexity (or refinement of the current tier) would provide a sufficient benefit to warrant the additional effort.

Exhibit 3-5. Generalized Representation of the Tiered Risk Assessment Concept



The deliberation cycle also provides an opportunity to evaluate the direction and goals of the assessment as new information becomes available. It may include evaluations of both scientific and policy information.

This representation, which provides an example of a tiered assessment process consistent with that described in the *Residual Risk Report to Congress*,[8] depicts three tiers of analysis. Each successive tier represents more complete characterization of variability and/or uncertainty as well as a corresponding increase in complexity and resource requirements.

- **Tier 1** is represented as a relatively simple, screening-level analysis using conservative exposure assumptions (e.g., receptors are located in the area with the highest estimated concentrations) and relatively simple modeling (e.g., a model that requires few inputs, most of which can be "generic," yet conservative).
- **Tier 2** is represented as an intermediate-level analysis using more realistic exposure assumptions (e.g., use of actual receptor locations) and more detailed modeling (e.g., a model that requires additional site-specific inputs).
- **Tier 3** is represented as an advanced analysis using probabilistic techniques such as Monte Carlo analysis (see Part VII of this reference manual for a discussion of these techniques) and more detailed and/or intensive modeling.

This representation does not imply that there is a clear distinction between Tiers 1, 2, and 3. For example, a series of refinements in a Tier 1 analysis might be indistinguishable from a Tier 2 analysis, or a Tier 2 analysis could incorporate probabilistic techniques.

This representation also notes the decision-making cycle that occurs between each tier. In this cycle, the existing risk assessment results are evaluated to determine whether they are sufficient for the risk management decision, and if not, what refinements to the risk assessment are needed (including moving up to the next tier).

While the tiered risk assessment concept usually contains three tiers of complexity (as in Exhibit 3-5), these three tiers are best thought of as points along a spectrum of increasing complexity and detail in the risk assessment. The important focus is the specific ways in which a given risk assessment is refined in successive iterations, rather than whether or not it would be considered Tier 1, 2, or 3.

3.4 Uncertainty and Variability in Air Toxics Risk Assessment

Risk assessment is based on a series of questions that the assessor asks about available scientific information that is relevant to human health and/or ecological risk. Each question calls for analysis and interpretation of the studies, selection of the concepts and data that are most scientifically reliable and most relevant to the problem at hand, and conclusions regarding the question presented. For example, in the exposure assessment, through the use of modeling and/or monitoring, the risk assessor asks what is known about the principal environmental fate and transport of contaminants and the patterns and magnitudes of human or ecosystem exposures. The toxicity assessment asks what is known about the ability of an air toxic to cause cancer or other adverse health effects in humans, laboratory animals, or wildlife species and what is known about the biological mechanisms and dose-response relationships underlying any effects observed in the laboratory or in epidemiology studies. The risk characterization integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about estimated risk that is complete, informative, and useful for risk managers.[7]

Air toxics risk assessments make use of many different kinds of scientific concepts and data (e.g., exposure, toxicity, epidemiology, ecology), all of which are used to characterize the estimated risk in a particular environmental context. Informed use of scientific information from many different sources is a central feature of the risk assessment process. Highly accurate information is often not available for many aspects of a risk assessment. However, since **scientific uncertainty** is inherent in the risk assessment process, and risk managers often must make decisions using assessments that are not as definitive in all important areas as would be desirable, it is important that the most current and complete information that is available be used to support decision making. Risk assessors and decision makers must understand that it may be necessary to revise risk estimates and to alter decisions in light of new information.

Risk assessments also incorporate a variety of professional judgements (e.g., which models to use, where to locate monitors, which toxicity studies to use as the basis of developing dose-response values). Risk managers therefore need to understand the strengths and the limitations of each assessment and to communicate this information to all participants and the public.

This section provides an overview of **uncertainty** and **variability**, two critically important characteristics of risk assessment that need to be understood and described at some level in every air toxics risk assessment. It describes several sources of uncertainty and variability in air toxics risk assessments, discusses approaches for describing and analyzing uncertainty and variability, and describes how uncertainty and variability are often addressed at different tiers of the risk assessment process.

A full discussion of this subject, including quantitative techniques for uncertainty analysis, is beyond the scope of this reference manual. Risk assessment is an evolving discipline, and improvements in scientific understanding and techniques will continue to provide new avenues and insights into uncertainty and variability analysis. Because this manual is intended as an introduction to risk assessment approaches and tools, our discussion focuses on relatively simplistic, deterministic risk assessment techniques (i.e., Tier 1 approaches to risk characterization that lead to single value estimates of risk). Readers are encouraged to consult the references at the end of this Chapter for additional information about uncertainty analysis in the risk assessment process.

3.4.1 Distinguishing Uncertainty and Variability

Variability refers to true heterogeneity or diversity. For example, among a local community that is exposed to an air toxic originating from the same source, and with all people breathing the same contaminant concentration in ambient air, the risks from inhalation of the contaminated air will still vary among the people in the population. This may be due to differences in exposure (i.e., different people have different exposure frequencies and exposure durations), as well as differences in response (e.g., differences in metabolic processes of chemical uptake into target organs). Differences among individuals in a population are referred to as inter-individual variability, while differences for one individual over time (e.g., change in sensitivity to air toxics with aging, illness) are referred to as intra-individual variability.

Uncertainty occurs because of a lack of knowledge. For example, we can be very certain that different people are exposed to contaminated air for different time periods, but we may be uncertain about how much variability there is in these exposure durations among the people in the population. Data may not be available concerning the amount of time specific people spend indoors at home, outdoors near home, or in other "microenvironments."

Uncertainty can often be reduced by collecting more and better data, while variability is an inherent property of the population being evaluated. Variability can be better characterized with more data, but it cannot be reduced or eliminated. Often, however, it is difficult to distinguish between uncertainty and variability in a risk assessment, particularly if available data are limited. For that reason, in many cases variability can be treated as a type of uncertainty in the risk assessment.

Uncertainty is an inherent characteristic of each step of the risk assessment process. Assessing uncertainty in risk assessment is an involved process because of the complex nature of the risk assessment process itself (i.e., risk assessment is a combination of a variety of data gathering and analytical processes, each with their own associated uncertainties). Specifically, risk assessment requires the integration of the following:

- Information on emissions of air toxics into the environment;
- Information on the fate and transport of air toxics, in a variety of different and variable environments, by processes that are often poorly understood or too complex to quantify completely;
- Information on the potential for adverse health effects in humans and/or ecosystems, often extrapolated from surrogate animal studies; and
- Information on the likelihood of adverse effects in a human population that is highly variable genetically, as well as factors such as age, activity level, lifestyle, and underlying disease.

Uncertainty, when applied to the process of risk assessment, is defined as "a lack of knowledge about specific factors, parameters, or models."[9] Such uncertainties affect the confidence of any risk estimates that were developed for individuals exposed to the substances in question.[10] It is important to keep in mind that many parameter values (e.g., emissions rates) may be *both* uncertain and variable. Also, the presence of uncertainty in risk assessment does not imply that the results of the risk assessment are wrong, but rather that the risks cannot be estimated beyond a certain degree of confidence.

The relatively simple, deterministic (i.e., single value estimate) approach outlined in this reference manual generally relies on a combination of point values – some which may be set at protective (i.e., high end) levels and some which may be set at typical (i.e., central tendency) levels. The result is a point estimate of exposure, and risk that falls at some percentile within the full distributions of exposure and risk. The degree of conservatism in high end risk estimates depends on the combination of input values selected.[11]

One of the key purposes of the uncertainty analysis is to provide an understanding of where the estimate of exposure, dose, or risk is likely to fall within the range of possible values. Often this is expressed as a subjective confidence interval (one based on incomplete data supplemented by professional judgment) within which there is a high probability that the estimate will fall. A related analysis, termed "sensitivity analysis" or "analysis of uncertainty importance," is often performed to identify the relative contribution of the uncertainty in a given parameter value (e.g., emission rate, ingestion rate) or model component to the total uncertainty in the exposure or risk estimate. This is often used either to identify which parameter values should be varied to provide high-end vs. central-tendency risk estimates, or to identify parameter values where additional data collection (or modeling effort) can increase the confidence in the resulting risk estimate.

3.4.2 Sources of Uncertainty in Air Toxics Risk Assessment

Although other taxonomies are sometimes used, sources of uncertainty in risk assessment are often divided into four categories (variability is sometimes included as a fifth category).[12]

- **Scenario uncertainty** occurs when information to fully define exposure and/or risk is missing or incomplete. This may include descriptive errors regarding the magnitude and extent of chemical exposure or toxicity, temporal and spatial aggregation errors, incomplete analysis (i.e., missing exposure pathways), and potential mis-specification of the exposed population or exposure scenario.

- **Model uncertainty** is associated with all models used in all phases of a risk assessment, including (1) animal models used as surrogates for evaluating human carcinogenicity, (2)

dose-response models, (3) computer models used to predict the fate and transport of chemicals in the environment, and (4) models used to estimate exposures for populations of concern. Model uncertainty also is sometimes referred to as specification uncertainty.

Computer models are simplifications of reality that use mathematical approximations to describe the most important processes governing the modeled relationships, while excluding what are believed to be less important processes, or processes that are too complex to be easily approximated. The risk assessor needs to consider the potential importance, in consultation with the modeler, of the level of detail and comprehensiveness of the models being used, because specific processes may have important impacts on uncertainty in some instances and not in others. A similar problem can occur when a model that is applicable under average conditions is used for a case in which conditions differ from the average. In tiered analyses, resource considerations and the level of precision required to support decision making may enter into considerations of model selection. Model uncertainty may be particularly important in multipathway analyses, because the modeling effort is much more complex (as compared to inhalation analyses). In addition to air quality modeling, multipathway analyses involve analysis of the transfer of air toxics from the air to other media (e.g., soil, sediment, water); the subsequent movement of the air toxics between these media (e.g., soil runoff to surface water); uptake and metabolism by biota; and subsequent ingestion by humans and wildlife. Uncertainties are associated with all of these analytical steps.

Model uncertainty is often difficult to deal with quantitatively. It is rarely possible to directly evaluate the merits of competing models, either due to resource constraints, or because direct comparisons are inherently complex (e.g., the models may take different input parameters, and produce outputs that are not directly comparable). Statistical methods (Bayesian analyses) can sometimes be used to combine the results of different models, but these approaches are often complex, and generalizability to specific cases is hard to predict. Thus, model selection tends to be based primarily on profession judgement and cost/complexity considerations.

- **Parameter Uncertainty** refers to the limitations in the modelers' ability to estimate precise values for certain parameters (variables) in the chosen models. It is a generic term that in common usage can refer either to variability or uncertainty, and generally indicates a situation where a given variable may take a range of values, rather than a single point estimate. Parameter uncertainty is generally addressed in risk assessment through gathering additional data, sensitivity analysis, or probabilistic modeling (discussed in Section 3.3.4).

- **Decision-rule uncertainty** is a type of uncertainty associated with policy and other choices made during the risk assessment. For example, the number of chemicals of potential concern (COPC) evaluated at a given tier of assessment may be reduced through use of a toxicity-weighted or risk-based screening analysis. In this example, the decision rule could be something like "Calculate the toxicity weighted emission for each chemical in the emissions inventory, rank the scores from highest to lowest and, starting with the highest score and working down, select as COPCs those chemicals that contribute to 99 percent of the cumulative toxicity weighted sum." This type of judgment introduces uncertainties about the contribution of the omitted air toxics to overall exposure or risk. As another example, risk managers may decide to select as chemicals for risk reduction efforts (i.e., the Chemicals

of Concern or COCs) only those COPCs that, individually, pose a risk above some specified level (e.g., one per million general population lifetime cancer risks). In this case, the decision rule would be "COCs are those COPCs which have a risk, on an individual chemical basis, of one in one million or greater." For any given risk assessment, some or all of these practices may be questioned, either on technical grounds (e.g., a risk number has been generated, but it is highly uncertain) or for policy reasons. The risk assessor needs to be sensitive these considerations when planning, conducting, and reporting the results of the risk assessment.

3.4.3 Sources of Variability in Air Toxics Risk Assessment

As noted previously, variability refers to true heterogeneity or diversity that occurs within a population or sample. Factors that lead to variability in exposure and risk include variability in contaminant concentrations in an environmental medium (e.g., air, water, soil) and differences in other exposure parameters such as ingestion rates and exposure frequencies.

Temporal and spatial variability in contaminant concentrations is often a very important aspect to consider in air toxics risk assessments. Spatial variability arises from many factors, including the release forms, physical and chemical dilution and transformation processes, and physical characteristics of the source or surrounding environment. Ecological receptors and humans may exhibit spatial variability in their contact with an exposure medium. Likewise, temporal variability can result from a variety of factors. For example, a source may only emit a chemical at specific times during the year (e.g., during the processing of a batch of product). Meteorological changes between seasons also can cause variable exposure (even though source emissions remain relatively constant). Because variability is an intrinsic property of the quantities being evaluated, it cannot be reduced by data gathering or refinements in models. However, understanding and/or analysis of variability are still important, especially during problem formulation. For example, it may be thought that certain air toxic emission source characteristics or potentially exposed populations are very heterogeneous and that a more robust description of the numbers and types of people at different risk levels is necessary to meet risk management decision goals

Confusion often arises about whether data are describing variability or uncertainty. For example, consider a group of 10,000 office workers who spend part of the time indoors at home and part of the time indoors at work. To assess the fraction of time spent indoors at a home or the office, a randomly chosen group of 100 office workers are asked to fill out a survey (resources preclude surveying all 10,000 people). Once we have our data, we draw a frequency diagram of the number of workers who spend specified amounts of time indoors at home and at the office. The picture we get clearly shows that different people spend different amounts of time inside at home and at the office – there is variability in the parameter for this population.

However, is our picture of variability correct (i.e., how certain are we that we have a good picture of the true variability of all 10,000 people)? Since we did not survey every possible worker and because some of the workers may have given incorrect responses, we have to admit to ourselves that there is probably some amount of uncertainty as to whether our frequency diagram is an accurate representation of variability in full worker population. In other words, we have developed an expression of variability that we think is uncertain. But only having a sense that our picture of variability may not be an accurate representation may not be enough (knowing just how uncertain our estimate of variability is may be important in our risk assessment).

Fortunately we have a variety of methods to look at the uncertainty in just one parameter (e.g., how variable is time spent indoors versus outdoors) and in the combination of parameters to provide estimates of exposure and risk. We can, for example, look at our data to see if patterns of time use vary for different subgroups of workers, or we can look for "outliers" (individuals with unusual patterns of indoor/outdoor time use). Alternatively, we could gather data from a larger sample of workers. Any of these would decrease the level of uncertainty in worker behavior, by providing more accurate representations of the variability of time usage for more clearly defined categories of workers. The newly developed worker categories would then be included in the exposure modeling.

3.4.4 Characterizing Uncertainty and Variability

Ideally, one would like to carry through the risk assessment, in a quantitative fashion, the uncertainty associated with each element in order to characterize the overall uncertainty associated with the final risk estimates. However, this is not always possible (because data are extremely limited) and, in some cases, may not be necessary (when all reasonable modeling assumptions and parameter values lead to the same recommendation). Nevertheless, it is always a good idea to provide some level of uncertainty analysis (be it qualitative, semi-quantitative, or quantitative). For example, one important use of uncertainty characterization can be to identify areas where a moderate amount of additional data collection might significantly improve the risk assessment, and hence the decision on the need for risk reduction or the risk reduction strategy to be used.

- **Qualitative characterization**. In a qualitative uncertainty analysis, a description of the uncertainties in each of the major elements of the risk analysis is provided, often with a statement of the estimated magnitude of the uncertainty (e.g., small, medium, large) and the impact the uncertainty might have on the risk element (e.g., the uncertainty is large and risk estimate is likely underestimated due to this element).

- **Quantitative characterization**. When appropriate, quantitative approaches to the uncertainty analysis are used to better characterize the uncertainty associated with the risk assessment. In this case, the first step is usually to characterize the probability distributions for key input parameter values (either using measured or assumed distributions). The second step would be to propagate parameter value uncertainties through the analysis using analytic (e.g., first-order Taylor series approximation) or numerical (e.g., Monte Carlo simulation) methods, as appropriate. Analytic methods might be feasible if there are a few parameters with known distributions and linear relationships. Numerical methods (e.g., Monte Carlo simulation) can be suitable for more complex relationships. "Two-dimensional" Monte Carlo analyses may be used where separate estimates of uncertainty and variability are available for some or all variables. Specific approaches are likely to be highly variable depending on the nature of the assessments being performed. Examples of approaches applied to a variety of assessments are provided in the reference list at the end of this chapter in Exhibit 3-8 (Hope, 1999; Moore et al., 1999; Smith, 1994).

- Both qualitative and quantitative uncertainty characterization is subject to scope-related limitations and uncertainty. For example, ecological risk assessments that are limited to primary effects evaluation for organisms or populations are uncertain with regard to secondary effects for communities or ecosystems. Similarly, human health assessments that

are restricted to the HAPs may ignore exposures and potential effects from other chemicals in the same emissions. Such uncertainties persist regardless of the assessment's refinement level (Tier). Their communication provides important contextual information for decision making.

Guidance developed by the National Council on Radiation Protection and Measurements[13] provides useful insights as to when to perform a quantitative uncertainty analysis in environmental risk assessments (Exhibit 3-6).

Exhibit 3-6. When to Perform a Quantitative Uncertainty Analysis
Quantitative uncertainty analysis is NOT recommended when: • Conservative, screening-level calculations indicate that the risk from potential exposure is clearly below regulatory or other risk levels of concern; • The cost of an action to reduce exposure is low; and/or • Data for characterizing the nature and extent of contamination or exposure are inadequate to permit even a bounding estimate (an upper and lower estimate of the expected value).
Quantitative uncertainty analysis IS recommended when: • An erroneous result in the exposure or risk estimate may lead to large or unacceptable consequences; • Whenever a realistic rather than a conservative estimate is needed; and/or • When it is important to identify those assessment components for which additional information will likely lead to improved confidence in the estimate of exposure or risk.
Source: NCRP. 1996. [13]

3.4.5 Tiered Approach to Uncertainty and Variability

Building on the approach outlined in Exhibit 3-6, the following description provides one possible tiered approach to deciding when and how to perform an uncertainty analysis.[14]

Single-Value Estimates of High-End and Central Tendency Risk. This approach starts with simple risk estimates using both representative and more conservative scenarios, models, and input values, using point estimates to represent each of the major parameters. This "deterministic" approach, which is described extensively in this document, may provide sufficient information for the risk management question being addressed. For example, if risks for a suitably defined high-end receptor are below levels of concern, then no additional uncertainty analysis (or risk analysis) may be needed to support a risk management decision. It is important to recall, however, that using single values for inputs, essentially ignores uncertainty and variability – information that may be very important for risk managers and the public.

Despite some limitations, single-value estimates or point estimates are an important tool in the risk assessment process. Single-value estimates are particularly useful as a screening tool to identify situations in which even highly conservative assumptions about exposure and other model parameters indicate low risk. (Note that EPA risk assessors are directed to provide, in Agency risk assessments, information about the range of exposures derived from exposure

scenarios and on the use of multiple risk descriptors [e.g., central tendency, high end of individual risk, population risk, important subgroups, if known] consistent with terminology in the Guidance on Risk Characterization, Agency risk assessment guidelines, and program-specific guidance.[7])

Qualitative Evaluation of Model and Scenario Sensitivity. Where the single-value high-end and central tendency point estimates do not provide sufficient information to make a risk management decision, qualitative analyses can be conducted to determine the range of values within which the risk estimate is likely to fall and the major factors that contribute to uncertainty. The sensitivity of the high-end and central tendency estimates to the plausible range of values for various parameters can usually be evaluated by conducting a manageable number of case studies using different parameter values and observing the resulting changes in risks. If scenario or model specification turns out to strongly affect risk estimates, a more refined analysis (see below) may be necessary. These may include Bayesian or decision-tree models.

Quantitative Sensitivity Analysis of High-End or Central Tendency Estimates. The risk assessor may want to evaluate the sensitivity of the point estimates of risks to variability and uncertainty in model input parameters. This may be done through sensitivity analysis or through the use of more detailed probabilistic methods (see Chapter 31). If sensitivity analyses are used, care must be taken to ensure that the combinations of parameter values that have the greatest impact on risks are identified.

Full Quantitative Characterization of Uncertainty and Uncertainty Importance. For many risk assessments, the systematic sensitivity analyses can provide sufficient information to provide reasonable confidence in the risk estimate. If they do not, the next step is explicit probability modeling, which is described in Chapter 31. Using such approaches, uncertainty and variability distributions can be defined for the major parameter values used in the derivation of the risk estimates. This approach is referred to as **parameter uncertainty analysis** and includes the following steps:[15]

- **Define the assessment endpoint** (i.e., the specific measure being evaluated). Examples would include an estimate of exposure concentration, hazard index, or a quantitative estimate of individual cancer risk.

- **List all potentially important uncertain parameters**. Include additional parameters, if necessary, to represent uncertainty in the assessment approach itself.

- **Specify the maximum conceivable range of possibly applicable values for each parameter with respect to the endpoint being assessed**.

- **For this range, specify a probability distribution for the parameter**. The probability distribution quantitatively expresses the state of knowledge about alternative values for the parameter (i.e., defines the probability that the true value of the parameter is located in various sub-intervals of the indicated range). These may include statistical distributions (e.g., "normal" or other distributions derived from data) or simpler approximations (triangular distributions defined by high, medium, and low values).

- **Determine and account for dependencies that are suspected to exist among parameters**. For example intake rate may not be independent of age or body weight.

- **Using either analytical or numerical procedures, propagate the uncertainty in the model parameters to produce a probability distribution for the assessment endpoint**. This results in the development of a probability distribution function (PDF) representing the state of knowledge for the endpoint.

- **Derive quantitative statements of uncertainty in terms of a probability or confidence interval about the assessment endpoint.**

- **Identify parameters according to their relative contribution to the overall uncertainty in the prediction of the value of the assessment endpoint.**

- **Present and interpret the results of the analysis.**

A full quantitative characterization of uncertainty requires a number of assumptions, including:

- The most important sources of uncertainty and variability are identified;
- The assumed probability distributions are correct; and
- The assumed dependence structure for different sources of uncertainty or variability is correct.

A comprehensive quantitative analysis may be a daunting task, particularly if a large number of sources, chemicals, receptors, exposure pathways, and endpoints, are of concern. Furthermore, the difficulty in justifying a large number of distributional assumptions (often based on professional judgement) needed for an uncertainty analysis might make such an analysis in itself unreliable.

In practice, the number of "tiers" available to the risk assessor may be limited. Often the practical choice is between using simple "screening" models (e.g., SCREEN3), and highly refined, fully parameterized modeling packages (e.g., ISCST3). In such cases, it may be easier to do a highly refined analysis with the state-of-the art models than to incrementally improve on the screening methods.

3.4.6 Assessment and Presentation of Uncertainty

The assessment and presentation of uncertainty is a very important component of the risk characterization. Based on the amount of information about sources and emissions and the degree of uncertainty associated with estimates of risk, decision-makers will weigh the importance of the risk estimates in the eventual decision. As noted previously, when the uncertainty analysis is qualitative in nature, a description of the uncertainties in each of the major elements of the risk analysis is usually described, often with a statement of the estimated magnitude of the uncertainty (e.g., small, medium, large) and the impact the uncertainty might have on the risk element (e.g., the uncertainty is large and risk estimate is likely underestimated). Important uncertainties to discuss include, but are not limited to:

- Scope issues such as the choice of air toxics, receptors, or endpoints that are evaluated in the assessment and the choice of air quality or multimedia models used to characterize exposure;
- Data quality issues, such as the quality of available sampling, emissions inventory, or toxicity data;
- Uncertainties inherent in the toxicity values for each substance used to characterize risk; and
- Uncertainties that are incorporated in the risk assessment when exposures to several substances across multiple pathways are summed.

When the analysis is more quantitative in nature, the description of uncertainty generally is separated into two parts:

- The first part is a summary of the values used to estimate exposure and risk (including model inputs), the range of these values, the midpoint or other descriptive values, and the value used to estimate exposure.
- The second part is a narrative discussion that identifies which variables or assumptions used in the risk assessment have the greatest potential to affect the overall uncertainty in the exposure assessment.

Chapter 13 provides additional discussion of how to assess and present uncertainty in an air toxics risk assessment. Exhibit 3-7 provides additional references on uncertainty analysis.

Example of a Six-step Process for Producing a Quantitative Uncertainty Estimate

Finkel (1990)[12] presents another example of a quantitative uncertainty analysis process:

1. Define the measure of risk (such as deaths, life-years lost, maximum individual risk [MIR], or population above an "unacceptable" level of risk). More than one measure of risk may result from a particular risk assessment; however, the uncertainty may be quantified or reached individually.
2. Specify "risk equations" that present mathematical relationships that express the risk measure in terms of its components. This step is used to identify the important variables in the risk estimation process.
3. Generate an uncertainty distribution for each variable or equation component. These uncertainty distributions may be generated by using analogy, statistical inference techniques, expert opinion, or a combination of these.
4. Combine the individual distributions into a composite uncertainty distribution.
5. Re-calibrate the uncertainty distributions. Inferential analysis could be used to "tighten" or "broaden" particular distributions to account for dependencies among the variables and to truncate the distributions to exclude extreme values.
6. Summarize the output clearly, highlighting the important risk management implications. Address specific critical factors, including (1) the implication of supporting a point estimate produced without considering uncertainty; (2) balance the costs of under- or over-estimating risks; and (3) unresolved scientific controversies, and their implications for research.

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Chapter 4 Air Toxics: Chemicals, Sources, and Emissions Inventories

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4.1 Introduction

This chapter identifies the set of chemicals broadly, and most commonly, considered "air toxics." This section also describes the general categories of air toxics sources that emit these chemicals as well as the primary places where air toxics emissions information (e.g., databases that contain information on the location and nature of emissions released from various types of sources) used in air toxics risk assessments can be found. Section 4.2 discusses air toxics; Section 4.3 describes air toxics sources; and Section 4.4 describes air toxics emissions data sources.

The exhaustive lists of air toxics discussed in this section do not include all of the hazardous chemicals of public health concern. Note also that other forms of air pollution (e.g., odors) are not addressed in this Reference Library.

4.2 Air Toxics

Chapter 2 of this Volume introduced Hazardous Air Pollutants (HAPs), criteria air pollutants, Toxic Release Inventory (TRI) chemicals, and persistent, bioaccumulative, and toxic (PBT) chemicals and discussed the relationships among these various groupings. This section will revisit each of these groups to provide more detailed information related to the chemicals on each of those lists. A thorough understanding of the different types of chemicals that may be of interest for an assessment, as well as the nuances of the various ways chemicals are written into those lists, will be important for the risk assessment team to comprehend before the assessment begins in earnest.

The term "air toxics" is a generic term that could conceivably encompass literally anything in the air that poses harm to people or the environment. This Volume uses the term "air toxics" in this general sense. Thus, while the focus of most air toxics risk assessments will be on the 188 chemicals and chemical compounds listed as HAPs in the Clean Air Act (CAA) section 112(b), some assessment teams may wish to have a broader focus. The use of the term "air toxics" in this general sense is meant to provide for this flexibility. Ultimately, the scope of any assessment must clearly identify the chemicals that will be evaluated and the reason for their inclusion or exclusion in the evaluation.

4.2.1 Introduction to Air Toxics Chemical Lists

The various lists that are the focus of this volume were all derived directly from the Clean Air Act, the Emergency Planning and Community Right to Know Act, or a specific EPA initiative (e.g., the PBT initiative list of chemicals). It is important to understand that there is not always consistency among these various lists in either the naming of chemicals or the meaning of the names. For example, as noted in Chapter 2, "glycol ethers" are defined differently for the TRI and as HAPs (see box in Section 2.4.4).

Lists of toxic chemicals commonly provide the chemical identity by both a name and a unique identifying number, called a **Chemical Abstracts Registry Number**.[(a)] However, most

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[a]CAS (Chemical Abstracts Service) is a division of the American Chemical Society. A CAS Registry Number (CAS number or CASRN) is assigned in sequential order to unique, new substances identified by CAS scientists for inclusion in the CAS REGISTRY database. Each CAS Registry Number is a unique numeric identifier; designates only one substance; and has no chemical significance. A CAS Registry Number is a numeric

chemicals have multiple synonyms (sometime dozens). Fortunately, every unique chemical has only one unique CAS number and one can always refer to this unique number to identify the compound in question. For example, toluene and methylbenzene are synonyms for the same compound (which is normally referred to as toluene). However, there is only one CAS number for the compound: 108-88-3. No matter where one is in the world or what name is attached to a chemical, there is unanimity of identity through the CAS numbering system.

When there is any question about what a particular chemical name means, it is always advisable to try to pinpoint the identity through use of the CAS number. For example, a risk assessment team may ask for air sampling analysis for the HAP acetaldehyde (CAS number 75-07-0); however, when they receive the analytical lab report, acetaldehyde is not reported. A quick scan of the CAS numbers reported by the lab lists the CAS number 75-07-0 next to the name "ethanal." Ethanal is a synonym for acetaldehyde and, hence, has the same CAS number. EPA's *Handbook for Air Toxics Emission Inventory Development* includes a list (Appendix C) of synonyms and CAS numbers for HAPs that is helpful in overcoming the nomenclature obstacle.[1] (Note, however, that there are nuances even beyond this simplistic description. For example, some chemicals have one CAS number for their pure form and a different CAS number for a technical grade. A knowledgeable chemist can usually identify and clarify these issues.)

Some of the entries on chemical lists are for large groups of compounds and not just one single substance. For example, one of the HAPs is listed in the CAA as "polychlorinated biphenyls (aroclors)" and is most commonly referred to as PCBs. This listing is not for one single substance but, rather, for any one or a mixture of any of the 209 possible chemicals that are themselves PCBs. As another example, the pesticide "2,4-D" is written into the list of HAPs as "2,4-D (salts and esters)." This listing includes any possible salt of 2,4-D and any possible ester of 2,4-D. In our earlier lead example, the lead compound listing includes any compound known to exist in or be emitted to the environment that contains a lead molecule as part of the compound's molecular structure (a potentially huge number of possibilities). Another important group of chemicals is called "POM" for polycyclic organic matter. This includes organic compounds with more than one benzene ring, and which have a boiling point greater than or equal to 100° C (e.g., polycyclic aromatic hydrocarbons (PAHs) such as benzo(a)pyrene).

In reality, most risk assessments will deal with a relatively small number of chemicals because either the sources in a given place are releasing only a limited number of chemicals or the ability to model or monitor the numerous chemicals present is limited by the available inventories or monitoring/analytical methods, respectively.

In the initial stages of the assessment, risk assessors often sort the chemicals of interest into groups that, generally, have similar physical and/or chemical properties. This is a helpful thing to do as a way of making some educated guesses about how chemicals are likely to behave in the environment. The groupings also help an assessment team to plan for the types of sampling and analysis methods that will be needed, because the sampling and analytical methods tend to be broken out along these same lines. In general, all air toxics can be broadly categorized into three main groups, organic chemicals, inorganic chemicals, and organometallic compounds as follows:

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identifier that can contain up to nine digits, sometimes divided by hyphens into three parts. See http://www.cas.org/faq.html for more information.

Organic Chemicals

Organic chemical compounds are composed of carbon in combination with other elements such as hydrogen, oxygen, nitrogen, phosphorous, chlorine, and sulfur (not including carbonic acid or ammonium carbonate). Organic compounds can generally be split into two different groups, based on their propensity to evaporate. The following such groupings are commonly employed by analytical chemistry laboratories for purposes of sample analysis.

- **Volatile Organic Compounds (VOCs)**. These are organic chemicals that have a high vapor pressure and tend to have low water solubility.[b] Simply put, VOCs have a high propensity to evaporate and remain airborne. Many VOCs are human-made chemicals that are used and produced in the manufacture of paints, pharmaceuticals, and refrigerants, as industrial solvents, such as trichloroethylene, or produced as by-products, such as chloroform produced by chlorination in water treatment. VOCs are often also components of petroleum fuels (e.g., benzene), hydraulic fluids, paint thinners, and dry cleaning agents.[c]

  A subgroup of VOCs is termed **Carbonyl Compounds** and includes chemicals such as formaldehyde and acetaldehyde. While such chemicals are themselves VOCs due to their high vapor pressure, they are often grouped as a separate class from the VOCs because of the special sampling and analytical methods necessary to measure them in air.

- **Semivolatile Organic Compounds (SVOCs)**. SVOCs are organic chemicals that have a lower vapor pressure than VOCs and, thus, have a lower propensity to evaporate from the liquid or solid form. Once airborne, they also tend to more readily condense out of the gas phase. Examples of SVOCs include most organic pesticides (e.g., chlordane), and certain components of petroleum, such as polycyclic aromatic hydrocarbons. Note that the demarcation between SVOCs and VOCs is not exact. For example, the two separate air sampling and analytical methods for VOCs and SVOCs will both usually detect naphthalene when present, indicating that this chemical is on the lower end of the VOC scale of volatility and on the higher end of the SVOC scale of volatility. In general, as chemicals increase in molecular weight and/or polarity, they become more SVOC-like.

Inorganic Chemicals

This group includes all substances that do not contain carbon and includes a wide array of substances such as:

- Metals (e.g., mercury, lead, and cadmium) and their various salts (e.g., mercury chloride);
- Halogens (e.g, chlorine and bromine);
- Inorganic bases (e.g., ammonia); and
- Inorganic acids (e.g., hydrogen chloride, sulfuric acid).

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[b]The regulatory definition of VOC does not identify vapor pressure as a consideration. See 40 CFR 51.100(s).

[c]"VOC" refers to volatile organic compounds that contribute to ozone formation as defined by 40 CFR 50.100(s) as ozone precursors. VOC is a subset of VOCs. VOC emissions inventory information is sometimes used to derive estimates for specific chemicals; when this is done, the VOC number is said to have been speciated.

Organometallic Compounds

This group is comprised of compounds that are both organic and metallic in nature. The alkyl lead compounds that were added to gasoline to enhance its properties can be used for illustration. "Alkyl" refers to the organic portion of a compound which is attached to the inorganic metal lead. The result is a so-called "organometallic" material, a hybrid of both metallic and organic. (Note that salts, such as sodium benzoate, are usually classified as an organic chemical, rather than an organometallic compound.)

An understanding of the general characteristics of organic chemicals, inorganic chemicals and organometallic compounds will aid in planning a risk assessment and developing an appropriate analysis strategy. For example, most VOCs tend to remain airborne and also do not tend to bioaccumulate to the same extent as some of the non-volatile chemicals. Thus, if an assessment were being planned to evaluate the impact of a source from which only VOCs were released, it becomes less likely that a multipathway risk analysis will be necessary (since VOCs do not tend to migrate into soil or water and do not tend to bioaccumulate as strongly in living tissue).

In addition, the sampling and analytical methods available to test for chemicals in environmental media are generally broken out along the same chemical groupings noted above. Thus, if one were interested in testing for airborne chlordane (an SVOC), a VOC monitoring method would not be used. Detailed information on available monitoring methods and the chemicals for which they have been validated is provided in Chapter 10.

In air toxics studies, both individual substances and mixtures of substances are of interest. Particulate matter (PM), for example, is almost never comprised of just one substance; instead, PM is usually made up of numerous individual substances (sometimes in the hundreds). Both the physical and chemical nature of a mixture will influence the fate and transport of the chemicals in the environment as well as the potential for the mixture to cause harm. For example, a toxic chemical adsorbed onto the surface of a relatively large particle (> 10 microns in diameter) will usually be trapped in the upper portion of the respiratory system and either coughed/sneezed out of the body or swallowed. The same chemical adsorbed onto a very small particle (< 2.5 microns in diameter) has a much higher likelihood of being inhaled into the deep lung. As we will see in later chapters, both the route of exposure (in this example, ingestion or inhalation) as well as the toxic properties of the chemical in question are important determinants of potential harm.

4.2.2 Hazardous Air Pollutants (HAPs)

The HAPs are a group of 188 specific chemicals and chemical compounds and are identified in Section 112(b) of the CAA. The Agency provides additional information on the HAPs online.[(2)] HAPs are pollutants known to cause or suspected of causing cancer or other serious human health effects or ecosystem damage. They include individual organic and inorganic compounds and pollutant groups closely related by chemical structure (e.g., arsenic compounds, cyanide compounds, glycol ethers, polycyclic organic matter) or emission sources (e.g., coke oven emissions). EPA may add or remove pollutants from the HAP list as new information becomes available. A full list of the HAPs is provided in Appendix A.

When people talk about "air toxics risk assessment," they generally mean assessments of risks associated with one or more of the HAPs. This is largely because of the CAA listing of 188

HAPs and its requirement under Section 112(f)(2) (Residual Risk) that EPA assess the risks associated with HAPs that remain after the application of the Maximum Achievable Control Technology (MACT) standards (Section 112(d) of the Act). However, given that this is a relatively short list of chemicals, many communities may want to go beyond this list when assessing risk. It is for this reason, that assessors and other stakeholders must clearly identify why they are conducting an "air toxics" risk assessment and what they want to include in that assessment.

In its Integrated Urban Air Toxics Strategy, EPA identified a subset of 33 HAPs as those posing the greatest risk in urban areas (see Section 2.2.1). These 33 HAPs were selected based on a number of factors, including toxicity-weighted emissions, monitoring data, past air quality modeling analysis, and a review of existing risk assessment literature.

The national-scale assessment for 1996 (see Section 2.3.2) focused on 32 of these 33 Urban HAPs (dioxin was omitted) and also includes diesel particulate matter, which is used as a surrogate measure of diesel exhaust. EPA recently concluded that diesel exhaust is likely to be carcinogenic to humans by inhalation at environmental levels of exposure. Diesel exhaust is addressed in several regulatory actions and diesel particulate matter plus diesel organic gases are listed by EPA as a mobile source air toxic (see Section 4.3.3 below).

4.2.3 Criteria Air Pollutants

The "criteria air pollutants" are six substances regulated pursuant to Title I of the CAA, for which "criteria documents" are developed by the Agency prior to national standard setting decisions. There are already national ambient air quality standards (NAAQS) in place for each of these pollutants as well as established regulatory programs and activities in place to meet those standards. However, they are discussed here because there is some crossover between the realm of HAPs and criteria pollutants. The more important crossover issues are discussed below.

- **Particulate matter**. NAAQS have been established for particles with an aerodynamic diameter less than or equal to 10 microns (called PM_{10}) and particulate matter with an aerodynamic diameter less than or equal to 2.5 microns (called $PM_{2.5}$). As noted above, however, PM can be made up of as little as one or a few, or many hundreds of individual chemicals. In many cases (and depending on the source of the PM), any number of specifically listed HAPs may be a part of the PM mix. It is for this reason that risk assessors may opt to evaluate the composition of PM and to include the identified chemicals in risk calculations.

  For example, it is possible to collect samples of PM_{10} for purposes of determining the types and amounts of individual substances contained in the particles. The risks posed by those individual chemicals may then be estimated for the inhalation route of exposure. Because particles with diameters greater than 10 microns are not generally respirable, analysts usually select a PM_{10} monitor to capture samples for risk assessment purposes rather than a total suspended particulate (TSP) sampler, because TSP would capture larger particles that do not penetrate very far into the respiratory tract (thus leading to an overestimate in inhalation risk associated with the specific pollutants studied). Note that this would not be true for particle-bound chemicals that exert their toxic effects on the nasal passages.

- **Ozone and other criteria pollutants**. Certain other criteria pollutants are not specifically listed as HAPs, but HAPs may lead to their formation or they may lead to HAP formation. For example, ozone is produced by the interaction of certain VOCs, oxides of nitrogen (called NO_x), and sunlight. As noted previously, many of the HAPs are VOCs and may play a role in ozone formation. In contrast, sulfur dioxide is a criteria pollutant that can be transformed in the environment into sulfuric acid which, in turn, may become part of a listed HAP (e.g., cadmium sulfate). In general, the criteria pollutants ozone, nitrogen dioxide, sulfur dioxide, carbon monoxide are not usually considered in air toxics risk assessments.

4.2.4 Toxics Release Inventory (TRI) Chemicals

Data on TRI chemicals are reported pursuant to Section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA) of 1986 and Section 6607 of the Pollution Prevention Act of 1990 (PPA). EPCRA and the PPA are intended to inform communities and citizens about chemical hazards in their areas. EPA and states are required to collect data annually on releases (to each environmental medium) and waste management methods (e.g., recycling) of certain toxic chemicals from industrial facilities, and to make the data available to the public in the TRI.[3] EPCRA Section 313(d) permits EPA to list or delist chemicals based on certain criteria. In a 1994 rulemaking, EPA added 286 chemical categories to the TRI chemical list. The TRI chemicals are listed in 40 CFR Section 372.65, and information about the 667 currently-listed TRI chemicals is provided online.[4]

The current TRI chemical list contains 582 individually listed chemicals and 30 chemical categories (including three delimited categories containing 58 chemicals), for a total of 612 separate chemicals. If the members of the three delimited categories are counted as separate chemicals then the total number of chemicals and chemical categories is 667 (i.e., 582 + 27 + 58). The TRI list of toxic chemicals includes most (180) of the HAPs. Similar to the HAPs, the TRI chemicals include VOCs, SVOCs, inorganic compounds, and organometallic compounds.

The utility of the TRI for air toxics risk assessment is two fold. First, it provides a broader perspective of industrial emissions than the HAP list because it includes information on air releases of many hundreds of additional chemicals. Second, accessing TRI information is extremely quick and easy. Using the TRI Explorer search engine (http://www.epa.gov/tri/tridata/index.htm), one may quickly identify the location of emissions sources and the identity and quantity of chemicals released to the air. The data is also updated annually (as opposed to the National Emissions Inventory (NEI), a nationwide inventory of emissions developed by EPA, which is only updated triennially). However, other characteristics of the TRI data may limit their use for risk assessments (see Section 4.4.2).

4.2.5 Toxic Chemicals That Persist and Which Also May Bioaccumulate

Some toxic compounds have the ability to persist in the environment for long periods of time and may also have the ability to build up in the food chain to levels that are harmful to human health and the environment. For example, releases of metals from a source may deposit out of the air onto the ground where they remain in surface soils for long periods of time. Children playing in the area may ingest this contaminated dirt through hand-to-mouth behaviors. The chemicals in the dirt may also be taken up into plants through the roots and accumulate in foraging animals.

EPA's challenge in reducing risks from this category of toxic air pollutants stems from this ability to transfer from air, to sediments, water, land, and food; to linger for long periods of time in the environment; and for some substances, their ability to travel long distances. Many of these chemicals (e.g., DDT) have been banned for use in the U.S. As such, there should be no active air emissions of these chemicals (although releases into the air are still possible, e.g., by resuspension of previously contaminated soil). However some, such as mercury, are still in use today. A number of lists of these persistent and bioaccumulative chemicals have been developed through international and internal EPA efforts (see Exhibit 4-1). A number of the HAPs appear on one or more of these lists.

Exposure to persistent and bioaccumulative air toxics through a pathway other than inhalation of contaminated air is termed **an indirect exposure pathway** because contact with the chemical occurs in a medium that is not the original medium to which the chemical was released (i.e., air). In contrast, a **direct exposure pathway** is one in which contact occurs with the chemical in the medium to which it was originally released. When exposure of a person to a chemical (or chemicals) occurs through more than one pathway, a **multipathway analysis** may be considered.

In air toxics risk assessment, the inhalation pathway is commonly assessed (i.e., the release of a chemical to air and human exposure through breathing that air). However, indirect exposure pathways are usually assessed for a limited set of chemicals released to the air. EPA has identified a preliminary set of HAPs for which indirect exposure pathway analyses should generally be conducted for situations involving significant emissions of these chemicals in a study area. This new list of chemicals is termed **Persistent Bioaccumulative HAP Compounds (PB-HAP Compounds)** (Exhibit 4-2); however, all of the PB-HAP compounds occur on one or more of EPA's existing lists of PBT chemicals. The designation "PB-HAP" was developed to distinguish this list from the existing lists of PBT chemicals (Exhibit 4-1) and specifically to clarify that chemicals on this new list are:

- HAPs;
- Relatively persistent in the environment; and
- For some chemicals, have a strong propensity to bioaccumulate and/or biomagnify.[(d)]

This preliminary list of PB-HAPs was derived primarily on the basis of human health concerns. It does not consider direct contact by plants or inhalation by animals. Additional HAPs may be identified as EPA gains more familiarity with ecological risk assessments for air toxics. Appendix D describes the process by which EPA identified the list of PB-HAPs.

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[d]Biomagnification is the process whereby certain substances transfer up the food chain and increase in concentration. Chemicals that biomagnify tend to accumulates to higher concentration levels with each successive food chain level. Biomagnification is a particular concern for ecological risk assessment.

Exhibit 4-1. "Lists" of Toxic Chemicals that Persist and Which Also May Bioaccumulate
LRTAP chemicals – The United States signed protocols on Persistent Organic Pollutants (POPs) and heavy metals pursuant to the Convention on Long-Range Transboundary Air Pollution (LRTAP) in June 1998 at a ministerial meeting in Aarhus, Denmark. Sixteen POPs and three metals are regulated (http://www.epa.gov/oppfead1/international/lrtap2pg.htm):
• aldrin • cadmium • chlordane • dieldrin • endrin • hexabromobiphenyl • kepone (chlordecone) • mirex • toxaphene • hexachlorobenzene • heptachlor • lead • mercury • polychlorinated biphenyls (PCBs) • dichlorodiphenyltrichloroethane (DDT) • lindanedioxins (polychlorinated dibenzo-p-dioxins) • furans (polychlorinated dibenzofurans) • hexachlorobenzene • polycyclic aromatic hydrocarbons
PBT Chemicals – EPA has identified the following priority persistent, bioaccumulative, and toxic (PBT) chemicals and has developed the PBT program to address the cross-media issues associated with these chemicals (http://www.epa.gov/opptintr/pbt/):
• aldrin/dieldrin • mercury and its compounds • benzo(a)pyrene • mirex • chlordane • octachlorostyrene • DDT • dichlorodiphenyldichloroethane (DDD) • dichlorodiphenyldichloroethylene (DDE) • PCBs • hexachlorobenzene • dioxins and furans • alkyl-lead • toxaphene
Great Lakes Priority Substances. In keeping with the obligations of the Great Lakes Water Quality Agreement, Canada and the United States on April 7, 1997, signed the "Great Lakes Binational Toxics Strategy: Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes" (http://www.epa.gov/glnpo/p2/bns.html). This Strategy seeks percentage reductions in targeted persistent toxic substances so as to protect and ensure the health and integrity of the Great Lakes ecosystem. The list of "Level 1" substances is identical to EPA's priority PBT pollutants.
Great Waters Pollutants of Concern. The 1990 Clean Air Act Amendments established research and reporting requirements related to the deposition of hazardous air pollutants to the Great Lakes, Lake Champlain, Chesapeake Bay, and certain other "Great Waters." The Program has identified the following pollutants of concern (http://www.epa.gov/airprogm/oar/oaqps/gr8water/index.html):
• cadmium and cadmium compounds • chlordane • DDT/DDE • dieldrin • hexachlorobenzene • α-hexachlorocyclohexane • lindane (γ-hexachlorocyclohexane) • lead and lead compounds • mercury and mercury compounds • PCBs • polycyclic organic matter • tetrachlorodibenzo-p-dioxin (dioxins) • tetrachlorodibenzofuran (furans) • toxaphene • nitrogen compounds

Exhibit 4-1 (continued)

TRI PBT chemicals. EPA has published two final rules that lowered the Toxics Release Inventory (TRI) reporting thresholds for certain persistent bioaccumulative and toxic (PBT) chemicals and added certain other PBT chemicals to the TRI list of toxic chemicals (http://www.epa.gov/tri/lawsandregs/pbt/pbtrule.htm). The following PBT chemicals are subject to reporting at lowered thresholds:

- dioxin and dioxin-like compounds
- lead compounds
- mercury compounds
- polycyclic aromatic compounds
- aldrin
- benzo(g,h,i)perylene
- chlordane
- heptachlor
- hexachlorobenzene
- isodrin
- lead
- mercury
- methoxychlor
- octachlorostyrene
- pendimethalin
- pentachlorobenzene
- PCBs
- tetrabromobisphenol A
- toxaphene
- trifluralin

Waste Minimization Priority Chemicals. EPA's National Waste Minimization Partnership Program focuses on reducing or eliminating the generation of hazardous waste containing any of 30 Waste Minimization Priority Chemicals (WMPCs). This list replaces the list of 53 chemicals EPA identified in 1998 (*Notice of Availability: Draft RCRA Waste Minimization Persistent, Bioaccumulative and Toxic (PBT) Chemical List*, Federal Register 63(216): 60332-60343, November 9, 1998). Twenty six of the chemicals in the current list were also in the draft list published in 1998. The remaining four chemicals on the current list were added in response to comments and new information EPA received from the public regarding the Agency's methodology for selecting the 53 chemicals in the draft list (http://www.epa.gov/epaoswer/hazwaste/minimize/chemlist.htm).

- 1,2,4-trichlorobenzene
- 1,2,4,5-tetrachlorobenzene
- 2,4,5-trichlorophenol
- 4-bromophenyl phenyl ether
- acenaphthene
- acenaphthylene
- anthracene
- benzo(g,h,i)perylene
- dibenzofuran
- dioxins/furans
- endosulfan, alpha and endosulfan, beta
- fluorene
- heptachlor and heptachlor epoxide
- hexachlorobenzene
- hexachlorobutadiene
- hexachlorocyclohexane, gamma-
- hexachloroethane
- methoxychlor
- naphthalene
- PAH group (as defined in TRI)
- pendimethalin
- pentachlorobenzene
- pentachloronitrobenzene
- pentachlorophenol
- phenanthrene
- pyrene
- trifluralin
- cadmium and cadmium compounds
- lead and lead compounds
- mercury and mercury compounds

Exhibit 4-2. PB-HAP Compounds			
PB-HAP Compound	**Pollution Prevention Priority PBTs**	**Great Waters Pollutants of Concern**	**TRI PBT Chemicals**
Cadmium compounds		X	
Chlordane	X	X	X
Chlorinated dibenzodioxins and furans	X[(a)]	X	X[(b)]
DDE	X	X	
Heptachlor			X
Hexachlorobenzene	X	X	X
Hexachlorocyclohexane (all isomers)		X	
Lead compounds	X[(c)]	X	X
Mercury compounds	X	X	X
Methoxychlor			X
Polychlorinated biphenyls	X	X	X
Polycyclic organic matter	X[(d)]	X	X[(e)]
Toxaphene	X	X	X
Trifluralin			X

[(a)] "Dioxins and furans" ("" denotes the phraseology of the source list)
[(b)] "Dioxin and dioxin-like compounds"
[(c)] Alkyl lead
[(d)] Benzo[a]pyrene
[(e)] "Polycyclic aromatic compounds" and benzo[g,h,i]perylene

4.2.6 Other Chemicals

The chemicals included in the various lists of air toxics described above – HAPs, criteria pollutants, TRI chemicals, and toxic chemicals that persist and which also may bioaccumulate – do *not* represent all of the chemicals potentially emitted to air in a given place. EPA is required to maintain an inventory, known as the "Toxic Substances Control Act (TSCA) Inventory," of each chemical substance which may be legally manufactured, processed, or imported in the U.S. The TSCA inventory currently contains over 75,000 chemicals (see: "enforcement programs" at http://www.epa.gov/compliance/civil/programs/tsca/). At best, we have the capability to assess only a few hundred in detail. As noted previously, this does not imply that risk assessments are always missing important information. To the contrary, the actual number of chemicals used in significant amounts and released to air are relatively small compared to the number of chemicals known. Nevertheless, it is important to keep in mind that the ability to evaluate air toxics releases is limited by current technology, the lack of toxicity information for all but a relatively small number of chemicals and, in some cases, costs (e.g., a single sample for certain analytes such as dioxin can cost upwards of $1,000 per sample, making multiple sampling events cost prohibitive).

The HPV Challenge Program

EPA, in partnership with industry and environmental groups, recently created a voluntary chemical testing effort, the high production volume (HPV) Challenge Program. This program was developed to make publicly available a complete set of baseline health and environmental effects data on HPV chemicals (those manufactured in, or imported into, the United States in amounts equal to or exceeding 1 million pounds per year). Information on HPV chemicals is available at http://www.epa.gov/chemrtk/rtkfacts.htm.

4.3 Sources of Air Toxics

Many anthropogenic and natural activities are sources of air pollutants. Examples of human activities that result in the release of air toxics include:

- Fuel combustion activities in power plants, factories, automobiles, and homes;
- Biomass burning and other agricultural activities;
- Use of consumer products, such as pesticides and cleaning agents;
- Commercial activities, such as dry cleaning; and
- Industrial activities, such as petroleum refining, chemical manufacture, and metal plating.

Sources of air toxics can be categorized in various ways – whether they occur indoors or out, whether they are stationary or mobile, by the amount of chemicals they release, or by other approaches. For the purposes of this discussion, air toxics have been placed into several major groupings that track EPA's programs and emissions inventories. Note that some differences in terminology exist between the CAA and the NEI (Exhibit 4-3).

- Point sources;
- Nonpoint sources;
- On-road mobile sources;
- Nonroad mobile sources;
- Indoor sources;
- Natural sources; and
- Exempt sources.

The first four categories are groupings of emission sources of HAPs and criteria air pollutants in EPA's **National Emissions Inventory (NEI)**. The NEI is a nationwide inventory of emissions that has been developed by EPA with input from numerous state, local, and tribal (S/L/T) air agencies. The NEI is discussed in more detail as a source of quantitative emissions release data in Section 4.4.1 below. For detailed information on NEI, refer to EPA's main NEI web page.[5] NEI summaries were posted in October 2003.

Exhibit 4-3. Terminology Related to Groupings of Source Types

Source Type	How Defined in CAA	How Reported in NEI
Point source – Major	Point source – Major	Point source
Point source – Area	Point source – Area	Point source if location coordinates reported Area source if coordinates not reported
Nonpoint source	Nonpoint source	Area
Mobile source – On-road	Mobile source – On-road	Modeled
Mobile source – Nonroad	Mobile source – Nonroad	Modeled or estimated
Indoor	Not defined	Not reported
Natural	Not defined	Not reported
Exempt	Not defined	Not reported

4.3.1 Point Sources

Point sources of air toxics are stationary sources (i.e., sources that remain in one place) that can be located on a map. A large facility that houses an industrial process is an example of a point source – the facility and its emission release points (e.g., stacks, vents, fugitive emissions from valves) are stationary, and the emission rates of air toxics can be characterized, either through direct measurements, such as stack monitoring, or indirect methods, such as engineering estimates based on throughput, process information, and other data. The CAA divides point sources into two main categories primarily on the basis of annual emissions rates:

- **Major sources** are defined in Section 112(a)(1) as "any source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate, 10 tons per year (tpy) or more of any hazardous air pollutant or 25 tpy or more of any combination of hazardous air pollutants."

- **Area sources** are defined in Section 112(a)(2) as "any stationary source of hazardous air pollutants that is not a major source. For purposes of this section, the term 'area source' shall not include motor vehicles or nonroad vehicles subject to regulation under Title II." Examples of area sources include dry cleaners, gas stations, chrome electroplaters, and print shops. Though emissions from individual area sources may be relatively insignificant in human health terms, collectively their emissions can be quite significant, particularly where large numbers of sources are located in heavily populated areas. Note that sources that are classified as "area sources" pursuant to the CAA may be reported in the NEI as "point sources" if they can be located on a map.

Many sources of HAPs are subject to **National Emission Standards for Hazardous Air Pollutants (NESHAPs)** pursuant to Section 112 of the CAA. This Section of the CAA directs EPA to issue regulations listing categories and subcategories (commonly referred to collectively as **source categories**) of major sources and area sources of HAPs and to develop standards for each listed category and subcategory.[6] EPA periodically updates the list of source categories (see Appendix E).[7]

Physical Forms of Emissions	
Gas	Emissions that are distinguished from solid and liquid states
Fume	Tiny particles trapped in vapor in a gas stream
Mist	Liquid particles measuring 40 to 500 micrometers that are formed by condensation of vapor
Particulate Matter (and Aerosols)	Fine liquid or solid particles

Air pollutants can be found in all three physical phases: solid, liquid, or gaseous. The distinct chemical and physical attributes of each phase contribute to the pollutant's transport and fate. For example, as reported in the *Mercury Study Report to Congress*,[8] elemental mercury vapor is not thought to be susceptible to any major process of direct deposition to the earth's surface due to its relatively high vapor pressure and low water solubility. Therefore, it is carried by the wind and subsequently dispersed throughout the atmosphere. However, divalent mercury, in either vapor or particulate phase, is thought to be subject to much faster atmospheric removal, and is expected to be deposited near its source. For further details on fate and transport analysis, see Chapter 8.

As noted in Chapter 2, EPA regulates stationary sources in a two-phase process. First, EPA issues technology-based MACT standards that require sources to meet specific emissions limits. The emission limits are typically expressed as maximum emission rates, or minimum percent emission reductions, for specific pollutants from specific processes. In the second phase, EPA applies a risk-based approach to assess how well MACT emissions limits reduce health and environmental risks. Based on these **residual risk assessments**, EPA may implement additional standards to address any significant remaining, or residual, health or environmental risks (see Chapter 2 for a more detailed discussion of the MACT and residual risk programs).

Area sources may be subject to either MACT or **Generally Available Control Technology (GACT)** standards. GACT standards are generally less stringent than MACT standards. Area sources subject to MACT standards include Commercial Sterilizers using Ethylene Oxide, Chromium Electroplaters and Anodizers, Halogenated Solvents Users, and Asbestos Processors.

4.3.2 Nonpoint Sources

The term nonpoint source refers to smaller and more diffuse sources within a relatively small geographic area. In the context of EPA's NEI, nonpoint sources of air toxics are stationary sources for which emissions estimates are provided as an aggregate amount of emissions for all similar sources within a specific local geographic area, such as counties or cities, rather than on a facility- or source-specific basis. Emission estimates for nonpoint sources are generated using "top-down" methods, when detailed information at the local level is lacking. Instead, the total emissions over a large geographic area (e.g., n tons in the northeastern states) are allocated to the

local level (e.g., x percent is assigned to locality 1, y percent is assigned to locality 2, and so on). Note that for the purposes of this discussion, the nonpoint source category includes only stationary sources and does *not* include mobile sources.

Source-specific information may be available for *some* (but not all) of the specific facilities within a certain nonpoint source type. Area sources may be reported as either point or nonpoint sources in the NEI. If a state or local agency reports an area source emission as a point source, then the NEI retains the area source emission as a point source. The NEI does not aggregate point area sources as nonpoint sources, and **EPA has taken steps to avoid "double-counting" of emissions in the point and nonpoint source inventories**.

To compile nonpoint estimates for a category, the EPA first estimates county level emissions for nonpoint source categories. Then EPA replaces nonpoint EPA generated estimates with state and local agency and tribal estimates. If a state or local agency or tribe includes point source estimates for an EPA generated nonpoint source category, EPA removes the nonpoint estimate that it had generated and the point source inventory contains the S/L/T estimate. For example, in the Denver area, the State of Colorado inventories dry cleaners and service stations as point sources. The NEI contains point sources estimates for these two categories in the six county area of Denver and the NEI does not contain nonpoint estimates for these two categories. Dry cleaners and service station emissions are contained in the NEI nonpoint inventory for the other fifty counties on Colorado.

A variety of sources are categorized as nonpoint sources in the NEI, including some small industrial/commercial processes (e.g., small dry cleaning facilities, hospital sterilization facilities, and dental offices). Additional nonpoint sources that contribute to air pollution are agricultural activities, residential trash and yard-waste burning, wood stoves and fireplaces, releases from spills and other accidents, and volatilization and resuspension of pollutants from contaminated sites. Examples of agricultural activities contributing to air pollution are biomass burning (e.g., for land clearing) and the application of fertilizers and pesticides. The open burning of forests (including wildfires) are also categorized as nonpoint sources. (Note that forest fires are generally considered for the purposes of the NEI to be an anthropogenic source of air toxics because they are assumed to be directly or indirectly, for purposes of the NEI, caused by man.)

Some nonpoint sources emit HAPs and are subject to NESHAPs pursuant to Section 112 of the CAA (see Section 4.3.1 above for more information on NESHAPs). These nonpoint sources are area sources in that they emit less than 10 tpy of a single air toxic or less than 25 tpy of a mixture of air toxics. For example, facilities that perform perchloroethylene dry cleaning belong to a source category that is subject to NESHAPs.

4.3.3 On-Road and Nonroad Mobile Sources

Mobile sources pollute the air with fuel combustion products and evaporated fuel. These sources contribute greatly to air pollution nationwide and are the primary cause of air pollution in many urban areas. Section 202(l) of the CAA gives EPA the authority to regulate air toxics from motor vehicles. Based on 1996 National Toxics Inventory data (the NTI is the former name of the air toxics portion of the current NEI), mobile sources contributed 2.3 million tpy or about half of all air toxics emissions in the U.S. Mobile sources emit hundreds of air pollutants – for example, exhaust and evaporative emissions from mobile sources contain more than 700

compounds. EPA's Final Rule, *Control of Emissions of Hazardous Air Pollutants from Mobile Sources*, commonly known as the "Mobile Source Air Toxics" (MSAT) rule,[9] identified 21 compounds as HAPs emitted by mobile sources (see Chapter 2). All of these compounds except diesel particulate matter and diesel exhaust organic gases (DPM + DEOG) are included on the CAA Section 112 HAPs list. Although some mobile source air toxics are TRI chemicals, mobile sources are not generally subject to TRI reporting. Other mobile source regulations address emissions of criteria pollutants and their precursors, including carbon monoxide (CO), nitrogen dioxide (NO_2), particulate matter (PM), volatile organic compounds (VOCs), and sulfur dioxide (SO_2). These criteria air pollutant control programs for mobile sources have and will continue to result in substantial reduction of HAP releases.

Mobile sources include a wide variety of vehicles, engines, and equipment that generate air pollution and that move, or can be moved, from place to place. In the NEI, EPA divides mobile sources into two broad categories. **On-road mobile sources** include motorized vehicles that are normally operated on public roadways for transportation of passengers or freight. This includes passenger cars, motorcycles, minivans, sport-utility vehicles, light-duty trucks, heavy-duty trucks, and buses. **Nonroad mobile sources**, (sometimes also called "off-road") include aircraft, commercial marine vessels (CMVs), locomotives, and other nonroad engines and equipment. The other nonroad engines and equipment included in NEI comprise a diverse list of portable equipment, such as lawn and garden equipment; construction equipment; engines used in recreational activities; and portable industrial, commercial, and agricultural engines.

EPA's National Air Pollutant Trends Report, 1900–1998[10] indicates that about 60 percent of mobile source air toxics emissions in the U.S. are from on-road sources, and 40 percent of mobile source air toxics emissions are from nonroad sources. The emissions distribution between on- and off-road sources emitting criteria pollutants depends on the chemical. CO comprises the majority of criteria pollutants emitted, with over 100 million tons per year emitted in the U.S. Releases of CO are *primarily* the result of mobile sources – like HAPs, these emissions are split approximately 60/40 between on-road and off-road sources. (The use of CO as a monitoring surrogate for mobile source emissions is discussed in Section 4.4.1.)

Within the two broader categories of mobile sources, EPA further distinguishes on-road and nonroad sources by size, weight, use, horsepower and/or fuel type. For example, categories of on-road vehicles include light-duty gasoline vehicles (i.e., passenger cars), light-duty gasoline trucks, heavy-duty gasoline vehicles, and diesel vehicles. Examples of nonroad sources include nonroad *gasoline* engines and vehicles, (e.g., recreational off-road vehicles, construction equipment, lawn and garden equipment, and recreational marine vessels that use gasoline), nonroad *diesel* engines and vehicles (including the vehicles and equipment listed above, *except* those that use diesel fuel), aircraft, non-recreational marine vessels, and locomotives. An additional category covers all nonroad sources that use liquified petroleum gas or compressed natural gas.

4.3.4 Sources Not Included in the NEI or TRI

In addition to the four primary categories used in compiling the NEI, five other sources of air toxics which are not captured by either the NEI or TRI are described below: Indoor sources, natural sources, secondary formation of air toxics, exempt sources, and international transport.

4.3.4.1 Indoor Sources

Indoor pollution sources that release gases or particles into the air are the primary cause of indoor air quality problems in homes (Exhibit 4-4). Inadequate ventilation can increase indoor pollutant levels by not bringing in enough outdoor air to dilute emissions from indoor sources and by not carrying indoor air pollutants out of the home. High temperature and humidity levels indoors can increase the uptake of some pollutants, thereby magnifying negative health effects.

There are many sources of indoor air pollution in any home. These include combustion sources such as oil, gas, kerosene, coal, wood, and tobacco products; building materials and furnishings as diverse as deteriorated, asbestos-containing insulation, wet or damp carpet, and cabinetry or furniture made of certain pressed wood products; products for household cleaning and maintenance, personal care, or hobbies; central heating and cooling systems and humidification devices; and outdoor sources such as radon, pesticides, and outdoor air pollution.

The relative importance of any single source depends on how much of a given pollutant it emits and how hazardous those emissions are. In some cases, factors such as how old the source is and whether it is properly maintained are significant. For example, an improperly adjusted gas stove can emit significantly more carbon monoxide than one that is properly adjusted.

Some sources, such as building materials, furnishings, and household products like air fresheners, release pollutants more or less continuously. Other sources, related to activities carried out in the home, release pollutants intermittently. These include smoking, the use of unvented or malfunctioning stoves, furnaces, or space heaters, the use of solvents in cleaning and hobby activities, the use of paint strippers in redecorating activities, and the use of cleaning products and pesticides in housekeeping. High pollutant concentrations can remain in the air for long periods after some of these activities.

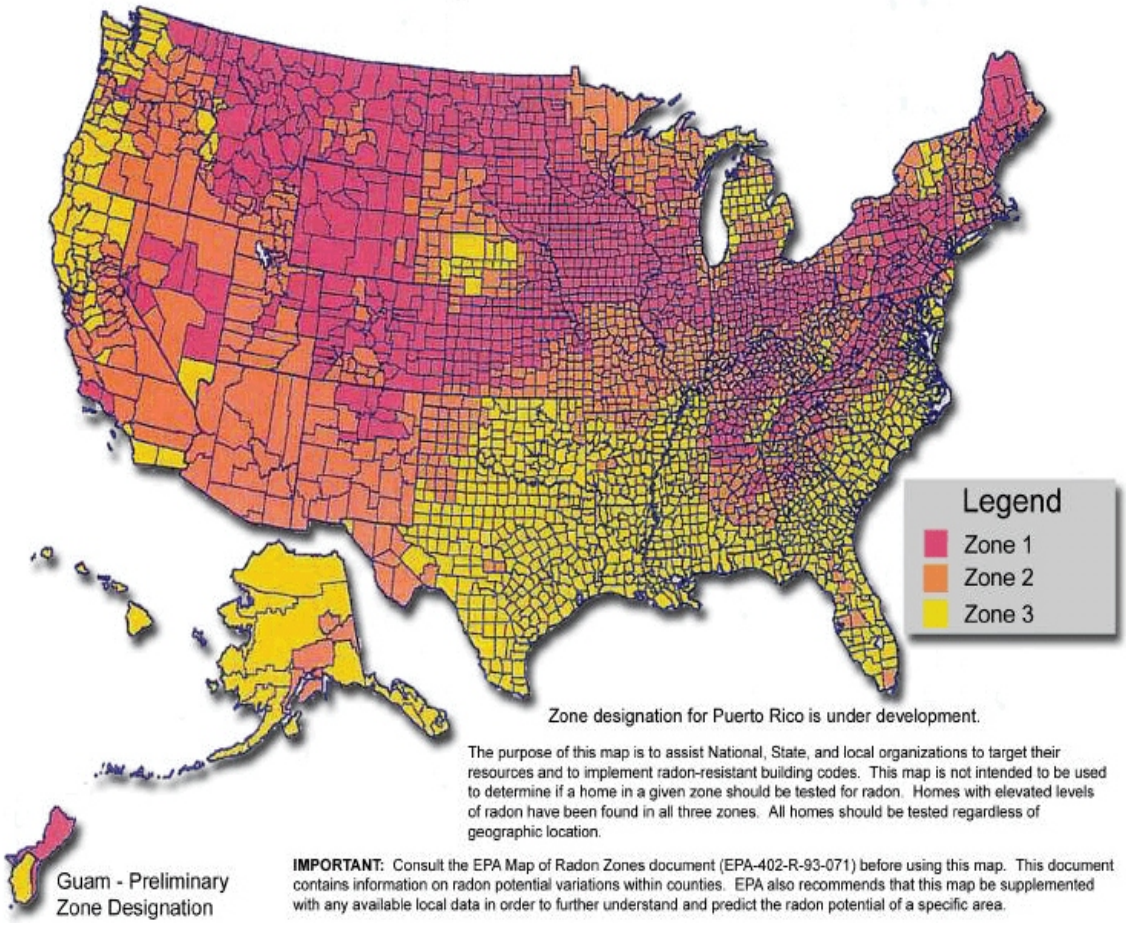
In addition to the same indoor air problems as single-family homes, apartments can have indoor air problems similar to those in offices, which are caused by sources such as contaminated ventilation systems, improperly placed outdoor air intakes, or maintenance activities.

One particularly important indoor air toxics problem actually results from an outdoor natural source. In fact, radon gas, a HAP, is one of the leading causes of lung cancer in the U.S. The most common source of indoor radon is uranium in the soil or rock on which homes are built (thus, a natural source becomes an indoor air quality problem). As uranium naturally breaks down, it releases radon as a colorless, odorless, radioactive gas. Radon gas enters homes through dirt floors, cracks in concrete walls and floors, floor drains, and sumps. When radon becomes trapped in buildings and indoor concentrations build up, exposure to radon becomes a concern.

Sometimes radon enters the home through well water. In a small number of homes, the building materials can give off radon, too. However, building materials alone rarely cause radon levels of concern (see http://www.epa.gov/radon/risk_assessment.html for more information on radon risks). Exhibit 4-5 shows EPA's map of radon zones in the U.S.

Exhibit 4-4. Major Indoor Air Pollutants and their Sources	
Major Indoor Air Pollutants	**Sources**
Radon (Rn)	Earth and rock beneath home; well water; building materials
Environmental Tobacco Smoke (includes carbon monoxide, nitrogen dioxide, and respirable particles)	Cigarette, pipe, and cigar smoking
Biologicals (e.g., pollen, mold, animal dander, and fungi)	Wet or moist walls, ceilings, carpets, and furniture; poorly maintained humidifiers, dehumidifiers, and air conditioners; bedding; household pets
Carbon Monoxide	Unvented kerosene and gas space heaters; leaking chimneys and furnaces; back-drafting from furnaces, gas water heaters, woodstoves, and fireplaces; gas stoves. Automobile exhaust from attached garages
Nitrogen Dioxide (NO_2)	Kerosene heaters, unvented gas stoves and heaters. Environmental tobacco smoke
Volatile Organic Compounds (such as xylene)	Paints, paint strippers, and other solvents; wood preservatives; aerosol sprays; cleansers and disinfectants; moth repellents and air fresheners; stored fuels and automotive products; hobby supplies; dry-cleaned clothing
Respirable Particles	Fireplaces, wood stoves, and kerosene heaters. Environmental tobacco smoke
Formaldehyde	Pressed wood products (hardwood plywood wall paneling, particle board, fiberboard) and furniture made with these pressed wood products. Urea-formaldehyde foam insulation (UFFI). Combustion sources and environmental tobacco smoke. Durable press drapes, other textiles, and glues
Pesticides	Products used to kill household pests (insecticides, termiticides, and disinfectants). Also, products used on lawns and gardens that drift or are tracked inside the house
Asbestos	Deteriorating, damaged, or disturbed insulation, fireproofing, acoustical materials, and floor tiles
Lead	Lead-based paint, contaminated soil, dust, and drinking water
Source: U.S. Environmental Protection Agency and the United States Consumer Product Safety Commission. 1995. Office of Radiation and Indoor Air (6604J) EPA/402/K/93/007, April 1995. Available at: http://www.epa.gov/iaq/pubs/insidest.html.	

Exhibit 4-5. EPA Map of Radon Zones



- **Zone 1** counties have a predicted average indoor radon screening level greater than 4 pCi/L (pico curies per liter)
- **Zone 2** counties have a predicted average indoor radon screening level between 2 and 4 pCi/L
- **Zone 3** counties have a predicted average indoor radon screening level less than 2 pCi/L

4.3.4.2 Natural Sources

Natural processes are significant sources of some air pollutants, including VOCs, NO_x, O_3, PM and other pollutants (Exhibit 4-6). Examples of natural sources of air pollutants that are *not* covered by the four main categories described above include natural processes occurring in vegetation and soils (e.g., emissions from trees), in marine ecosystems, as a result of geological activity in the form of geysers or volcanoes, as a result of meteorological activity such as lightning, and from fauna, such as ruminants and termites. Sources associated with biological activity are called biogenic sources.

Natural pollutants contribute significantly to air pollution. For example, biogenic emission estimates for the United States were 28.2 million tons of VOC and 1.53 million tons of NO_x in 1997.[10]

Exhibit 4-6. Categories of Natural Sources		
Category	**Examples of Emissions**	**Sources**
Geological	• Sulphuric, hydrofluoric and hydrochloric acids • Radon • Nitrogen oxides	• Volcanic gases • Radioactive decay of rock • Soils, lightning
Biogenic	• Ammonia • Methane • VOCs	• Animals wastes • Animal wastes, plant decay • Vegetation
Marine	• Dimethyl sulfide, ammonia, chlorides, sulfates, alkyl halides, nitrous oxides	• Sea spray released by breaking waves
Source: International Fertilizer Industry Association. 2001. Food and Agriculture Organization of the United Nations. *Global estimates of gaseous emissions of NH3, NO and N2O from agricultural land.* ISBN 92-5-104698-1. Available at: www.fao.org/DOCREP/004/Y2780E/y2780e01.htm.		

4.3.4.3 Formation of Secondary Pollutants

Some air pollutants, in addition to being directly emitted to the atmosphere by identifiable sources, are generated in the atmosphere by the chemical transformation of precursor compounds (a process called **secondary formation**). For example, under some meteorological conditions, up to 90 percent of ambient formaldehyde originates from secondary formation from a variety of precursor compounds in the presence of light (i.e., via a **photochemical reaction**). Some of the precursor compounds include isoprene (an organic compound released from trees), isobutene, and propene. The secondary formation of pollutants like formaldehyde and acetaldehyde is a complex process but can be estimated by some photochemical models (e.g., UAM-Tox, a special version of the Urban Airshed Model (UAM)). Other available models also address secondary formation but in a much more limited way (see Chapter 9 for a more detailed discussion of air models).

The NEI and other emission inventories generally do not include estimates of pollutants formed through secondary formation – only the initially emitted species are included. Because the formation of secondary pollutants depends on the meteorological conditions and the presence or absence of other compounds and/or light, a model that incorporates chemical transformation algorithms is required to estimate how much secondary product is formed from precursor compounds once they enter the atmosphere. EPA has in some instances developed estimates of secondarily formed chemicals to better inform the assessment of exposure of people to toxic air pollutants. For example, for the 1996 NATA, National-scale Air Toxics Assessment, risk characterization exercise, EPA developed a special inventory of precursor compounds to supplement the NTI, which was used in conjunction with the Assessment System for Population Exposure Nationwide (ASPEN) model to calculate ambient concentrations (see http://www.epa.gov/ttn/atw/nata/). Formation of secondary pollutants is discussed in greater detail in Chapter 8.

4.3.4.4 Other Sources Not Included in NEI or TRI

Many air toxics sources, usually relatively small ones, may not be covered or are exempt from various emissions control, reporting, and other requirements, and in some cases the number or stringency of requirements is tiered according to source size or other criteria. For example, air pollution regulations for municipal waste combustors (MWCs) promulgated pursuant to Section 129 of the CAA include separate rules for large MWCs (i.e., with capacities greater than 250 tons per day) and small MWCs (i.e., with capacities between 35 and 250 tons per day). However, there are no rules for MWCs with capacities less than 35 tons per day.

Other miscellaneous sources of air pollution (e.g., agricultural and residential burning) are controlled primarily by other S/L/T requirements. However, EPA conducts research, provides information, and pursues other non-regulatory means of addressing some of these pollution sources. For example, EPA, in conjunction with the Consumer Product Safety Commission and the American Lung Association, has published a guide for reducing pollution from residential wood combustion, including design information for less-polluting stoves and fireplaces.[11] Some local areas have ordinances that require new fireplace and wood stove installations to comply with the certification program, and others have ordinances that prohibit the use of a wood stove or fireplace on days that are conducive to the concentration of wood smoke emissions.

International Transport of Air Toxics

As noted earlier in Chapter 2 and Section 4.2.5, certain air toxics may be transported over long distances, sometimes across international borders. International sources may be an important contributor to local pollutant levels in some study areas.

Ultimately, there is no single comprehensive source of information on all sources of air toxics in a given area. The NEI and TRI are good places to start an investigation of what is being released in a study area, but as noted above, in any given place, there are probably a number of air toxics sources that are not accounted for in these inventories. Nonregulated sources, natural sources, and material moving into a study area from distant sources all have an impact on overall air quality. Assessors need to clearly understand what these limitations are as they move into the planning and scoping stage of the risk assessment (see Chapter 6). (A description of how EPA addressed background concentrations for the NATA national-scale assessment is provided at http://www.epa.gov/ttn/atw/nata/natsa2.html.)

4.4 Emissions Inventories

As mentioned previously, information on releases of air toxics is primarily compiled and maintained in **emissions inventories**. The primary emission inventory for HAPs and criteria pollutants is EPA's NEI. EPA's TRI is a second inventory that has some utility for planning and scoping an air toxics risk assessment, but is of limited use for risk assessment because of the nature of the way the data are reported. In addition to the NEI and the TRI, S/L/T air agency permit files and, in some instances, S/L/T inventories that have been developed, but not submitted to the NEI, can also provide information on the location, identity, magnitude, and source characteristics of air toxics releases.

The best inventory data are collected near the ground, literally at the source. For example, an urban scale study might opt to do a "drive by" or "windshield" verification of the number and

location of dry cleaners and gas stations in the study area rather than rely on an aggregate county-level estimate. Ultimately, the needs of the assessment (e.g., screening level or more refined) will determine the level of accuracy needed in the emissions inventory. This section will describe the NEI and the TRI. Other potential sources of air toxics data are described in Chapter 7. The process of developing an emissions inventory is also described in Chapter 7.

4.4.1 National Emissions Inventory (NEI)

EPA's Office of Air and Radiation compiles and maintains the **National Emissions Inventory (NEI)** that includes quantitative data on anthropogenic emissions of criteria pollutants and HAPs and characteristics of the sources of these air toxics.[5] It includes point, non-point, and mobile sources for all 50 states, Washington, D.C., and U.S. territories.

Previously, emissions of criteria pollutants and HAPs were tracked separately by EPA in databases that preceded the NEI. Criteria pollutant emissions data for 1985 through 1998 are available in the National Emission Trends (NET) database. Hazardous air pollutant (HAP) emissions data are available for 1993 and 1996 in the National Toxics Inventory (NTI) database. For 1999 (the most recent year for which data are available), criteria and HAP emissions data have been prepared separately but in a more integrated fashion. The final version of both the criteria and HAP inventories (for 1999) are available at http://www.epa.gov/ttn/chief/net/1999inventory.html. Note that the data collection and processing requirements for this undertaking are significant. As such, EPA plans to update the NEI every three years.

The NEI inventories are developed by EPA's Emission Factors and Inventories Group with input from S/L/T agencies, industry, and a number of EPA offices. In some cases, if a S/L/T agency does not submit data, EPA may use data from an earlier year and "grow" the emissions (e.g., for criteria stationary sources) or use only data available from other sources (e.g., HAP collected by EPA as part of the development of emission standards, or data submitted by sources under the Toxics Release Inventory program). Separate inventory documentation files have been prepared for each part of NEI (i.e., for criteria pollutants and HAPs, and for point, nonpoint, and mobile sources). These detailed documentation files are available online for criteria pollutants[12] and HAPs.[13] The reader should refer to these documentation files for detailed information on NEI. Summaries of data sources for the components of the current version of NEI are also provided below.

An important fact to keep in mind about the NEI is that it includes data on HAPs from both small and large stationary sources and both on- and off-road mobile sources. Equally important, it is much more likely to include the data necessary for modeling (although many of the data fields needed for modeling are not "mandatory," and thus states are not required to provide this information to the NEI). Information such as stack height, emission rate, and temperature are critical to developing reasonably accurate estimates of human exposure in the areas surrounding a source. It is for this reason that the NEI can be of more use than other databases, for example, for getting a better handle on realistic exposure and risk estimates in an actual study.

NEI for HAPs – Point Sources. For the NEI for HAP emissions from point sources, S/L/T agencies are asked to supply HAP emission inventory data to EPA. If they do not provide HAP emission inventory data to EPA, then EPA prepares default emission inventory data (this has been done for the 1993, 1996, and 1999 inventory years). As discussed previously, EPA uses a variety of methods to develop data and fill in gaps, where necessary (for point sources of HAPs,

EPA uses S/L/T data, EPA estimates for MACT and source categories, and TRI data; all the TRI facilities are in the NEI). This is one reason why the NEI provides, for some sources, data that may not accurately reflect actual emissions in any given place. Depending on a study's specific data quality objectives, closer inspection and verification of emissions estimates may be necessary.

The target area for the NEI includes every state and territory in the United States and every county within a State. There are no boundary limitations pertaining to traditional criteria pollutant nonattainment areas or to designated urban areas. If a facility was included in a S/L/T database, it is included in the NEI regardless of where in the state it was located. The pollutants inventoried included all 188 HAPs identified in Section 112(b) of the CAA. Some S/L/T agencies collect information on more than just these HAPs, but only the 188 are included in the HAP NEI. In addition to numerous specific chemical species and compounds, the list of 188 HAPs includes several compound groups (e.g., individual metals and their compounds, polycyclic organic matter [POM], and glycol ethers); the NEI includes emission estimates for the individual compounds within these groups wherever possible. Appendix F lists all of the specific pollutants and compound groups included in the 1999 NEI along with their Chemical Abstract Services (CAS) numbers (for individual compounds).

NEI for Criteria Pollutants – Point Sources. For the NEI for criteria emissions from point sources, EPA solicits point source data from S/L/T governments. EPA uses S/L/T point source data preferentially, except for NO_x and SO_2 emissions from utilities. For utilities, EPA uses NO_x and SO_2 emissions that facilities report to the Emissions Tracking System/Continuous Emissions Monitoring (ETS/CEM) Scorecard database. Some other criteria pollutant emissions data in the most recent version of NEI have been supplemented by EPA based on submissions to other emissions databases. In addition, emissions of ammonia (NH_3) (which is not a criteria pollutant, but is a precursor for PM) have been added to NEI based on reports submitted by S/L/T offices, TRI data, and (for locations where reports were not submitted) also based on EPA estimation methods.

Nonpoint Sources (Both HAPs and Criteria Pollutants). Much of the nonpoint source data in NEI for HAPs was initially compiled as a national-level inventory. National-level emission estimates are spatially allocated to the county-level using a number of allocation factors, such as population and employment within certain industries. For example, aggregate amounts of dry cleaner emissions for a county might be estimated from the number of people living within a county. For HAPs, EPA uses MACT data and S/L/T data, where available.

When S/L/T- or locality-specific emissions data are available, those data are substituted for data that had been allocated from national emission estimates. EPA prepares emissions for several area source categories for the NEI each year using the most current activity and emission factor data available. Emissions for other area source categories for which methodologies were not prepared in a given year are extrapolated (and assumed to increase some percentage each year) from the most recent S/L/T inventory submitted previously to EPA. For example, if an inventory was submitted in the past 3 years to EPA for the 1996 base year, the 1999 NEI emissions are extrapolated from the 1996 inventory. In some cases, criteria air emissions may also be extrapolated from other inventories (e.g., the 1985 National Air Pollutant Assessment Program inventories). A more detailed discussion of emissions estimation routines for source categories with national-level emission estimates are described in the documents referenced above.

EPA uses an emissions estimation model known as the **Biogenic Emissions Inventory System (BEIS)** to predict emissions of VOC and NO_x from forests, crop lands, and fertilized lands. Emission rates are dependent on several meteorological factors. VOC emissions are dependent on temperature and sunlight, and NO_x emissions from fertilized soils are dependent on temperature and soil moisture. The BEIS model is used to predict emissions that are included in the NEI inventory for criteria pollutants. (Keep in mind that VOCs, as a group, are inventoried, but not speciated, to help evaluate an area's potential for ozone production. Non-speciated VOC data are of limited use for performing air toxics risk assessments.)[e]

On-road Mobile Sources. In the final Version (V 3.0) of the 1999 NEI, EPA used the most recent version of the MOBILE6 (Version 6.2) model to calculate emission factors for criteria pollutants and 36 HAPs. On-road emissions inventories for CO, NO_x , VOC, PM_{10}, $PM_{2.5}$, SO_2, NH_3, and the 36 HAPs are calculated by multiplying an appropriate emission factor in grams emitted per mile by the corresponding vehicle miles traveled (VMT) in millions of miles, and then converting the product to units of tons of emissions. Emission estimates include calculations by month, county, road type, and vehicle type, with VOC broken down by exhaust and evaporative emissions and PM_{10} and $PM_{2.5}$ broken down by exhaust, brake wear, and tire wear emissions. The MOBILE6 model used is the publicly available version from EPA's Office of Transportation Air Quality's (OTAQ) Website (http://www.epa.gov/otaq/m6.htm). This model incorporates both MOBILE6.0, which is used to estimate emission factors of VOC, CO, and NO_x , and MOBILE6.1, which is used to calculate emission factors of PM_{10}, $PM_{2.5}$, SO_2 and NH_3 and MOBTOX, which is used to calculate certain HAPs. The particulate and SO_2 emission factors were previously calculated using EPA's PART5 model.

Nonroad Mobile Sources. To develop this component of the NEI, data were compiled on criteria and HAP emissions data for aircraft, commercial marine vessels, and locomotives. HAP emissions for other nonroad engines operating in the United States were estimated using the latest nonroad model. S/L/T data are used when provided. In this effort, national emission estimates were often developed for each of the above types of nonroad sources and allocated to counties based on available Geographic Information System (GIS) data. For some pollutants associated with the nonroad category, county-level (instead of national) data were used to estimate emissions. The methodologies used to estimate emissions and the procedures used to spatially allocate them to the county level vary by source category and pollutant. For some pollutants and categories, the NONROAD model was utilized to estimate emissions (see http://www.epa.gov/otaq/nonrdmdl.htm).

Concurrent with the development of the national emission estimates, S/L/T agencies developed and provided to EPA emissions inventory data for their areas based on local knowledge and activity information. These S/L/T agency data replaced the national emission estimates when the pollutant, source type, and emission type matched with the national estimates. Submitted S/L/T data that did not match the nationally-derived data were retained along with the national estimates. S/L/T data were used as provided and not adjusted to better match the national data. Some S/L/T inventories did not provide estimates for all of the pollutants included in the

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[e]Volatile Organic Compound means any organic compound which participates in atmospheric photochemical reactions; or which is measured by a reference method, an equivalent method, an alternative method, or which is determined by procedures specified under any subpart (40 CFR Part 60).
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nationally-derived emission estimates; in these cases, the submitted S/L/T data were used and the national estimates were included only for the missing pollutants.

Although the current NEI data files represent a valuable source of emissions data, there are numerous uncertainties associated with the current versions of these inventories that should be considered when using the data in a risk assessment. Sources of uncertainty include the following:

- The emission data included in NEI are of variable, and in some cases, undocumented derivation. Many of the emission estimates were submitted by the sources of the emissions to S/L/T air agencies, and then to EPA, without full explanations of how the emissions were estimated.

- Not all sources are accounted for. In some S/L/T data sets, very small sources have been reported, while in others only the largest sources in certain types of industry are included.

- Not all S/L/T agencies have submitted data. Specifically, for the NEI for criteria pollutants, 35 out of 50 states submitted data to EPA for the 1999 version of NEI. For the other states, EPA extrapolated the affected portions of the inventory from an earlier year. This omits sources that came online in the target year and erroneously include sources that have shut down. For more information on which S/L/T governments submitted data and for which states the inventory is extrapolated, the user can refer to the documentation for the respective inventory sector and the respective pollutant type (see website addresses above). Some of the states for which 1999 data were not available when these inventory versions were compiled have now provided EPA with their data, and EPA is working to incorporate this data into the next versions. For HAPs, 46 states have participated in the development of the 1999 NEI (with some revisions from states still under way).

- Duplicate facilities may be present, but most of the duplicates have been removed. Facility identification (ID) codes are a potential source of confusion. The NEI Unique Facility ID is the ID for the entire facility, while the state IDs are usually for individual processes; therefore an NEI Unique Facility ID can have multiple state facility IDs.

- The primary source of uncertainty associated with the inventory is the methodology used to generate the emission estimates. The emission estimation methodology is often poorly documented in the NEI Input Format - this data field is not mandatory. Data in the 1999 NEI for HAPs are made using different estimation methods. Future versions of the NEI will include a data quality rating to each emissions record, which should help characterize the quality of the emissions estimate.

Emissions data in the NEI are submitted to EPA according to the **NEI Input Format (NIF) Shell** (see http://www.epa.gov/ttn/chief/nif/index.html). This format consists of data fields grouped into tables that provide the basic structure of NEI. The NIF shell consists of eight tables for point sources, five tables for area sources, three tables for mobile sources, and two tables for biogenic sources. EPA has developed data element descriptions and data element validation rules to enforce mandatory data fields and relationships between the various tables and records of the NIF. As the NEI has evolved (and continues to be improved and developed), the NIF shell has evolved as well. Version 3.0 of the NIF shell was released in May 2003 and updated in November 2003.

In June 2002, EPA promulgated the final Consolidated Emissions Reporting Rule,[14] which simplifies and consolidates emission inventory reporting requirements (for criteria air pollutants only) to a single location within the *Code of Federal Regulations* (CFR), establishes new reporting requirements related to $PM_{2.5}$ and regional haze, and establishes new requirements for the statewide reporting of area source and mobile source emissions. Many state and local agencies asked EPA to take this action to consolidate reporting requirements; improve reporting efficiency; provide flexibility for data gathering and reporting; and better explain to program managers and the public the need for a consistent inventory program. Consolidated reporting should increase the efficiency of the emission inventory program and provide more consistent and uniform data.

In conjunction with the NIF shell, EPA has developed an automated software program to help NIF users perform **quality assurance/quality control (QA/QC) checks** on their files to ensure correct format specification. This software, available for download from the NIF shell web page, separates QA/QC checks into format and content. Format checks ensure that the submitted information includes the minimum data elements required for Emission Factor and Inventory Group (EFIG) to accept the submitted data. Content checks are provided for the user as a way to highlight possible errors in the submitted data. The latest version of the software allows the user to choose whether to perform QA/QC checks on the data for format, the minimum standards required to put the data in the database, or the more resource intensive content or reasonableness checks. When checking for content, the format is also checked as the format must be correct in order for content checks to be performed at all.

4.4.2 Toxics Release Inventory (TRI)

The **Toxics Release Inventory (TRI)** is a publicly available EPA database that contains information about releases and other waste management activities reported annually by certain covered industry groups as well as federal facilities for over 650 toxic chemicals (see http://www.epa.gov/tri/). This inventory was established under the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and expanded by the Pollution Prevention Act of 1990.

TRI reporting is required only for facilities that meet all of the following three criteria:

- They have ten or more full-time employees or the equivalent (i.e., a total of 20,000 hours or greater; see 40 CFR 372.3);
- They are included in specified industrial sectors (see Exhibit 4-7); and
- They exceed any one reporting threshold for manufacturing, processing, or otherwise using a TRI chemical (see Exhibit 4-8).

If a facility meets these criteria, then it must report releases to environmental media as well as waste management data. In 2001 (the latest year for which data are publicly available), air emissions of toxic chemicals totaled 1.7 billion pounds (over a quarter of all releases of TRI chemicals to the environment).

Exhibit 4-7. Standard Industrial Classification (SIC) Codes in TRI Reporting			
Original Industries			
SIC Code	**Industry Group**	**SIC Code**	**Industry Group**
20	Food	30	Rubber and Plastics
21	Tobacco	31	Leather
22	Textiles	32	Stone, Clay, and Glass
23	Apparel	33	Primary Metal
24	Lumber and Wood	34	Fabricated Metals
25	Furniture	35	Machinery (excluding electrical)
26	Paper	36	Electrical and Electronic Equipment
27	Printing and Publishing	37	Transportation Equipment
28	Chemicals	38	Instruments
29	Petroleum and Coal	39	Miscellaneous Manufacturing
New Industries Reporting to TRI as of the 1998 Reporting Year			
SIC Code	**Industry Group**		
10	Metal mining (except for SIC codes 1011,1081, and 1094)		
12	Coal mining (except for 1241 and extraction activities)		
4911, 4931, and 4939	Limited to electrical utilities that combust coal and/or oil for distribution in commerce (SIC codes 4911, 4931, and 4939)		
4953	Limited to hazardous waste treatment and disposal facilities regulated under the Resource Conservation and Recovery Act (RCRA) Subtitle C		
5169	Chemicals and allied products wholesale distributors		
5171	Petroleum bulk plants and terminals		
7389	Solvent recovery services primarily engaged on a contract or fee basis		
Source: U.S. Environmental Protection Agency. 2004. Toxic Release Inventory (TRI) Program. *Standard Industrial Classification (SIC) Codes in TRI Reporting.* Updated March 2, 2004. Available at: http://www.epa.gov/tri/report/siccode.htm. (Last accessed April 2004.)			

Exhibit 4-8. Thresholds for Reporting to the TRI

EPCRA Section 313 non-PBT chemicals (Section 372.25). A facility meeting the SIC code (or Federal facility) and employee criteria must file a TRI report for a non-PBT Section 313 chemical if the facility:

- Manufactured (including imported) more than 25,000 pounds per year; or
- Processed more than 25,000 pounds per year; or
- Otherwise used more than 10,000 pounds per year.

EPCRA Section 313 PBT chemicals (40 CFR372.28). If a facility manufactures, processes, or otherwise uses any chemicals that are listed as persistent, bioaccumulative, and toxic (PBT), the threshold quantity is one of the following (per Section 313 chemical or category per year):

Type of Chemical	Reporting Threshold by Activity		
	Manufacture	Process	Otherwise Used
Highly persistent and bioaccumulative compounds	10 pounds	10 pounds	10 pounds
Dioxin and dioxin-like compounds	0.1 grams	0.1 grams	0.1 grams
Other persistent and bioaccumulative compounds (lead and lead compounds)	100 pounds	100 pounds	100 pounds

Activity thresholds are calculated independently of each other based on cumulative quantities per Section 313 chemical over the reporting year.

Current list of Section 313 PBT Chemicals

- aldrin
- benzo(g,h,i)perylene
- chlordane
- dioxin and dioxin-like compounds
- heptachlor
- hexachlorobenzene
- isodrin
- lead
- lead compounds
- mercury
- mercury compounds
- methoxychlor
- octachlorostyrene
- pendimethalin
- pentachlorobenzene
- polychlorinated biphenyl
- polycyclic aromatic compounds
- tetrabromobisphenol A
- toxaphene
- trifluralin

Note in Exhibit 4-7 that additional industries have been added to the TRI over time. Thus, some industries were not required to report in the past and, as such, no records will exist for these facilities in the historical TRI files. The list of covered chemicals has also grown over time. Thus, the ability to track trends for more recently added industries and chemicals is more limited than for industries and chemicals that have been covered throughout the history of the TRI.

Industrial sectors subject to TRI reporting are identified by Standard Industrial Classification (SIC) codes. SIC codes are numerical codes developed by the U.S. government as a means of consistently classifying the primary business of business establishments. A full list of the industry groups that are required to report can be found at http://www.epa.gov/tri/report/siccode.htm.

Although most of the existing emissions data in the TRI system are organized according to SIC codes, EPA has proposed regulations that would result in the use of the North American Industry Classification System (NAICS) rather than SIC codes (see http://www.census.gov/epcd/www/naics.html). Rather than classifying industries on the basis of several different economic concepts (as the SIC structure does), NAICS classifies establishments according to similarities in the processes used to produce goods and services. The TRI program issued a proposed rule to implement the NAICS system classification on March 21, 2003. (See 66 *Fed. Reg.* 13872.) It is expected that the use of NAICS in the TRI system will allow EPA to more accurately characterize the current state of the national economy (including new and emerging industries not adequately covered by SIC codes). The existing SIC structure will not be updated in the future because the Office of Management and Budget has adopted NAICS as the United States' new industry classification system. In addition, using NAICS for TRI reporting purposes will enable more efficient database integration and will promote public access to commonly defined data from disparate sources. This change will not affect the universe of facilities that is currently required to report to TRI.

EPCRA requires only that facilities report their releases of the listed chemicals. There are no additional control or mitigation actions required. The information collected through the TRI program is made public, however, and pressure from local citizen groups has been an incentive to many industries to reduce the quantity of pollutants they release.

While the TRI data have utility for the scoping out of an air toxics risk assessment project, they have several limitations that assessors must understand. Importantly for risk assessors, the TRI program requires only that one single annual value representing total releases to the air (segregated only by stack releases and fugitive releases) be reported by the individual affected facilities. So while annual average emissions may be useful in screening-level assessments for chronic exposures, it may be difficult to assess acute noncancer hazard associated with short-term, peak emission levels. Source-specific information within the facility is not routinely reported through the TRI. Likewise, no information is reported on release parameters critical to air dispersion modeling (e.g., location of release on the facility property, release rates, stack height, stack diameter, release temperature). (See Chapter 9, for more information on modeling parameters used in air quality and exposure modeling.)

As discussed in Section 4.2, the list of TRI pollutants is organized differently than the list of HAPs in CAA Section 112, causing some complications in interpreting emission data. It is difficult to correctly relate some of the SIC codes (under which TRI emissions are grouped) to specific air emission processes. Because quantities are only reported if a statutory threshold is

met, a facility may report emissions for one year but not the next, even though the facility is still in operation. Similarly, individual pollutants may not be reported consistently from year to year due to the thresholds that apply to individual pollutants (e.g., a facility may report releases of 10 pollutants one year and releases of only five pollutants the next year because the others dropped below the reporting threshold).

Furthermore, for some facilities, it is possible that, for a variety of releases, the data included for a facility's emissions in the TRI do not match the same data reported to the NEI, indicating a potential problem with either or both data sets. The risk assessor should apply care and discretion when using TRI information to estimate exposures and risk from individual facilities. Ultimately, the TRI provides information about the location, identity, and amount of air toxics emissions in a community. However, due to the nature of the way the data are developed and reported, TRI data should generally be considered a source of limited information about a facility and should not be used in risk assessments involving modeling (as noted above, S/L/T and NEI data are more likely to be useful for modeling). For robust analysis, it should generally be considered a starting point, not an end.

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PART II

HUMAN HEALTH RISK ASSESSMENT: INHALATION

Chapter 5 Getting Started: Planning and Scoping the Inhalation Risk Assessment

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5.1 Introduction

The background discussion in Part I of this manual introduced the general air toxics risk assessment process (see Exhibit 3-4). Part II describes the tools and approaches risk assessors use to evaluate human health risks associated with inhalation exposures to air toxics. Section 5.2 below describes the framework used for air toxics risk assessment, including its three phases: (1) planning, scoping, and problem formulation; (2) analysis (which includes exposure assessment and toxicity assessment); and (3) risk characterization. Part II includes nine chapters that describe these three phases in detail.

- The remainder of the current chapter describes planning and scoping (Section 5.3).
- Chapter 6 describes problem formulation.
- Because exposure assessment is generally the most labor and financially-intensive step in the analysis phase, and because it involves a variety of related (but heterogeneous activities), the discussion of exposure assessment includes five chapters:
  - Chapter 7 describes how to characterize sources and quantify emissions;
  - Chapter 8 explores the fate and transport of air toxics in the atmosphere;
  - Chapter 9 discusses air quality modeling;
  - Chapter 10 discusses monitoring; and
  - Chapter 11 discusses quantifying exposure, including exposure modeling.
- Chapter 12 describes the remainder of the analysis phase, toxicity assessment.
- Chapter 13 describes the risk characterization phase for inhalation assessments.

5.2 Framework and Process for Air Toxics Risk Assessments

The original risk assessment framework developed in 1983 by the NRC (see Chapter 3) has been refined based on the risk assessment experience gained by EPA and other agencies. Two descriptions of this refined framework are particularly useful for air toxics risk assessments: EPA's framework for cumulative risk assessment, and EPA's general framework for assessing residual risks.

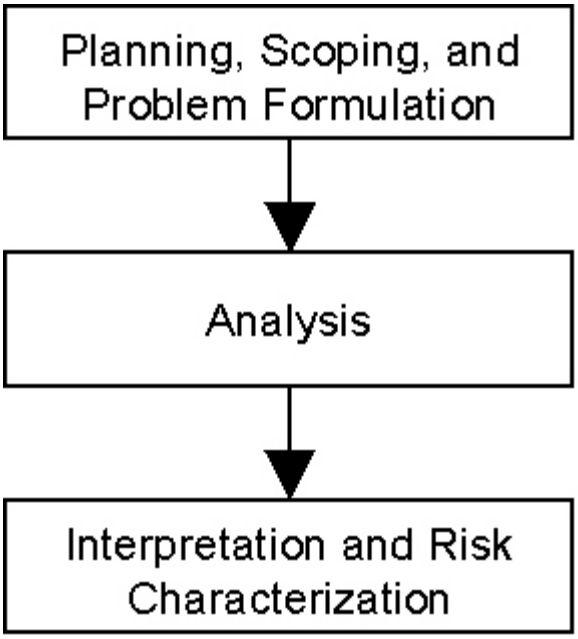
Cumulative Risk Assessment

An analysis, characterization, and possible quantification of the combined risks to health or the environment from simultaneous exposure to multiple agents or stressors.

5.2.1 Framework for Cumulative Risk Assessment

EPA's *Framework for Cumulative Risk Assessment*[1] describes three main phases to a risk assessment: (1) planning, scoping, and problem formulation; (2) analysis; and (3) risk characterization (Exhibit 5-1).

Exhibit 5-1. Three-Phase Framework for Cumulative Risk Assessment



Source: EPA *Framework for Cumulative Risk Assessment*[1]

- In the **planning, scoping, and problem formulation phase**, a team of risk managers, risk assessors, and other stakeholders identify the problem to be assessed and establish the goals, breadth, depth, and focus of the assessment. The end products of this phase are a conceptual model and an analysis plan. The conceptual model establishes the air toxics, exposure pathways, and health and ecological effects to be evaluated. The analysis plan lays out how the elements of the conceptual model are going to be studied.

- The **analysis phase** (the elements of which are described by the analysis plan) is primarily an analytic process in which risk experts apply risk assessment approaches to evaluate the problem at hand. Specifically, the analysis plan specifies how data, modeling, or assumptions will be obtained, performed, or defined for all aspects of the exposure evaluation. Additionally, the analysis plan specifies the strategy for obtaining and considering hazard and dose-response information for these stressors and the method for combining the exposure information with the hazard and dose-response information to generate risk estimates. As the risk analysis is refined, it may be appropriate to revisit and refine the exposure, hazard, and dose-response information in an iterative fashion.

- The **risk characterization** phase integrates and interprets the results of the analysis phase and addresses the problem(s) formulated in the planning, scoping, and problem formulation phase. It describes the qualitative and/or quantitative risk assessment results and lists the important assumptions, limitations, and uncertainties associated with those results; and discusses the ultimate use of the analytic-deliberative outcomes.

5.2.2 General Framework for Residual Risk Assessment

EPA's *Residual Risk Report to Congress*[2] outlines a general framework for assessing residual risks to implement the requirements of CAA sections 112(f)(2) through (6). Those sections require EPA to promulgate standards beyond MACT when necessary to provide "an ample margin of safety to protect public health" and to "prevent, considering costs, energy, safety, and other relevant factors, an adverse environmental effect." EPA developed the general framework using knowledge gained from past risk assessments and guidance gained from reports such as the NRC and CRARM reports (see Chapter 3). The framework calls for an iterative, tiered assessments of the risks to humans and ecological receptors through inhalation and, where appropriate, non-inhalation exposures to HAPs.

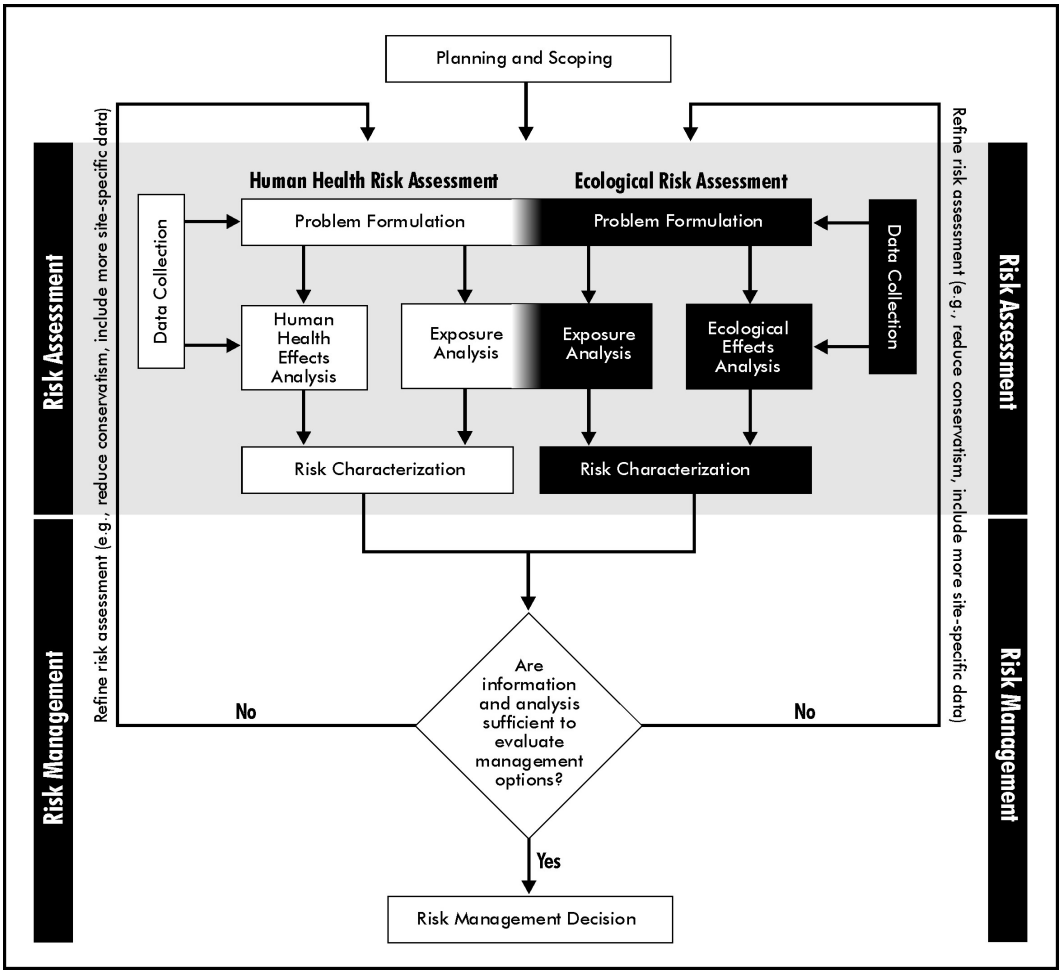
As shown in Exhibit 5-2, each human health and ecological risk assessment is organized into three phases: (1) the problem formulation phase, in which the context and scope of the assessments are specified (this phase also includes planning and scoping activities); (2) the analysis phase, in which the toxicity of HAPs and exposures to humans or ecological receptors are evaluated; and (3) the risk characterization phase, in which the toxicity and exposure analyses are integrated to determine the level of risk that may exist. The problem formulation and analysis phases of the human health and ecological risk assessments will partially "overlap" in that some pathway of concern for humans (e.g., consumption of contaminated fish) may also be pathways of concern for ecological receptors (e.g., fish-eating wildlife). Consequently, exposure analyses for some air toxics may be designed to provide information for both ecological and human health assessments.

In both human health and ecological risk assessments, there is essentially a continuum of possible levels of analysis from the most basic screening approach to a highly refined, detailed assessment. The screening level or tier of analysis is designed, through the use of simplifying assumptions and conservative inputs, to identify for no further action or analysis, exposure pathways and air toxics for which risks are unlikely to be of concern. Screening tier analyses are designed to be relatively simple, inexpensive, and quick, using existing data, defined decision criteria, and models with simplifying conservative assumptions as inputs. More refined levels of analysis include the refinement of aspects of the analysis that are thought to influence risk most or may contain the greatest uncertainty. They may also allow a more quantitative analysis of uncertainty and variability. Refined analysis requires more effort, but produces results that are hopefully less uncertain and less conservative (i.e., less likely to overestimate risk).

5.2.3 The Air Toxics Risk Assessment Process

Building on the Cumulative and Residual Risk frameworks discussed above, the human health portions of this reference manual describe the risk assessment process for air toxics in three general phases (Exhibit 5-3; the process for ecological risk assessment is provided in Part IV). [Note that Exhibit 5-3 is consistent with both the Cumulative and Residual Risk frameworks discussed above. The benefit of Exhibit 5-3 is that it helps to better visualize the *detailed elements* that are usually performed in an air toxics risk assessment.]

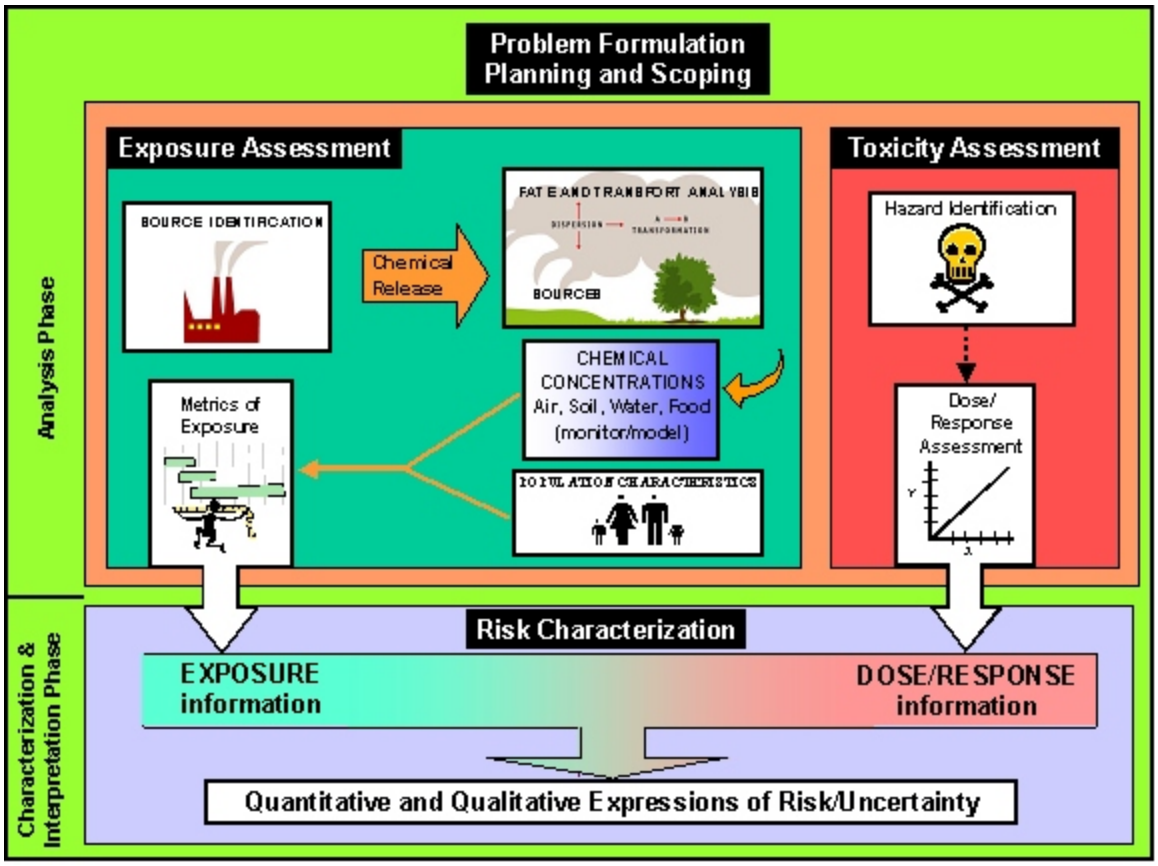
Exhibit 5-2. General Framework for Residual Risk Assessment



Source: Modified from *EPA's Residual Risk Report to Congress*[2]

- The **planning, scoping, and problem formulation** phase is divided into two general steps: planning and scoping, and problem formulation. These two steps consist of the activities described above in the cumulative risk assessment framework. The end products of this phase are a conceptual model and an analysis plan. As shown in the Exhibit 5-3, planning, scoping, and problem formulation encompass the entire risk assessment process because stakeholders aim to understand and state the problem they want to study using the risk assessment process and plan how they are going to study the problem *before* the risk assessment is performed. They also must recognize that they may need to refine the problem statement and study methodology as new information is gained during the assessment.

Exhibit 5-3. The Detailed Air Toxics Risk Assessment Process



- The **analysis** phase is divided into two general steps: **exposure assessment** and **toxicity assessment** (the general process for ecological risk assessments is described in Part IV). Exposure assessment is a relatively complex process involving source identification; development of an emissions inventory; fate and transport analysis (through modeling and/or monitoring) to estimate chemical concentrations in air (and soil, food, and water for multimedia assessments); and combining information on chemical concentrations with population characteristics to obtain one or more metric(s) of exposure. Toxicity assessment includes hazard identification and dose-response assessment.

- The **risk characterization** phase integrates the information from the exposure assessment and the toxicity assessment to provide both quantitative and qualitative expressions of risk. The risk characterization also includes a thorough discussion of uncertainty associated with each of the major elements of the risk assessment.

The remainder of Parts I, II, and III of this Volume will rely on the general approach outlined in Exhibit 5-3 as a roadmap for describing the air toxics risk assessment process.

Risk Assessment: Is it a Linear Process?

It may be useful to think of the risk assessment process as a set of steps that proceed in a linear fashion. But it does not always work out that way. For example, through good planning, scoping, and problem formulation (e.g., a thorough identification of sources and chemicals while developing the conceptual model), much of the preliminary exposure assessment work may be accomplished. A prior basic knowledge and discussion of toxic and chemical/physical properties of the chemicals of potential concern (COPCs) (information often developed during the toxicity and exposure assessments, respectively) may help the risk assessment team rule out certain pathways for consideration during the planning, scoping, and problem formulation phase. Of course, a good analysis plan will include mechanisms to confirm and document all these decisions, but the fact still remains that the risk assessment process is actually a combination of a variety of steps, many of which may occur simultaneously.

5.2.4 Overview of Inhalation Exposure Assessment

Because exposure assessment is generally the most multifaceted and time-consuming part of an air toxics risk assessment, it cannot be discussed in a single chapter. This subsection provides an overview of exposure assessment and identifies where each step of the process is described in more detail in subsequent chapters (i.e., Chapters 6 through 11). EPA's *Guidelines for Exposure Assessment*[3] is the key reference document for the exposure assessment portion of the risk assessment, and air toxics risk assessors may want to obtain and become familiar with its contents.

Exposure assessment helps identify and evaluate a population receiving exposure to a toxic agent, and describe its composition and size, as well as the type, magnitude, frequency, route and duration of exposure. In other words, an exposure assessment is that part of the risk assessment that identifies:

- Who is potentially exposed to toxic chemicals;
- What toxics they may be exposed to; and
- How they may be exposed to those chemicals (amount, pattern, and route).

5.2.4.1 Exposure and Exposure Assessment: What's the Difference?

Exposure assessment is the overall process of evaluating who receives exposure to toxic chemicals, what those chemicals are, and how the exposure occurs. Exposure, on the other hand, (according to EPA definition[1]) represents contact with a chemical at the visible external boundary of a person, including skin and openings into the body such as mouth, punctures in the skin, and nostrils. This definition of exposure does not describe the contact of a chemical with the actual exchange boundaries in the body where absorption into the bloodstream can take place, such as the linings of the lung or digestive tract. (One exception to this is chemical contact with skin or punctures in the skin; in this case, the location of the exposure and the exchange boundary are one in the same.) Other than dermal exposure, chemicals must be physically taken into the body by ingestion or inhalation (a process called **intake**) before they can contact an exchange boundary and be taken into the bloodstream (a process called **uptake**).

The term **route of exposure** is used to describe the different ways a chemical enters the body. The three main routes of exposure are **inhalation**, **ingestion**, and absorbing a chemical through the skin (**dermal**). For inhalation risk assessments, we are only concerned with the inhalation route of exposure. The dermal and ingestion routes of exposure are generally only relevant to chemicals that persist and which also may bioaccumulate (e.g., the persistent, bioaccumulative HAP (PB-HAP) compounds). Discussion of these routes of exposure is reserved for Part III.

Some chemicals can cause harm in the part of the body where individuals take them in (e.g., in the respiratory system for inhaled chemicals or in the digestive tract for ingested chemicals). This is called a **portal of entry effect** because the adverse effect occurs at the place (i.e., the "portal") where the chemical enters the body. Other chemicals have to be taken into and distributed by the circulatory system to cause a harmful effect at a point distant from their portal of entry into the body. Such effects are called **systemic effects** because they have the potential to act at points throughout the system. As a chemical moves through the body, it may be metabolized (possibly to a more toxic entity); stored in the body; and/or eliminated in urine, feces, sweat, nails/hair, or exhaled breath.

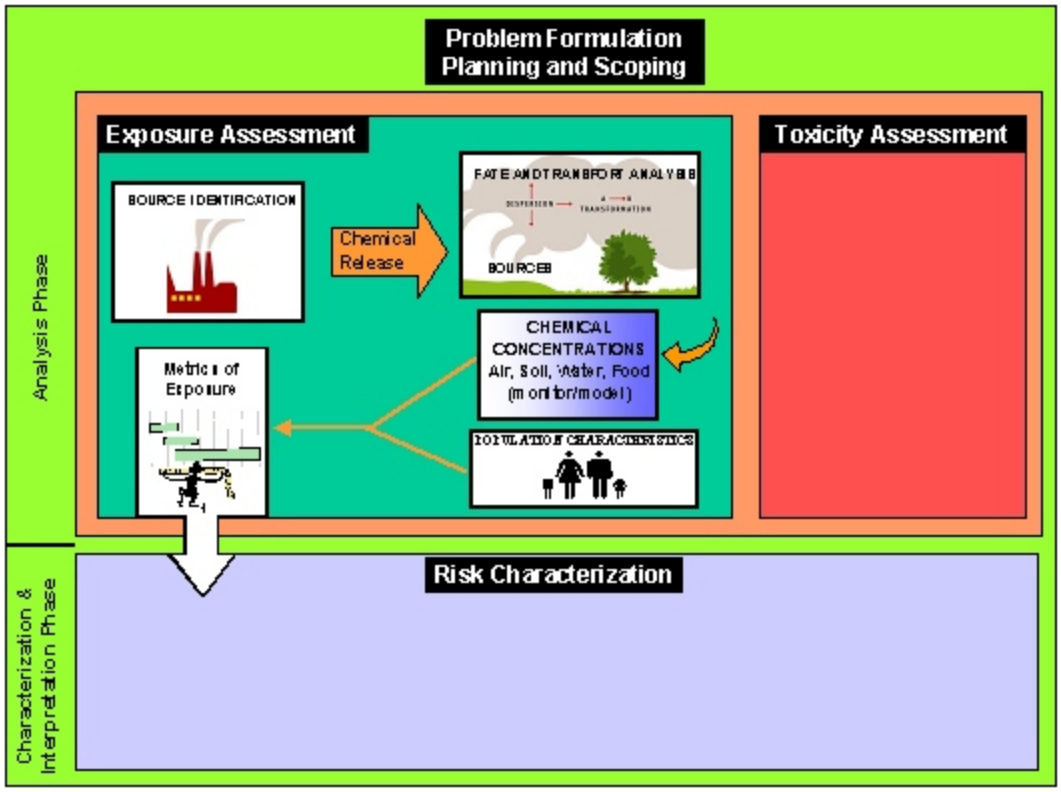
5.2.4.2 Components of an Exposure Assessment

The nature and complexity of the components within the exposure assessment are often functions of the particular risk management question (or other purpose) to be addressed. Simple screening analyses that rely on conservative default assumptions may be sufficient to rule out the need for further analyses or action. On the other hand, a more detailed exposure analysis may be needed to determine the necessity for emission controls, particularly when the application of those controls is associated with large economic consequences. Indeed, the exposure assessment raises and addresses many of the risk assessment's difficult and critical policy questions. As illustrated in Exhibit 5-4, the exposure assessment includes the following steps:

- **Characterization of the exposure setting**, including the physical environment, scale of the study area, important sources and chemicals, and potentially exposed populations and population characteristics (e.g., demographics). Most of this information is collected and organized during the problem formulation portion of the risk assessment (see Chapter 6).

- **Identification of exposure pathways**, including sources and mechanism of release, exposure points and routes of exposure, and transport media. Again, most of this information is collected and organized during problem formulation (see Chapter 6).

Exhibit 5-4. Exposure Assessment is the Most Time-Consuming Part of Risk Assessment



- **Quantification of exposure**, including an **evaluation of uncertainty** and **preparation of documentation**. Quantification of exposure includes three general steps which are discussed in several subsequent chapters.
  - Characterization of emissions is discussed in Chapter 7.
  - Evaluation of chemical fate and transport is discussed in three chapters. Chapter 8 discusses dispersal, transport, and fate of air toxics in the atmosphere. Chapter 9 discusses air quality modeling. Chapter 10 discusses air toxics monitoring.
  - Estimation of exposure concentrations (EC) is discussed in Chapter 11, along with exposure modeling, evaluation of uncertainty, and preparation of documentation.

5.3 Planning and Scoping

Planning and scoping is the first step in an air toxics risk assessment (good planning and scoping is important for any scientific study). It is both a *deliberate* and *deliberative* process that identifies the problems to be assessed; identifies stakeholders in the risk assessment process; establishes the bounds (i.e., the scope) of the analysis, including elements to be included or excluded from the analysis; develops a description of the potential interrelationship between air pollutants and receptors; and articulates the overall analysis plan for the assessment. This section provides an overview of how to plan for and scope an air toxics risk assessment. The discussion focuses on four key elements of planning and scoping:

- Why is planning and scoping important?
- What is the process?
- Who should be involved?
- What are the key products?

More detailed discussions of the planning and scoping process can be found in the EPA guidance documents *Guidance on Cumulative Risk Assessment*[4], *Framework for Cumulative Risk Assessment* [5], and *Risk Assessment Guidance for Superfund (RAGS): Volume I* [6] (Chapter 2 of this RAGS document discusses the role of the risk assessor in planning and scoping).

5.3.1 Why is Planning and Scoping Important?

Planning and scoping may be the most important step in the risk assessment process. Without adequate planning, most risk assessments will not succeed in providing the type of information that risk management needs to make a well-founded decision. Thorough planning and scoping is commonly conducted ***before*** any substantive work is done on the risk assessment. Planning and scoping is important for developing a common understanding of why the risk assessment is being conducted, the scope of the assessment, the quantity and quality of data needed to answer the assessment questions, and how risk managers will use the results. This step is also a focal point for stakeholder involvement in the risk assessment process. The specific goals of planning and scoping include:

- The approaches, including a review of the risk dimensions and technical elements that may be evaluated in the assessment;
- The relationships among potential assessment end points and risk management options;
- An analysis plan and a conceptual model (articulated in the problem formulation phase - see Chapter 6);
- The resources (for example, data or models) required or available;
- The identity of those involved and their roles (for example, technical, legal, or stakeholder advisors); and
- The schedule to be followed (including provision for timely and adequate internal, and independent, external peer review).

5.3.2 The Planning and Scoping Process

The five essential steps in the planning and scoping process include (1) identifying the concern; (2) identifying who needs to be involved; (3) determining the scope of the risk assessment; (4) describing why there may be a problem (i.e., describing the presumed interrelationship among sources of risk, humans receiving the exposure, and potential health effects); and (5) determining how risk managers will evaluate the concern. Each is described in a separate subsection below.

5.3.2.1 What is the Concern?

Most risk assessments are conducted because of a regulatory requirement, a community need or concern, or some other reason. The specific concerns and the resources available to address those concerns will largely shape the risk assessment scope and methods. For example, a simple, screening-level risk assessment may be adequate to support a typical pollution permitting process

while a detailed analysis may be necessary to respond to a particular community concern (e.g., are children in a nearby school exposed to harmful levels of air toxics from all sources in the community?).

At the end of this first step, risk assessors usually identify the full breadth of the concerns of the participating stakeholders and clearly articulate which of those concerns will be the focus of the risk assessment and why. For example, in a community-level multisource analysis, some community stakeholders may be concerned about nuisance odor while others are concerned about potential cancer health risks from airborne pollutants. At the end of this step, all stakeholders should be clear that the risk assessment cannot address the odor issue but, rather, will focus on the cancer concern. This is also the time to identify other resources or means for attempting to address the non-risk related odor issue.

Stakeholders often identify a wide range of concerns in the risk assessment process that risk assessment methods may be unable to address. It is always important to acknowledge the legitimacy of stakeholder concerns and to work to clarify the limitations of the risk assessment process – especially when assessors are working to respond to community concerns. At the same time, risk assessors often assist in identifying the proper path for responding to non-risk related issues. Proceeding in this manner will help create an attitude of trust, foster buy-in of the risk assessment process and results, and avoid creating false expectations.

5.3.2.2 Who Needs to be Involved?

The key participants in the planning and scoping process include, at minimum, the risk managers who will use the results of the risk assessment and the risk assessment technical team who will perform the analysis.

- **Risk managers** are the persons or groups with the authority to make the decisions about the acceptability of risk and how an unacceptable risk may be mitigated, avoided, or reduced. For regulatory requirements (e.g., permitting, compliance), the risk manager usually is a government agency such as EPA or a S/L/T authority. For voluntary efforts, the risk manager(s) generally will include members of the potentially affected or interested parties (e.g., industry representatives, community leaders, local government).

- The **risk assessment technical team** includes those experts who will perform the activities involved in the risk assessment, including environmental scientists, modelers, chemists, toxicologists, ecologists, and engineers.

These individuals need to understand the goals of the risk assessment, how the results will be used, the amount and quality of information necessary to make key decisions, and the uncertainties associated with the inputs, risk assessment methods, and resulting risk estimates.

The specific concerns from step one may generate the need for a diverse set of individuals or groups with an interest in having the assessment done ("interested or affected parties").[7] Each group may have a unique set of questions, concerns, and fears. It is important to design the risk assessment to address as many of these issues as possible within available time and resources. Planning and scoping begins with a dialogue among these individuals and groups; consequently, the initial planning and scoping team may need to expand over time to include additional

participants, including public officials, citizens, and industry representatives. In many cases, technical experts who live in the affected communities can be effective participants because they have both the trust of the local community and the technical skills to explain complex issues. A strong community involvement effort early in the process can help identify these concerns (see Part V of this Volume).

Examples of Possible Interested or Affected Parties

State governments	Affected industry
Tribal governments	Civic organizations
Local governments	Business owners
Community groups	Trade associations
Grassroots organizations	Labor unions
Environmental groups	Public health groups
Consumer rights groups	Academic institutions
Religious groups	Impacted citizens
Civil rights groups	Other federal agencies

One tool helpful in translating general goals into specific metrics is an objectives hierarchy, which is a hierarchic list starting with the overall goal of a project and moving down in levels to (component) purposes or outcomes, outputs and specific activities (see http://www.iac.wur.nl/ppme/content.php?ID=353&IDsub=338). A discussion of this is found in EPA's *Planning for Ecological Risk Assessment: Developing Management Objectives* (Section 3.4.2) at http://www.epa.gov/NCEA/raf/pdfs/eco_objectives-sab_6-01.pdf.

It is beneficial if planning and scoping participants understand the following six questions *before* the risk assessment begins:

- **What is the goal of the risk assessment and how will the results be used?** A risk assessment might be conducted to compare the costs of various emissions control options versus the benefits in terms of reduced risks. Some conduct risk assessments primarily for informational purposes – for example, how much do individual pollution sources contribute to total risks within a given community? Risk management goals may be risk-related (e.g., reducing risks from exposure to air toxics; reducing the incidence of a specific adverse effect such as cancer); economic (e.g., reducing risks without causing job loss or raising taxes); or related to public policy (e.g., protecting children and other sensitive populations). Generally, each risk assessment is designed to provide information that will support the identified goals.

- **What information will the risk assessors collect and what analyses will they perform on those data?** The risk assessors develop the scope of the risk assessment during planning and scoping. For example, participants may select a limited number of chemicals from all those released in an area to be analyzed throughout the risk assessment process (the chemicals of potential concern or COPC), or the assessment may focus on only a limited number of exposure pathways that may be most important. Stakeholders should understand exactly what the risk assessment is (and by extension, what it is not) going to evaluate.

- **What are the major concerns of the local community?** Significant concerns that the risk assessment does not address can result in "show stoppers" that complicate or delay the risk management decision. Clarifying what the risk assessment is not going to study, and why, before the assessment begins will help to reduce this possibility. As an example, many communities express concerns about perceived disease clusters. All stakeholders need to understand that the risk assessment process is not used to evaluate disease clusters or establish cause-effect relationships between air pollution and existing cases of disease. However, stakeholders often raise this concern, and it is imperative that the planning and

scoping team acknowledge these concerns and direct them to the appropriate resources. Given the prevalence of this concern in areas with air toxics concerns, this Volume includes a lengthy discussion in Part VI of this Volume on options for addressing such issues.

- **What are the roles and responsibilities of each participant?** Stakeholders often address many administrative issues during planning and scoping, including who will lead the risk assessment, who will perform each of the various tasks, who will pay for it, and when the participants need the results.

- **What are the available resources and schedules?** Time and money are always limited; therefore, the planning and scoping process will almost certainly involve trade-offs between the amount and quality of information participants desire and the time and monetary resources available to obtain and analyze the information. Participants often choose to determine critical milestones and institute a clear, yet reasonably flexible, schedule to keep the assessment on track.

- **What documentation and other products are required?** Regulatory requirements often include specific types of information in specific formats. In a community-level analysis, stakeholders may want specific information such as maps indicating estimated levels of air pollutants in different parts of the community. Thus, documentation requirements are meant to provide transparency throughout the risk assessment process, from the initiation of the planning and scoping step to the presentation of the final product. Participants are urged to document all important decisions, goals, discussions, schedules, resource allocations, roles and responsibilities, data quality objectives. Participants also may document the analytical approach such that anyone may follow the methodology of the risk assessment.

Finally, risk assessors, risk managers, and all other stakeholders generally recognize the sensitivity of their roles throughout the risk assessment process. Specifically, there must be no direct or indirect actions on the part of any stakeholder to influence the outcome of the science-based analysis. Even the appearance of such activity can severely undermine trust in the risk assessment as a valid analysis tool.

5.3.2.3 What is the Scope?

The risk assessment scope helps determine how comprehensive the analysis will be. The scope of a risk assessment may be narrow or broad, depending on the specific risk management goals. For example, a relatively broad goal such as “reducing risks from exposure to air toxics” may require a relatively broad risk assessment that examine many types of sources (e.g., stationary, mobile) and dozens of specific air toxics. In contrast, a more narrow goal such as “reducing the potential cancer risk in the community” may result in a risk assessment that focuses more narrowly on only those air toxics that contribute to cancer. Geography (e.g., political boundaries), demographics (e.g., focusing on a subset of exposed populations), legal requirements (e.g., statutes or regulations), or methodological or data limitations can all narrow the scope. Most importantly, time and money will almost always limit the scope of the risk assessment.

Participants can determine scope by listing and answering critical **assessment questions** such as:

- What specific sources are to be included?
- What specific air toxics are to be included?
- What are the physical boundaries of the study area?
- What are the temporal constraints of the study?
- What potential exposure pathways will be evaluated?
- What potentially exposed populations will be assessed?
- What types of health risks will be evaluated?

The details of scope (e.g., what sources are to be included, what potential pathways will be included) are developed during the problem formulation stage (see Chapter 6).

The goal of the scoping process is to produce a clear understanding of what the risk assessment should and should not include and why. For example, if available data or methods make it impossible to assess a potential exposure pathway, the planning and scoping team may need to re-evaluate the goals and expectations of the risk assessment process.

5.3.2.4 Why is There a Problem?

The **problem statement** often summarizes the end result of the scoping process, describing the specific concerns that the risk assessment will address. Problem statements often also include statements about how the risk assessors will evaluate these concerns. The problem statement is commonly as specific as possible and may also include explicit statements of what will not be assessed in the risk assessment.

Example Problem Statement

Air toxics emissions may be causing increased long-term inhalation health risk (both cancer and noncancer concerns) to people in the immediate vicinity of Acme Refining Company. A modeling risk assessment will be performed to evaluate potential long-term human health impacts of inhalation exposures to all air toxics emitted by the facility. Inhalation risks for populations within 50 km of the Acme property boundary will be assessed under residential exposure conditions. Non-inhalation pathways will not be assessed for either human or ecological receptors.

5.3.2.5 How will Risk Managers Evaluate the Concern?

The risk assessments are most often designed to provide input to risk managers to help inform the decisions they must make. Part of the planning and scoping process is developing an understanding of the types of information needed by the risk managers and the level of uncertainty in that information that can be tolerated. It does not make sense to conduct an expensive risk assessment if the eventual results will not be helpful to decision makers.

5.3.2.6 Lessons Learned on Planning and Scoping

EPA's Science Policy Council has evaluated the planning and scoping process, particularly as it relates to cumulative risk assessments (http://www.epa.gov/osp/spc/2cumrisk.htm). From an assessment of five case studies, a working group identified the following lessons learned:[8]

- Early and extensive involvement of the risk manager (decision maker) helped focus the process toward a tangible product.

- Purporting that planning and scoping will be quick and easy is likely to be counterproductive; it is a lot more work than people assume. However, it ultimately saves time by helping to organize everyone's thinking and usually results in a better quality assessment.

- Stakeholder engagement is essential at the beginning, because their patience is directly proportional to their sense of influence in the process. They have been helpful in identifying important public health endpoints that were not initially considered by EPA in the process of developing a conceptual model.

- Conceptual models are helpful in demonstrating how one program relates to other regulatory activities as well as the relationship between stressors and effects beyond traditional regulatory paradigms.

- Debate over terminology and brainstorming sessions are necessary to reach a consensus. A clear set of definitions aids this process.

- The planning and scoping process cannot be prescriptive, because the context of each situation is different. Planning and scoping is particularly valuable when the assessment will be complex, controversial, or precedential. At this time, planning and scoping usually precede cumulative risk assessments.

- Clear objectives, resource commitments, and estimated schedules from management will drive the approach and level of detail that can be considered.

- Explaining uncertainty to stakeholders is critical despite a hesitancy to reveal all that is known and not known about chemical risks. While revealing these uncertainties may lead to criticism and political ramifications, it can also develop a sense of trust, credibility, and support for the decision making process.

It should also be noted that the entire planning and scoping (and risk assessment process) is inherently iterative in nature. As the analysis proceeds and participants learn more about the study area, participants may find the initial assumptions in the conceptual model inadequate and they will need to modify the conceptual model (and, thus, the analysis plan). For example, suppose a conceptual model was developed that assumed a chemical was released from a facility that is generally thought to deposit quickly from the air, is highly persistent, and has a large bioaccumulation potential, thus requiring a multipathway analysis. Once the emissions inventory is verified, it is found that this chemical is actually not used or produced by facility, rendering the multipathway analysis moot for this chemical. (Multipathway analysis may still be needed for other chemicals in the emissions.)

When such changes are required in the conceptual model and analysis plan, all key stakeholders may be apprised of the change and ideally agree to any alterations in the goals of the overall assessment. The initial goal of "no surprises at the end of the assessment" is still maintained in light of evolving information.

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Chapter 6 Problem Formulation: Inhalation Risk Assessment

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6.1 Introduction

This chapter discusses the problem formulation step, which takes the results of the planning and scoping process and translates them into two critical products:

- A **conceptual model** that explicitly identifies the sources, receptors, exposure pathways, and potential adverse human health effects that the risk assessment will evaluate (described in Section 6.2); and

- An **analysis plan** that outlines the analytical approaches that will be used in the risk assessment (described in Section 6.3).

An additional section on data quality (Section 6.4) is also included as a reference for those portions of the risk assessment that involve data collection (e.g., emissions inventories, monitoring). EPA's *Framework for Cumulative Risk Assessment*[1] provides a more detailed discussion of the problem formulation process.

6.2 Developing the Conceptual Model

The general concern and approach articulated in the problem statement usually receives more detail in a **study-specific conceptual model**. This model explicitly identifies the sources, receptors, exposure pathways, and potential adverse human health effects that the risk assessment is going to evaluate. The study-specific conceptual model comprises both a picture and written description that illustrate: the current understanding of what sources are releasing air toxics in a particular place; how the chemicals may be transported from the point of release to the point where people can breathe them; and the types of health effects that may result. Risk assessors commonly include both a pictorial illustration (such as a technical drawing) and a narrative description of each of the above elements in the conceptual model.

The conceptual model establishes the physical boundaries of the assessment area and focuses the risk assessment on several key elements, including sources, chemicals released, fate and transport mechanisms, potentially exposed populations, potential exposure pathways and routes of exposure (e.g., breathing, ingesting), and potential adverse effects. Although participants may revise or refine the conceptual model during the risk assessment, it is important to develop an initial conceptual model early on.

Critical elements to be included in the conceptual model include:

- **The sources of air toxics**. The identity, location (latitude/longitude), and physical nature of the sources being evaluated (which may include factories, small businesses, cars/trucks, forest fires, etc.), including general emissions characteristics (e.g., stack locations, heights, other stack parameters, control device efficiency, operating schedules).

- **Stressors**. The specific air toxics that will be evaluated. Information on air toxics may come from emissions inventories, previous monitoring or modeling studies, permits, or estimates based on the principal processes or activities occurring at the source or site. Many risk assessments begin with a relatively large number of stressors that are of potential concern

(**chemicals of potential concern**, or COPC) and narrow these to the subset that contributes most to exposure and risk.

- **The exposure pathways/media of concern**. The environmental compartments into which the air toxics move after they are released and through which human exposure can occur. Once released from the sources, air toxics begin to disperse by the wind away from the point of release and may remain airborne; convert into a different substance; and/or deposit out of the air onto soils, water, or plants. People may be exposed to air toxics by breathing contaminated outdoor and/or indoor air (inhalation); ingestion (for the small number of air toxics that can accumulate in soils, sediments, and foods – a process called bioaccumulation); and skin (dermal) contact with deposited air toxics. Air toxics risk assessments always evaluate the inhalation exposure pathway. However, when sources release chemicals that persist and which also may bioaccumulate, analysis of non-inhalation pathways may also be necessary (see Parts III and IV for information on inhalation pathways).

> **Chemicals of Potential Concern (COPC)**
>
> Chemicals of potential concern (COPC) are those air toxics that are evaluated in the risk assessment because they have the potential to affect the risk management decision. The corresponding term for ecological risk assessment are chemicals of potential ecological concern (COPEC). The risk assessment often finds that most of the risk is associated with a subset of the COPC. The subset, which drives the risk management decisions, is referred to as chemicals of concern (COC).

- **Routes of exposure**. Potential routes of exposure include inhalation, ingestion, and dermal absorption.

- **Subpopulations**. The human populations potentially receiving exposure to the air toxics, including information about demographics (race, ethnicity, economic status, etc.) and potentially sensitive subgroups (e.g., elderly, children). Depending on the goals of the risk assessment, the conceptual model may need to consider populations currently living in a given area as well as those that might move into the area in the future.

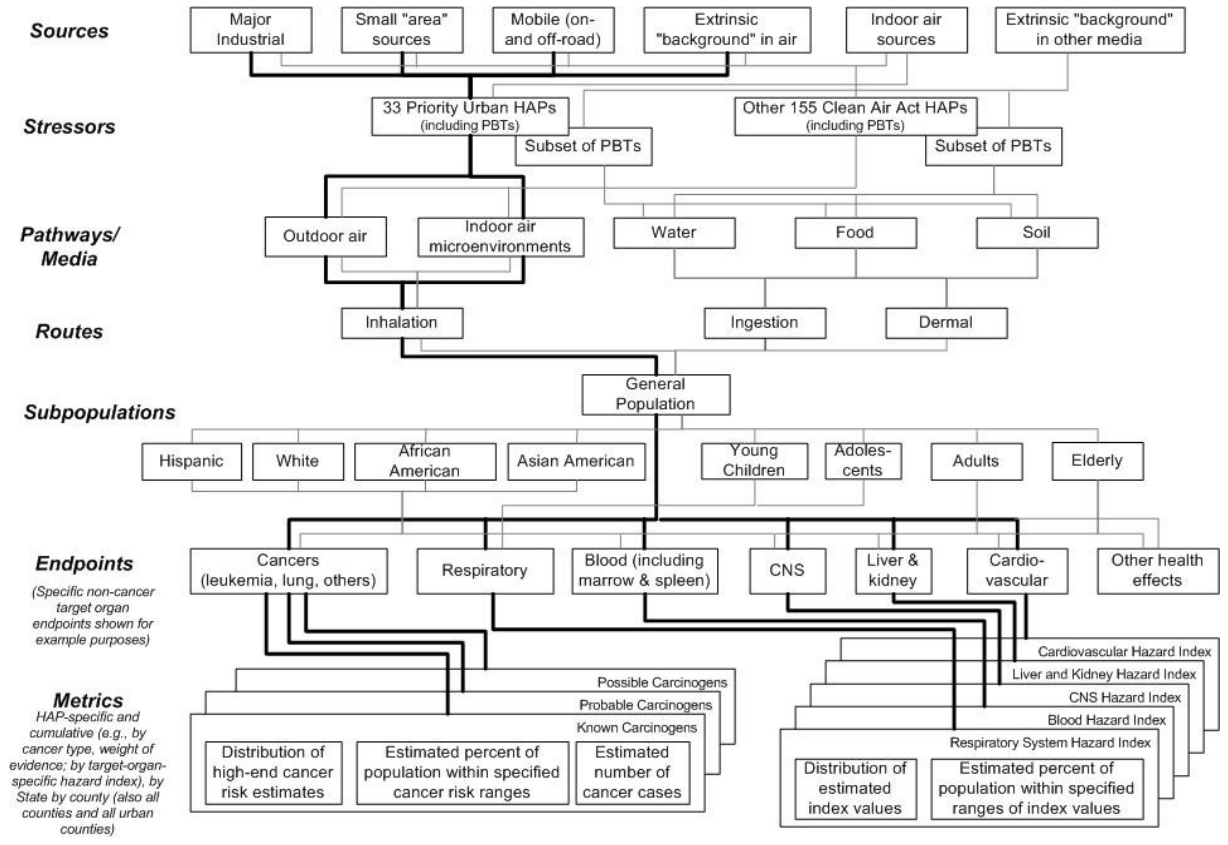
- **Endpoints**. The harmful effects that may result from exposure to air toxics, including cancer, respiratory effects, birth defects, and reproductive and neurological disorders. Air toxics can damage the organs at the initial point of contact or enter the body and move via the bloodstream to other target organs or tissues. Choice of endpoints generally depends on the toxic effects exhibited by the specific air toxics being assessed. Risk assessors generally represent potential adverse health effects to humans from exposure to air toxics through the inhalation pathway as cancer and noncancer outcomes (see Exhibit 5-3). Unless risk assessors study a specific chemical that is linked to a specific health outcome (which is not usually the case), a general statement that "risk of cancer and noncancer hazard will be evaluated" is usually sufficient.

- **Metrics**. It should be determined how cancer risk and noncancer hazard will be estimated and reported.

Exhibit 6-1 provides an example of a generalized conceptual model for air toxics risk assessments with examples of possible linkages. The example shown is a graphical illustration;

it would also be possible to develop a pictorial illustration. The conceptual model for a specific risk assessment will likely include only part of this general model. For example, pathways involving soil, water, and food will only be included if PB-HAP compounds are COPC. In the conceptual model, the sources, pathways, and expected health outcomes are drawn to illustrate what the assessors think may be happening in the study when sources are releasing air toxics to the environment. For a specific study, risk assessors would augment the illustration with the actual names/locations of sources, the COPC they release, the populations of concern and their location, and the specific health outcomes of concern (the generic endpoints of cancer and noncancer health outcomes, as drawn here, are usually sufficient for this stage of the assessment). The accompanying narrative will describe each of the elements of the illustration in detail and will provide sufficient information to clarify the critical elements of each piece of the picture.

Exhibit 6-1. Generalized Conceptual Model for Air Toxics Risk Assessments



This figure illustrates a general conceptual model for air toxics risk assessments with examples of potential linkages. The conceptual model for a specific risk assessment will likely include only part of this general model. In this figure, the heavy lines represent the conceptual model used for the initial National-scale Air Toxics Assessment (*Draft for EPA Science Advisory Board Review*, available online at http://www.epa.gov/ttn/atw/sab/sabrev.html). This assessment focused on 33 air toxics and was limited to inhalation exposures. Cancer and noncancer endpoints were assessed using distributions, estimated percentages of the population within specified risk or hazard index ranges, and estimated incidence (only for cancer cases).

If PB-HAP compounds identified in Exhibit 4-2 (or other air toxics that persist and may bioaccumulate and/or bioconcentrate) are present in emissions, both the conceptual model and the analysis plan may need to consider pathways other than inhalation (e.g., deposition to soil and surface waters, uptake by biota, and ingestion of these media and biota) for human and ecological receptors. For purposes of this Reference Manual, we discuss the elements/considerations for the conceptual model and analysis plan that are particular to multipathway human health risk assessment in Part III and ecological risk assessment in Part IV. However, the planning, scoping, and problem formulation process specific to multipathway analyses is generally integrated with the process for the inhalation analysis as early as feasible.

6.3 Developing the Analysis Plan

Risk assessors use the study-specific conceptual model as a guide to help determine what types, amount, and quality of data are needed for the study to answer the questions the risk assessment has set out to evaluate. Specifically, the analysis plan matches each element of the conceptual model with the analytical approach that the assessors will use to develop data about that element (Exhibit 6-2).

Most often, the analysis plan details the link between each element of the conceptual model and the specific analytical approach. The participants would then describe each of the analytical approaches in sufficient detail to provide the risk assessors with sufficient direction to allow them to produce the desired high quality data. For example, when determining exposure concentrations of COPC at the point of exposure to humans, the analysis plan will describe the exact sampling/analytical lab methods and/or models that risk assessors will use to generate this data, who will perform the analyses, when the analyses will be done, quality assurance/quality control requirements (including data validation procedures), roles/responsibilities of analysts, and documentation requirements. This section of the analysis plan would also provide a discussion of how data gaps should be identified and documented and how assessors will address uncertainties.

The analysis plan may also include a comparison between the level of confidence needed for the management decision and the actual level of confidence it expects from alternative analytical approaches; this will determine which alternative best meets the management goals, within the constraints of time and resources. In addition, the analytical approach may include a phased or tiered risk assessment approach to facilitate management decisions (see Section 6.4 below).

The analysis plan is most helpful when it contains explicit statements of how participants selected the various analytical approaches, what piece of the conceptual model they intended the approach to evaluate, how the approach integrates with other analytical elements, and specific milestones for completing the risk assessment. Assessors generally include uncertainties associated with analyses, and approaches for addressing these uncertainties, in the analysis plan when possible.

Exhibit 6-2. Important Elements to be Included in an Analysis Plan	
Sources	How will information on the sources in the analysis (e.g., source location, important release parameters) be obtained and analyzed?
Pollutants	How will chemicals of potential concern (COPC) be confirmed and their emissions values be estimated?
Exposure pathways	How will the identified exposure pathways be assessed? How will ambient concentrations be estimated?
Exposed population(s)	How will exposures to populations of interest be characterized? How will their exposure concentrations be estimated? What will be the temporal resolution? What sensitive subpopulations may be affected?
Endpoints	How will information on the toxicity of the COPC be obtained (what are the data sources)? What risk metrics will be derived for the risk characterization?
In addressing the above aspects of the analysis, the plan should also clearly describe the following: • How will *quality* be ensured in each step (e.g., what will be included in the quality assurance/quality control plans)? • How will *uncertainty and variability* in the results be assessed? • How will all stages of the assessment be *documented*? • Who are the *participants* and what are their *roles and responsibilities* in the various activities? • What is the *schedule* for each step (including milestones)? • What are the *resources* (e.g., time, money, personnel) being allocated for each step?	

The analysis plan may not result in just one document, but rather in a combination of multiple work plans that, taken together, constitute "the analysis plan." For example, for a study where assessors will perform both air dispersion modeling and air monitoring, participants may develop a separate work plan for both modeling and monitoring. However, assessors usually develop a master plan that describes all the different pieces and their relationship to one other.

The remainder of this subsection describes the important elements of the analysis plan, including:

- Identification of sources;
- Identification of chemicals of potential concern;
- Identification of exposure pathways/routes;
- Identification of exposed populations; and
- Identification of endpoints and metrics.

6.3.1 Identification of the Sources

As noted in Part I, EPA classifies sources of air toxics into a variety of categories for regulatory purposes, including stationary sources, mobile sources, and indoor sources (see Chapter 4). In addition, risk assessors also commonly group substances by their chemical and physical properties to both better estimate the fate and transport of chemicals in the environment and to

make inferences about the types of exposure pathways likely to be important in the exposure assessment.

This part of the analysis plan specifies the approach to be used to identify the specific sources that will form the initial focus of the analysis. Depending on the goals of the risk assessment, these sources may be limited to a single source or multiple sources at a facility (i.e., facility-specific risk assessments discussed in Volume II of this reference library) or may cover a wider variety of sources, including mobile sources, stationary sources, and possibly other sources such as indoor and natural sources (e.g., community-based risk assessments discussed in Volume III of this reference library). Identifying sources may be relatively straightforward (e.g., for facility-specific risk assessments) or may involve considerable research, particularly when dealing with a large number of smaller sources. In such an analysis, the initial tier of evaluation generally focuses on all identifiable sources within the assessment area. In subsequent tiers, it may be possible to remove some of these sources from the exposure assessment if one can determine that they contribute a very small fraction to the total risk estimate. Chapter 12 contains the techniques for conducting this type of screening.

6.3.2 Identification of the Chemicals of Potential Concern

This part of the analysis plan specifies the approach to be used to identify the most important air toxics that sources release (i.e., the chemicals of potential concern, or COPC). The COPCs will be the primary focus of the exposure and risk assessment. The initial tier of analysis often includes all of the air toxics released from the identified important sources. Depending on the specific air toxics of concern, the risk assessment also may need to consider secondary compounds that are formed from the reaction in the atmosphere.

Two techniques are available to focus the risk assessment on the most important air toxics:

- During problem formulation, a simple toxicity-emissions weighted screening approach can be conducted (discussed in Section 6.3.2.1).

- Once an initial risk characterization has been performed, subsequent tiers of analysis may remove specific chemicals from the COPC list if they are determined to contribute only a very small fraction to the total risk estimate (discussed in Section 6.3.2.2).

(Note that some assessors may wish to simply carry through the analysis all of the chemicals emitted to the assessment area. This is appropriate; however, it may require sufficient resources and result in little useful information.)

6.3.2.1 Toxicity-Weighted Screening Analysis

To determine which air toxics to include in the Tier 1 inhalation risk assessment, a relative risk evaluation called a **toxicity-weighted screening analysis (TWSA)** may be calculated based on the emissions data for all air toxics released from the facility/source being assessed. A TWSA is particularly useful if there are a large number of air toxics in the facility/source emissions and there is a desire to focus the risk analysis on a smaller subset of air toxics that contribute the most to risk. A TWSA can be performed as described below.

The TWSA is intended to be entirely emissions- and toxicity-based, without considering dispersion, fate, receptor locations, and other exposure parameters. It essentially compares the emissions rates of each air toxic to a hypothetical substance with an inhalation unit risk value of 1 per $\mu g/m^3$ (for carcinogenic effects) and/or a reference concentration (RfC) of 1 mg/m^3 (for noncancer effects). It requires emissions (release) information as well as the applicable dose-response values (see Chapter 12). However, is also can be used even with a single emission point and many air toxics. The steps for emissions-based toxicity-emissions weighted screening are presented below.

1. Identify all the inhalation unit risks (IURs) and RfCs for the air toxics in the facility/source emissions.
2. Determine the emission rate (e.g., tons/year) of each air toxic.
3. Multiply the emission rate of each air toxic by its IUR to obtain a toxicity-emissions product.
4. Rank-order the toxicity-emissions products and obtain the sum of all products.
5. Starting with the highest ranking product, proceed down the list until the cumulative sum of the products reaches a high proportion (e.g., 99 percent) of the total of the products for all the air toxics. Include in the assessment all the air toxics that contributed that proportion (e.g., 99 percent) of the total (see Exhibit 6-3 for an example calculation).
6. Repeat steps 3-5, but instead divide the emissions rate by the RfCs to obtain "noncancer equivalent tons"/year (see Exhibit 6-4 for an example calculation).

Chemicals with no toxicity data will necessarily not be included in the initial list of COPCs identified by the TWSA screening process. However, this does not necessarily mean that they are not potential risk drivers. Chemicals with no toxicity data are to be evaluated as part of the overall uncertainty analysis for the risk assessment. If there is sufficient evidence to support the hypothesis that an omitted chemical is a potential risk driver, the risk assessment team may opt to develop a toxicity value for the chemical (see Chapter 12 for more information on identifying toxicity values for chemicals). Also, if evidence suggests that a chemical that is screened out (e.g., is below the 99th percentile in the TWSA) would nevertheless have an individual HQ or cancer risk greater than the selected screening level, the assessor may consider keeping the chemical in the list of COPCs.

6.3.2.2 Risk-Based Screening Analysis

In subsequent tiers of analysis, a **risk-based screening analysis** can be used to further focus the assessment on the significant air toxics of concern. This approach would be similar to the TWSA except that estimated individual cancer risk and noncancer hazard estimates would be used instead of toxicity-weighted emissions (an example risk-based screening analysis is presented in Chapter 13). A risk-based screening analysis might include the following steps:

1. Using applicable input data, run a simple dispersion and/or exposure model and calculate cancer risk at a selected point (e.g., maximum exposed individual location).
2. Rank-order the individual risk estimates for each emitted air toxic and obtain the sum of the cancer risk.
3. Starting with the highest ranking cancer risk, proceed down the list until the individual air toxics contributing a large proportion (e.g., 99 percent) of the total risk are included. Include those air toxics in subsequent tiers of analysis.
4. Repeat steps 1-3 for noncancer hazard.

Exhibit 6-3. Example TWSA Calculation for Cancer Effects					
Air Toxic	**Emissions (tons/year)**	**IUR**	**Cancer Equivalent Tons/year**	**Percent of Total**	**Cumulative Percent**
1,3-butadiene	8.2×10^{1}	3.0×10^{-5}	2.5×10^{-3}	23.8%	23.8%
carbon tetrachloride	1.5×10^{2}	1.5×10^{-5}	2.2×10^{-3}	21.3%	45.1%
beryllium compounds	8.6×10^{-1}	2.4×10^{-3}	2.1×10^{-3}	19.8%	64.9%
arsenic compounds	4.2×10^{-1}	4.3×10^{-3}	1.8×10^{-3}	17.5%	82.4%
2,3,7,8-TCDD	2.0×10^{-5}	3.3×10^{1}	6.6×10^{-4}	6.4%	88.8%
chromium (VI) compounds	3.7×10^{-2}	1.2×10^{-2}	4.4×10^{-4}	4.3%	93.1%
polycyclic organic matter[(a)]	4.3	2.1×10^{-1}	3.7×10^{-4}	3.6%	96.7%
cadmium compounds	1.0×10^{-1}	1.8×10^{-3}	1.8×10^{-4}	1.8%	98.4%
formaldehyde	8.9	1.3×10^{-5}	1.2×10^{-4}	1.1%	99.5%
1,3-dichloropropene	5.2	4.0×10^{-6}	2.1×10^{-5}	0.2%	99.7%
allyl chloride	2.8	6.0×10^{-6}	1.7×10^{-5}	0.2%	99.9%
methylene chloride	1.9×10^{1}	4.7×10^{-7}	8.7×10^{-6}	0.1%	100.0%
benzene	9.3×10^{-2}	7.8×10^{-6}	7.3×10^{-7}	0.0%	100.0%
Total			1.0×10^{-2}	100.0%	

Heavy line denotes 99% cutoff. In this example, 1,3-dichloropropene, allyl chloride, methylene chloride, and benzene could be dropped from the cancer analysis.
[(a)] Cancer equivalent tons/year and IUR are based on the assumption that benzo(a)pyrene represents 5% of emissions.

6.3.3 Identification of the Exposure Pathways/Routes

This part of the analysis plan specifies the approach to be used to identify the specific exposure pathways/routes that will be assessed. An exposure pathway/route describes the movement of air toxics from the point of release to the point where exposure may occur and generally consists of four elements:

1. A source and mechanism of release (emissions);
2. A transport medium (for inhalation, air);
3. A point of potential human contact with the contaminated medium (the **exposure point**); and
4. An exposure route at the contact point (e.g., inhalation).

Exhibit 6-4. Example TWSA Calculation for Noncancer Effects					
Air Toxic	**Emissions (tons/year)**	**RfC**	**Noncancer Equivalent Tons/year**	**Percent of Total**	**Cumulative Percent**
beryllium compounds	8.6×10^{-1}	2.0×10^{-5}	4.3×10^{4}	38.3%	38.3%
1,3 butadiene	8.2×10^{1}	2.0×10^{-3}	4.1×10^{4}	36.7%	75.0%
arsenic compounds	4.2×10^{-1}	3.0×10^{-5}	1.4×10^{4}	12.6%	87.6%
cadmium compounds	1.0×10^{-1}	2.0×10^{-5}	5.1×10^{3}	4.6%	92.1%
carbon tetrachloride	1.5×10^{2}	4.0×10^{-2}	3.7×10^{3}	3.3%	95.4%
allyl chloride	2.8	1.0×10^{-3}	2.8×10^{3}	2.5%	97.9%
formaldehyde	8.9	9.8×10^{-3}	9.1×10^{2}	0.8%	98.7%
2,3,7,8-TCDD	2.0×10^{-5}	4.0×10^{-8}	5.0×10^{2}	0.4%	99.1%
chromium (VI) compounds	3.7×10^{-2}	1.0×10^{-4}	3.7×10^{2}	0.3%	99.5%
toluene	1.3×10^{2}	4.0×10^{-1}	3.2×10^{2}	0.3%	99.8%
1,3-dichloropropene	5.2	2.0×10^{-2}	2.6×10^{2}	0.2%	100.0%
methylene chloride	1.9×10^{1}	1.0	1.9×10^{1}	0.0%	100.0%
benzene	9.3×10^{-2}	6.0×10^{-2}	1.6	0.0%	100.0%
		Total	1.1×10^{5}	100.0%	
Heavy line denotes 99% cutoff. In this example, chromium (VI) compounds, toluene, 1,3-dichloropropene, methylene chloride, and benzene could be dropped from the noncancer analysis.					

A critical determination in the exposure assessment is whether the potential exposure pathways identified during scoping are **complete** (i.e., there is a plausible mechanism by which the air toxic emitted from the source can reach the exposure point and a plausible mechanism by which the human receptor can come into contact with the chemical at the exposure point). Exposure cannot occur without a complete exposure pathway; and therefore if assessors determine that a potential exposure pathway is incomplete, they will generally document and drop the exposure from the risk assessment.

The exposures to be assessed depend on the needs articulated in the planning and scoping and problem formulation steps, including the specific laws and regulations that mandate a potential decision. For example, air toxics risk assessments commonly rely primarily on current land uses when evaluating exposures, while risk assessments conducted in the Superfund program commonly assess current and future land uses (i.e., air toxics risk assessments usually presume that the current land use within the area of impact of a source(s) will remain unchanged into the foreseeable future). The need, reasons, and methodology to evaluate alternate (e.g., future) land use conditions may be carefully considered and fully articulated during the problem formulation and planning/scoping phase of the assessment. As will be discussed later, in screening-level air

toxics risk assessments, it is common to assess exposures at the point of maximum offsite ambient concentrations, whether or not someone actually lives there (the maximum exposed individual or MEI location).

In addition, advanced tools (such as the RAIMI approach; see Volume III of this reference library) allow exposure assessments to evaluate the contemporaneous impact of multiple sources on a assessment area, identify the main contributors to the impact, and evaluate "what if" scenarios (e.g., what if this source cut its emissions by half; what if a roadway doubled its traffic?). Ultimately, the needs of the risk manager will drive such decisions.

For inhalation risk assessments, assessors evaluate only one exposure pathway (inhalation); multipathway risk assessments, on the other hand, focus on all relevant pathways (i.e., inhalation *and* any other relevant pathway, such as ingestion or dermal; see Part III of this Reference Manual for a description of how multipathway analyses are done). Exhibit 6-5 illustrates the exposure pathways/routes that are commonly assessed for air toxics inhalation risk assessments. Note that depending on the types of sources and specific COPCs they release, some of these pathways may or may not be relevant for any particular study.

Exhibit 6-5. Most Commonly Assessed Exposure Pathways/Routes for Air Toxics Inhalation Risk Assessments
Outdoor emissions of vapor phase chemicals → outdoor air → indoor air (by penetration of outdoor air into indoor spaces) Outdoor emissions of particles → outdoor air → indoor air (by penetration of outdoor air into indoor spaces)
Note: • Other media/routes may be applicable for particular risk assessments; • When available, information on indoor source contributions may also be considered.

Whether the exposures to be assessed include workers depends on the needs articulated in the planning/scoping and problem formulation steps. For example, the Department of Labor's Occupational Safety and Health Administration (OSHA) generally regulates the exposures of workers to the chemicals they are exposed to in their workplace, and therefore these exposures generally are not considered in an air toxics risk assessment. When workers are exposed to chemicals not generated in their workplace (e.g., office workers exposed by a nearby factory), a decision may be made to consider the risks.

Exhibit 6-6 provides an example of an exposure pathway evaluation summary for a hypothetical study. The exposure pathways identified for further assessment will depend on the specific types of chemicals released (including their chemical and physical form), the physical relationship of the sources to the human receptors, meteorological conditions, and the relationship between indoor and outdoor air for the chemicals under study (for indoor exposure component).

Exhibit 6-6. Example Illustrating Possible Complete Exposure Pathways for a Hypothetical Inhalation Air Toxics Risk Assessment			
Potentially Exposed Population	**Exposure Route, Medium, and Exposure Point**	**Pathway Selected for Evaluation?**	**Reason for Selection or Exclusion**
Current Land Use Residents living in Smallville, USA	Inhalation of vapor phase chemicals during outdoor activities	Yes	Residents live year-round in Smallville
	Inhalation of particulate matter during outdoor activities	No	Preliminary analysis suggests that no significant particulate matter is released from sources in the assessment area and that the chemicals released remain in the vapor phase
	Inhalation of vapor phase chemicals during indoor activities	Yes	Residents live year-round in Smallville and released chemicals have the potential to penetrate indoors; the COPC are also released by indoor sources
	Inhalation of particle phase chemicals during indoor activities	No	Residents live year-round in Smallville and no significant particulate matter is released from sources in the assessment area and the chemicals released remain in the vapor phase. There are no known indoor sources.
Note: Assessment of completed non-inhalation exposure pathways are discussed in Part III of this reference manual.			

The approach for characterizing exposure pathways/routes in the analysis plan usually considers a variety of information about the assessment area (as articulated in the conceptual model), including how it will be bounded for the analysis. The analysis plan also specifies how exposure will be estimated and quantified, including whether modeling and/or monitoring will be used. The following subsections discuss:

- Characteristics of the assessment area;
- Scale of the assessment area;
- Use of modeling versus monitoring; and
- Quantification of exposure.

6.3.3.1 Characteristics of the Assessment Area

The physical characteristics of the assessment area provide a basis for identifying potential exposure pathways/routes and receptor populations of concern. They also are important considerations for selecting and providing input parameters for the air quality models to be used and/or for establishing monitoring sites. There is no universal classification system for describing the characteristics of the assessment area, but the following information is generally important for inhalation exposure assessments:

- **Urban versus rural setting**. This distinction provides general information about the way that air toxics will disperse in the environment once released and the expected number and types of receptors. For example, releases in rural areas may tend to move downwind with a relatively simple dispersion pattern, while releases in a large city are likely to disperse in very complex patterns depending the size and placement of buildings. Additionally, some of the newer dispersion models can adjust both for direction dependencies as well as time of year due to changes in foliage.

- **Simple versus complex terrain**. Terrain affects both the way that air toxics will disperse in the environment once released and the amount of dilution that will occur before they reach receptors. For example, a plume might pass over nearby receptors in simple terrain, but might intercept receptors located on elevated terrain (e.g., a plateau or hill) at the same distance from the source. Assessors can determine the terrain of any area in the United States from topographic maps available from the USGS (see below).

- **Climate and meteorology**. Climate features such as temperature and precipitation patterns, and meteorological features such as wind speed and direction will affect the fate and movement of air toxics in the atmosphere and after deposition. Seasonal and diurnal conditions may be major factors affecting rates of contaminant migration where precipitation rates or temperatures vary greatly according to the season or time of day. It also is important to note whether unusual weather conditions occur frequently within the assessment area, as these can have significant effects on contaminant fate and transport (see Appendix G).

- **Other important geographic features**. Nearby geographic features such as a lake or ocean can have significant effects on contaminant dispersion and may require the use of special dispersion models (see Chapter 9). For multipathway human health and/or ecological risk assessments, exposure setting also may include such elements as water bodies and associated watersheds, ecological receptors, and agricultural lands (see Parts III and IV).

Current land use (and in limited instances, potential future land use) is an important factor to consider in determining the exposure pathways and specific exposure points that are commonly evaluated in the risk assessment (particularly for higher-tier risk assessments). Land use can typically be identified by reviewing hard copy and/or electronic versions of land use land classification (LULC) maps, topographic maps, and aerial photographs. Sources and general information associated with each of these data types or maps are presented below. Also, assessors may want to verify the Universal Transverse Mercator (UTM) coordinate system format (North American Datum 27 (NAD27) or NAD83) to ensure consistency and prevent erroneous geo-referencing of locations and areas.

- **Land Use Land Cover (LULC) Maps**. LULC maps can be downloaded directly from the U.S. Geological Survey website (http://edc.usgs.gov/geodata/), at a scale of 1:250,000, in a file type Geographic Information Retrieval and Analysis System (GIRAS) format. LULC maps can also be downloaded from the website (http://www.epa.gov/ngispgm3/spdata/EPAGIRAS/egiras/), at a scale of 1:250,000, in an Arc/Info export format. It is recommended that the exact boundaries of polygon land use area coverages, in areas being considered for evaluation, be verified using available topographic maps and aerial photographic coverages.

- **Topographic Maps**. Topographic maps are readily available in both hard copy and electronic format directly from USGS (http://mapping.usgs.gov/index.html) or numerous other vendors. These maps are commonly at a scale of 1:24,000, and in a TIFF file format with TIFF World File included for georeferencing.

- **Aerial Photographs**. Hard copy aerial photographs can be purchased directly from USGS (http://mapping.usgs.gov/index.html) in a variety of scales and coverages. Electronic format aerial photographs or Digital Ortho Quarter Quads (DOQQs) can also be purchased directly from USGS, or from an increasing number of commercial sources, such as Microsoft's® areal photo map server called "terraserver" (http://www.terraserver.com).

While these data sources do not represent the full universe of information available on human activities or land use, they are readily available from a number of government sources (typically accessible via the Internet), usually can be obtained at no or low cost, and when used together provide a good starting point to identify and define, in a defensible manner, land use areas to be considered for evaluation in the risk assessment. However, while the use of these or other data can be very accurate, verifying identified land use areas "on the ground" may be important for higher-tier risk assessments. Discussions with representatives of private and government organizations which routinely collect and evaluate land use data (e.g., agricultural extension agencies, U.S. Department of Agriculture, natural resource and park agencies, and local governments) can also be helpful in updating current land use information or providing information regarding future land use. Information on reasonable potential future land use can also be obtained from local planning and zoning authorities, which may help determine what level of development is now allowed under current regulations and what development is expected in the future. EPA's Superfund program has developed a specific directive on the process of how to go about determining future land use in a particular place.[2] This directive may be consulted for information on how to formulate realistic assumptions regarding future land use.

6.3.3.2 Scale of the Assessment Area

The scale of the assessment area is determined to a large part by the specific question(s) or problem(s) being addressed in the risk assessment. In determining the scale of the assessment area, both the capabilities of the tools to be used and the physical characteristics of the assessment area are considered by assessors. For example, some commonly used air dispersion models are only considered by EPA to be valid out to about 50 km because of limitations in their conceptual basis (e.g., Gaussian plume modeling has this limitation). A 50-km limit may be sufficient for assessments that focus on highly impacted areas occurring within a few kilometers of the emissions sources. However, other situations may involve a more distant area of significant impact. For example, if there are unusual source characteristics such as very tall stacks or unusual physical characteristics such as a nearby plateau where people live, modeling may need to be extended to these more distant areas.

A separate, but related issue, is how to consider scale for assessments that incorporate monitoring to characterize exposure. Since a monitor only assesses exposure at the point where the monitor is located, the "scale" that this one point represents becomes much more difficult to determine. Thus, the term "scale" can represent two different things for exposure assessment. When using modeling, the "scale" of the assessment area is simply the geographical land area around the sources within which modeling nodes will be placed and modeling will be done (for example, the model may predict ambient concentrations at every point on a 100 × 100 m grid out to 50 km in all directions from the sources). When assessors use monitoring to evaluate exposure, the "scale" refers to the area around the monitoring location (and the types of exposures) the analysts consider the monitoring data to represent (for example, a monitor located in an urban area that does not directly receive the impacted of an identifiable point source is usually designated as an "urban scale" monitor because it reflects general urban ambient air concentrations for populations not directly impacted by point sources). A full discussion of this distinction is provided in Chapter 9.

Scale can also refer more generally to the coverage of the analysis (see Exhibit 6-7). For example, the 1996 NATA risk characterization provided risk estimates, at the county level, for every county in the US. The "scale" of this analysis was nationwide. A real person, on the other hand, who was outfitted with a personal monitoring device, might be described as "personal" or "individual" scale.

6.3.3.3 Use of Modeling versus Monitoring

As this document has previously noted, risk assessors can base estimates of exposure concentrations on either actual measurements (i.e., monitoring data) or air quality modeling. Exhibit 6-8 provides a brief comparison of modeling and monitoring. Many studies may benefit by using some combination of modeling and monitoring, because the two approaches can complement one another.

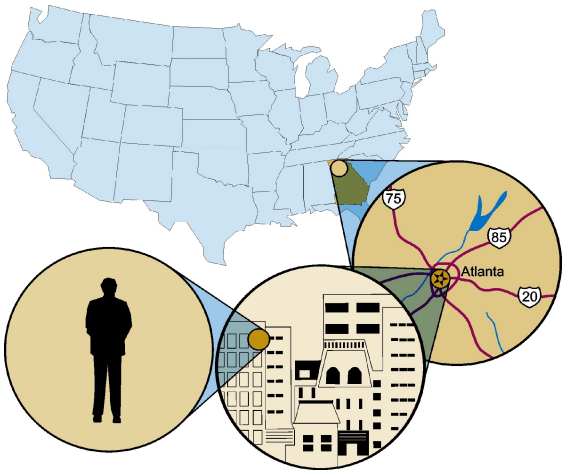
Benefits of modeling include the ability to:

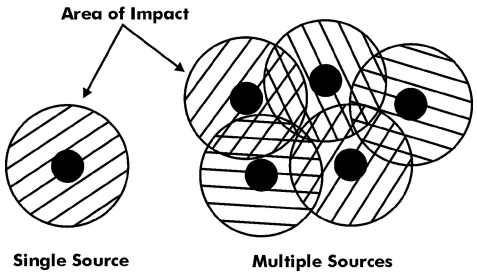
- Obtain a relatively quick, screening-level estimate of the potential for risk;
- Identify the subset of air toxics that contribute most significantly to the risk estimate;
- Identify the areas where the highest exposure concentrations are likely to occur;

- Estimate concentrations over a broad assessment area; and
- Examine individual variability in exposure.

One of the limits in the usefulness of modeling may be the accuracy of the air toxics emissions inventory (discussed in Chapter 7). Also, models can only provide estimates of exposure concentrations; often monitoring is performed to confirm model predictions.

Exhibit 6-7. Air Toxics Risk Assessments May be Conducted at Different Scales





Air toxics risk assessments may be performed on a variety of geographical levels ranging from the national level (e.g., the National-Scale Assessment), to the state, local, neighborhood, or even individual levels. Within a given scale, the risk assessment could look at the impact from a single source or multiple sources. The specific tools, approaches, and metrics used are likely to differ depending on the geographic scale of interest.

Benefits of monitoring include the ability to:

- Provide actual concentrations, which often provide a stronger basis for leveraging emissions reductions;
- Provide site-specific information to verify or calibrate model predictions;
- Provide time- and space-integrated measures of the actual concentrations at which individuals are exposed when they move from place to place within the assessment area; and
- Measure episodic releases, which are otherwise difficult to measure and quantify and are not well addressed in emissions inventories.

One of the limits in the usefulness of monitoring may be the representativeness of the location(s) in which monitors are placed (i.e., if placed in the wrong locations, monitors can provide incorrect and misleading information about exposures). Also, monitoring may not always be an effective tool to link ambient concentrations to specific sources (if, for example, one is monitoring benzene in an urban environment).

Exhibit 6-8. Comparison of Modeling and Monitoring Approaches for Estimating Ambient Air Concentrations	
Modeling	**Monitoring**
Modeling is relatively fast and inexpensive. Many screening-level models can be run in spreadsheet formats and require relatively simple input parameters. Many dispersion models, along with technical reference manuals and other support documents, are available for free download from EPA's Support Center for Regulatory Air Models (SCRAM) website (http://www.epa.gov/ttn/scram/). Resources normally need to be expended to enhance the local air toxics emission inventories to make air toxics modeling more precise.	Monitoring takes time to build data, and there are methodological limits and logistical issues. How expensive monitoring is depends on what you are trying to do and how much you have to buy or pay for. Monitoring does not always require equipment purchase and some states and local areas already have equipment. Some less expensive monitoring techniques are now available (i.e., passive samplers).
Modeling results can estimate concentration over a large spatial area (e.g., a 50-km radius from a source) and can provide a "big picture" view of the assessment area. Modeling also allows for analysis of exposure concentration at multiple points throughout the assessment area. The downside of modeling, however, is that these are predicted concentrations.	Monitoring results provide actual measured concentrations. Multiple locations may be required to characterize concentration over an area, although GIS methods facilitate interpolation between locations. The downside is that the monitoring may not be very representative of a large geographic area.
Screening-level models can provide a predicted estimate of whether significant concentrations are likely. A simple screening analysis may be sufficient to make a risk management decision that no action is required.	Monitoring can be used to identify and measure exposures for specific individuals at a specific location of concern (e.g., a school). This data can provide a quick screen to determine whether more extensive monitoring is needed.
Models can be used to identify areas where maximum concentrations are likely to occur, and thus to focus efforts for additional tiers of the assessment. Uncertainties in model parameters, and the discrete division of the wind field used in models (often with only eight wind directions) can result in incorrect identification of the locations of maximal concentration.	Monitoring can identify areas and actual levels of exposures occurring at the monitoring sites. Monitoring can also be used to indicate the point of maximal exposure if the monitoring is designed for that purpose. The selection of the monitoring locations is critical; if placed in the wrong locations, monitors can provide incorrect and misleading information about maximal exposures.
Models can be used to identify the subset of COPC and exposure pathways/routes that have the greatest contribution to risk. This can be helpful in focusing efforts for additional tiers of the assessment as well as determining appropriate risk management actions.	Monitoring can be used to confirm significant exposure pathways and routes. (Measured concentrations can be compared to risk-based screening levels.) It also can be used to identify compounds that may not have been suspected and, hence, were not included in models (i.e., monitoring allows identification of gaps in the emissions inventory).
Models allow "what if" scenarios to be evaluated (e.g., what if a permitted emission were doubled?).	Monitoring can only evaluate current conditions.
More complex modeling may allow explicit prediction and estimate of variability in exposure.	A large number of samples generally is needed to characterize variability; this may be prohibitively expensive. Monitoring, however, provides a direct and reliable means to characterize variability.
Models often use simplifying assumptions and data inputs that may or may not be representative of the specific assessment area. This introduces uncertainty into model predictions.	Monitoring can be used to confirm actual exposure levels as well as investigate assumptions or calibrate models to site-specific conditions, and to close gaps in data, reducing uncertainties.

6.3.3.4 Estimation of Exposure

An important element of the analysis plan is the specific approaches for developing numerical estimates of exposure concentrations for each of the COPC for each of the populations the assessment is studying (i.e., how exposure will be estimated and quantified). As noted in the previous subsection, this may involve the use of air quality models and/or monitoring data. Quantitation of exposure includes three general steps:

- **Characterization of releases to the air**. Characterizing the location, nature, and magnitude of emissions released from the sources being evaluated, including release parameters such as stack height and temperature of release (when modeling is being performed). This is discussed Chapter 7.

- **Estimation of chemical fate and transport**. Modeling and/or measuring the ambient concentrations of air toxics in the environment, as a result of transport, and including any physical or chemical transformations that may occur during this movement, from the emission point to the exposure points. This is discussed in Chapters 8, 9, and 10.

- **Estimation of exposure concentrations**. Developing a numerical estimate of exposure concentrations of air toxics to the selected exposure points. This is discussed in Chapter 11.

For the inhalation route of exposure, the metric of exposure is the concentration of the chemical in the air the population of interest is breathing over the period of interest. This concentration is called the **exposure concentration (EC)** and is the primary quantitative output of the inhalation exposure assessment. As we will see in Chapter 11, this metric is intended to represent the time weighted average exposure(s) to the population(s) of interest during the exposure period. (Note that exposure models are often also applied to better reflect how different people interact with contaminated air. In other words, the air quality model evaluates how chemicals move and change in the environment. The exposure model evaluates how different types of people interact with the resulting contaminated air - with the result that the EC is refined to provide more realistic estimates of exposure. A discussion of exposure modeling is provided below.)

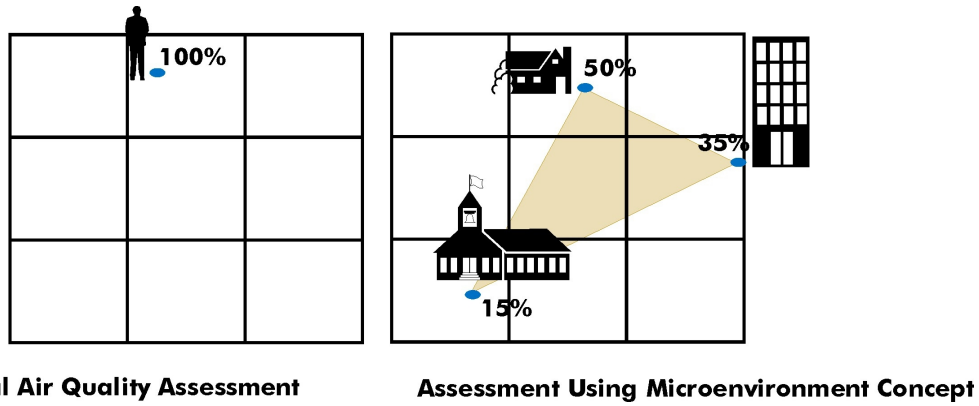
The Metrics of Exposure for Inhalation

The metric of exposure for inhalation is simply the **exposure concentration (EC)** – the concentration of a chemical in the air at the point where a person breathes the air.

There are two general ways to estimate the EC (Exhibit 6-9); these are discussed in greater detail in Chapter 11.

- **Ambient Air Concentrations**. For screening-level evaluations, assessors use the concentration of air toxics generated at each modeling node (or interpolated nodes) or the concentration determined by a monitor. The default assumption in such a screening assessment is that the population of interest is breathing air continuously around-the-clock at the modeled or monitor location. Proceeding in this manner, in the initial stages, is often done because of the additional cost, time, and specialized expertise needed to run the exposure model. Such results, depending on the purpose of the analysis, may be sufficient for some risk management decisions (Chapter 3 provides a discussion on how to phase or "tier" a risk assessment from simple but conservative to more complex yet realistic.)

Exhibit 6-9. Two General Ways to Estimate Inhalation Exposure Concentration

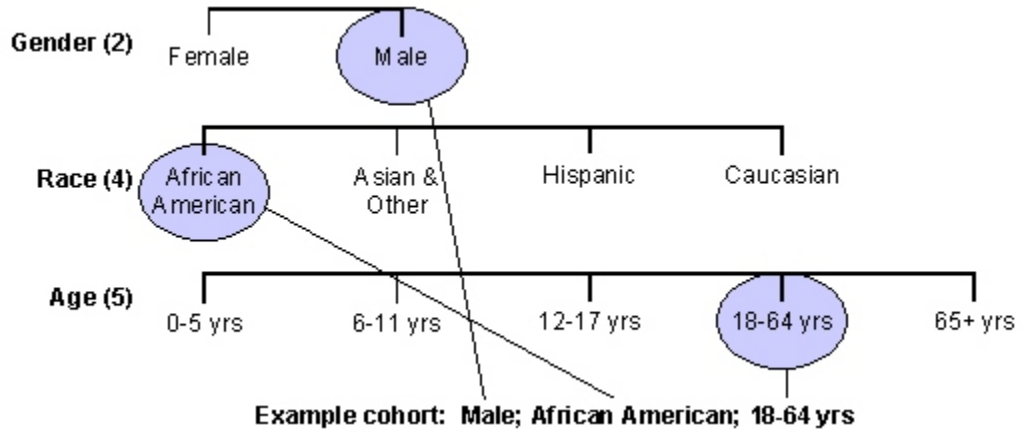


The left-hand side illustrates the use of ambient air concentrations as a surrogate for the EC. In this example, the analysis assumes that individuals spend 100 percent of their time at a given location, so the estimate of ambient concentration thus represents the EC. The right-hand side illustrates the use of exposure modeling. In this example, the analysis assumes that an individual spends 50 percent of his/her time at home; 15 percent at a school; and 35 percent at an office. The EC is the weighted sum of the product of the ambient concentrations at each location and the amount of time spent there. Both indoor and outdoor concentrations usually are considered at each location.

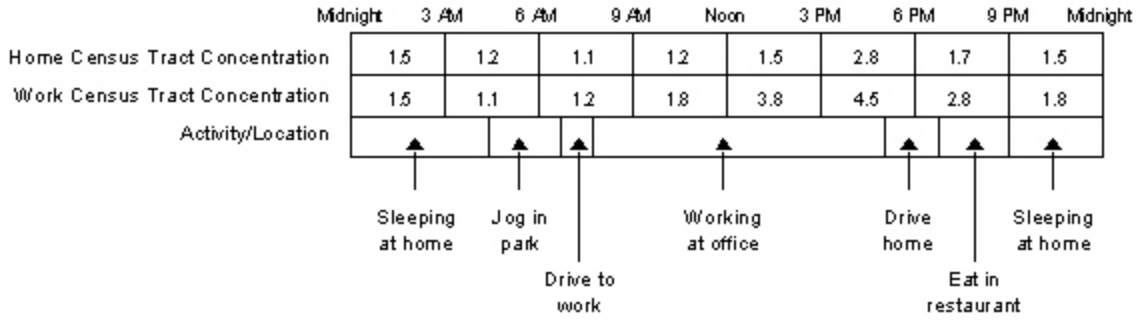
- **Exposure modeling**. More comprehensive inhalation exposure assessments combine estimates of ambient outdoor pollutant concentration (e.g., from air quality models) with information about the population of interest, including the types of people present (e.g., ethnicity, age, sex), time spent in different microenvironments, and microenvironment concentrations. The assessment objective is to obtain a representative estimate of the pollutant concentration in the inhaled air in each microenvironment. For risk assessments focusing on chronic effects resulting from chronic exposures, a long-term estimate of exposure is the EC of interest. As discussed in Chapter 9, the resulting estimate is a refined metric of personal exposure concentration (EC). This EC reflects the time spent in different microenvironments (and the activities within these microenvironments) throughout the daily routine of either representative individuals (selected statistically to be representative of the potentially exposed population) or different groups of people with similar attributes (called **cohorts**). The EC is essentially a time-weighted average exposure concentration for all of the cohorts combined (see Exhibit 6-10).

People living in the vicinity of one or multiple air toxics sources have the potential to receive exposure to emitted chemicals many different ways. For example, they might be exposed occasionally, but to very high concentrations (e.g., when an accident occurs that releases large amounts of chemical to the air in a very short amount of time). On the other hand, they might receive exposure quite often (or even continuously) to low levels that would likely go unnoticed. Air toxics inhalation exposure assessments usually focus on two of these different types of possible exposure scenarios:

Exhibit 6-10. Example Cohort Group



In this hypothetical example, cohort groups are defined based on gender (two categories); race (four categories), and age (five categories). This example illustrates an African American male aged 18-64 years.



In this hypothetical example, daily exposure scenarios are developed based on ambient air concentrations at work, and indoor and outdoor concentrations are assumed (for this example) to be equal at a given location, and home and the specific activity patterns modeled for each cohort. In this example, the African American male aged 18-64 years divides his activities among sleeping at home, jogging in the park, driving to work, working at the office, driving home, and eating at a restaurant. The daily exposure concentration is obtained by multiplying the time in each activity by the appropriate ambient air concentration(s) for the time period(s) of interest, then summing the products. For example, the product for jogging would be 1.2 (home concentration 3-6 AM) × 1.5 hours jogging (during the 3-6 AM time period) + 1.1 (home concentration 6-9 AM) × 0.5 hours jogging (during the time period 6-9 AM).

- **Chronic exposure** refers to situations in which the exposure occurs repeatedly over a long period of time (usually years to lifetime). If there is substantial variation in exposure concentration during segments of the chronic period, it may be appropriate to evaluate the segments separately using the appropriate dose-response values.

- **Sub-chronic exposure** refers to situations in which the exposure occurs repeatedly over a period of time that ranges between acute and chronic exposures (As toxicity values are less widely available for this duration, it is less routinely assessed than the others. For air toxics assessments, this exposure period is not commonly assessed.)

- **Acute exposure** refers to situations in which the exposure occurs over a short period of time (usually minutes, hours, or a day) and usually at relatively high concentrations. The averaging times commonly used to represent acute exposures concentrations (i.e., acute ECs) are a 24-hour average, a one-hour average, or a 15-minute average.

The EC values the assessor develops to represent acute and chronic exposures should match the assumptions built into the dose-response values that the assessor uses to characterize risk (see Chapter 12). For example, it would be inappropriate to compare a one-week average exposure concentration to a one-hour acute dose-response value. For chronic exposures, the scale of time-weighted averaging performed to develop the exposure estimate should be generally similar to that used in developing the dose-response value. For example, inhalation chronic RfCs are derived from studies involving regularly repeated exposures (e.g., six hours a day, five days a week in animal studies) over a chronic period. Thus, exposures occurring on a much lesser frequency (e.g., a several days a week on a handful of occasions during a couple of years), should not be averaged over the exposure period and compared to a chronic RfC. Such very infrequent exposures may be more appropriately assessed as separate shorter-term or sub-chronic exposures.

6.3.3.5 Evaluation of Uncertainty

This part of the analysis plan specifies the approach to be used to evaluate uncertainty in the exposure and risk estimates. Decision-makers will weigh the importance of the exposure (and resulting risk) estimates in the eventual decision in the context of the uncertainties inherent in these estimates. Assessment and presentation of uncertainty is discussed in Chapter 3.

6.3.3.6 Preparation of Documentation

This part of the analysis plan specifies the approach to be used to document all aspects of the risk assessment. For most individual air toxics risk assessments, the exposure assessment represents the majority of effort (and the majority of the documentation) and therefore may require the greatest amount of work. A comprehensive documentation of the methods, assumptions, and uncertainties associated with the exposure assessment is encouraged. Chapter 13 discusses documentation in greater detail.

6.3.4 Identification of the Exposed Population

This part of the analysis plan specifies the approach to be used to characterize the location and size of the populations of interest to the assessment. Additional information on population characteristics may assist in characterizing exposure, and in identifying sensitive sub-populations.

- **Population data**. In identifying and also characterizing a potentially exposed population, the U.S. Census Bureau (www.census.gov) is the primary source of population information (e.g., the most recent data on the US population is contained in the 2000 Census).

- **Sensitive sub-populations**. Human exposure and susceptibility and sensitivity to pollutant effects may vary with factors such as age, gender, intensity and amount of activity, time spent in microenvironments, diet, overall health, lifestyle, genetic factors, and the concentration of pollutant. The extent to which these factors are considered in the risk assessment depends on the purpose of the assessment as defined in the planning/scoping and problem formulation steps, available resources, uncertainties in the assessment, and data quality and quantity.

6.3.5 Identification of the Endpoints and Metrics

This part of the analysis plan specifies which human health endpoints will be evaluated in the risk assessment and the metrics by which they will be evaluated. For inhalation exposures, EPA generally evaluates individual cancer risk and noncancer hazard (see Chapter 12 for a more detailed discussion).

- Estimated individual cancer risk is generally expressed as a numerical probability that a person will develop cancer over the course of their lifetime as a result of the exposures under study.

- Noncancer effects are generally evaluated by comparing exposure concentrations to reference concentrations (RfCs), which are estimates (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime. Noncancer effects generally are assessed for both acute and chronic exposure times.

Risk is usually described as either the risk experienced by different individuals within a population or the risk experienced by groups of people. The former is called risk to an individual (or simply individual risk), and the latter is called risk to a population (or simply population risk). The difference between the two is that individual risk describes risk to one person at a time, while population risk generally describes the number of people in a population experiencing the same risk. Thus, in a city block containing 400 people with an estimated risk (calculated at the block internal point) of two in 10,000 (2×10^{-4}), one could describe the risk to each of the individual 400 people as "individual risk = 2×10^{-4}." Alternatively the population risk could be described as "400 people living at a risk of 2×10^{-4}." While this distinction may seem arbitrary, risk often varies substantially over the exposed population. The use of both types of risk estimates assists risk managers in balancing concerns of small numbers of highly exposed people and larger numbers of people with lower exposures.

It generally is preferable to present a range of risk estimates, particularly in higher-tier assessments. Distributions are often more useful than point estimates. However, since developing fully distributional estimates of risk is usually out of the scope of most risk assessments, a sense of the range of risks is usually provided by developing both central tendency and high end point estimates.

- **Central tendency** estimates are intended to give a characterization of risk for the typical individual in the population. This is usually either based on the arithmetic mean risk (average estimate) or the median risk (median estimate).

- **High end** estimates are intended to estimate the risk that is expected to occur in the upper range of the distribution (e.g., risk above about the 90th percentile of the population distribution).

Risk characterization is discussed in more detail in Chapter 13.

6.4 Data Quality in the Risk Assessment Process

All air toxics risk assessments involve some data collection (e.g., emissions inventories will be developed to support air quality modeling, and/or monitoring data will be collected). For data collection efforts, a central component to the analysis plan is data quality assurance. The credibility of the risk assessment depends in part on the quality of the data that it uses. EPA uses its Quality System to manage the quality of its environmental data collection, generation, and use. The EPA quality website (http://www.epa.gov/quality) is an excellent resource for quality-related information that assessors will want to become familiar with as they develop an analysis plan for a risk assessment project.

As part of its effort to develop an Agency-wide data quality program, EPA has developed a number of specific tools that have direct applicability in performing risk assessment projects, including:

- Data quality assessment;
- Systematic planning (and the Data Quality Objectives Process);
- Quality assurance project plans;
- Standard Operating Procedures;
- Technical Audits; and
- Verification and Validation.

The use of these tools will help in the development of enough high quality data to allow assessors to answer the assessment questions in a robust way. A brief discussion of each of these tools follows. More in-depth discussion of each of these tools can be found on EPA's Quality website.

- **Data Quality Assessment** helps assess the type, quantity, and quality of data. This assessment, in turn, helps to verify that assessors satisfy the planning objectives. A Quality Assurance Project Plan components and sample collection procedures help ensure that the data are suitable for its intended purpose. Data Quality Assessment is a five-step procedure for determining statistically whether or not a data set is suitable for its intended purpose. This assessment is a scientific and statistical evaluation of data to determine if it is of the type, quantity, and quality needed and may be performed either during a project to check the process of data collection or at the end of a project to check if objectives were met.

- **Systematic Planning** is necessary to define the type, quantity, and quality of data a decision maker needs before collecting or generating environmental data. The Data Quality Objectives Process is an example of a systematic planning process that assessors would use to translate a decision maker's aversion to decision error into a quantitative statement of data quality needed to support that decision. Data Quality Objectives are not required under EPA's quality system; however, EPA does require that a systematic planning process such as

the Data Quality Objectives Process be used for all EPA environmental data collection activities. EPA recommends using the Data Quality Objectives Process when decision-makers are using data to select between two opposing conditions, such as determining compliance with a standard.

- **Quality Assurance Project Plan (QAPP)** documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities. It integrates all the technical and quality aspects of the project in order to provide a "blueprint" for obtaining the type and quality of environmental data and information needed for a specific decision or use. *Note*: **All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP.**

- **Standard Operating Procedures** are written documents that describe, in great detail, the routine procedures to be followed for a specific operation, analysis, or action. Consistent use of an approved Standard Operating Procedure ensures conformance with organizational practices, reduced work effort, reduction in error occurrences, and improved data comparability, credibility, and defensibility. Standard operating procedures also serve as resources for training and for ready reference and documentation of proper procedures.

- **Technical audits** are systematic and objective examinations of a program or project to determine whether environmental data collection activities and related results comply with the project's QAPP and other planning documents, are implemented effectively, and are suitable to achieve its data quality goals. Technical audits are not management assessments nor are they data verification/validation processes, which occur during the assessment phase of the project. Technical audits include readiness reviews, technical systems audits, surveillance, and performance evaluations.

- **Data verification and validation** is used to evaluate whether data has been generated according to specifications, satisfy acceptance criteria, and are appropriate and consistent with their intended use. Data verification is a systematic process for evaluating performance and compliance of a set of data when compared to a set of standards to ascertain its completeness, correctness, and consistency using the methods and criteria defined in the project documentation. Data validation follows the data verification process and uses information from the project documentation to ascertain the usability of the data in light of its measurement quality objectives and to ensure that results obtained are scientifically defensible.

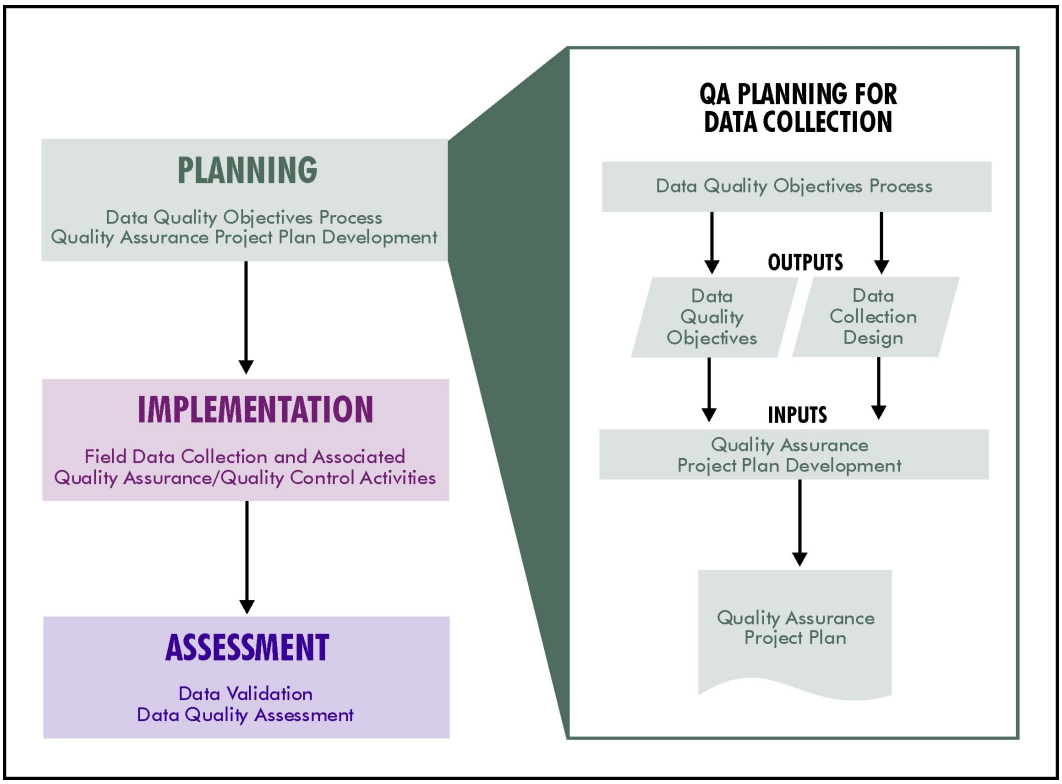
Quality Assurance is an integral part of data collection and analysis throughout the risk assessment project and the various activities addressed and documented in the QAPP cover the entire project life cycle, integrating elements of the planning, implementation, and assessment phases (Exhibit 6-11).

- **Planning**. The Data Quality Objectives (DQOs) are together a structured, systematic planning process that provides statements about the expectations and requirements of the data user (such as the decision maker).

- **Implementation**. The QAPP translates these requirements into measurement performance specifications and QA/QC procedures for the data suppliers to provide the information needed to satisfy the data user's needs.

- **Assessment**. The QAPP includes plans for data validation and data quality assessment.

Exhibit 6-11. QA Planning and the Data Life Cycle



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Chapter 7 Quantification of Exposure: Development of the Emissions Inventory for the Inhalation Risk Assessment

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7.1 Introduction

An emission inventory is a comprehensive listing, by source, of the air pollutant emissions within a specific geographic area in a specific time period. EPA prepares a **National Emissions Inventory (NEI)** with input from numerous state, local, and tribal (S/L/T) air agencies (see Chapter 4 and http://www.epa.gov/ttn/chief/net/index.html for more information on the NEI). NEI data are used for air quality modeling, regional strategy development, regulation setting, air toxics risk assessment, and tracking trends in emissions over time. The NEI Input Format (NIF) is the format most widely used by S/L/T agencies to transfer data to the NEI. The current versions of the NIF and all user documentation are available on the website noted above. The advantages, disadvantages, and uncertainties associated with NEI data are discussed in Chapter 4.

Emission inventories generally serve as the first step in quantifying exposure for an air toxics risk assessment. In addition to source information (e.g., location, chemicals released), they provide most of the critical input data for air quality models used to predict air toxics fate and transport in the atmosphere. The Emission Inventory Improvement Program (EIIP)[1] has published a ten-volume set of technical reports on the development of emissions inventories for the NEI.[2] Related technical documents, updates, reports, and information regarding the organization and progress of EIIP in developing new methods can be found linked to the main EIIP webpage. These include training manuals that provide in-depth descriptions of each step of the process, for various types of sources and air pollutants. Emissions inventories that are prepared in a manner consistent with these methods and guidance will provide data of known quality for a risk assessment.

For risk assessments, local enhancements of existing air toxics emissions inventories may be advantageous to a particular air toxics assessment effort as a very critical initial step. Air toxics inventories are not always at the quality that would provide the results desired in a modeling assessment, and improving the entire statewide toxics inventory may be unrealistic. An enhancement of the local air toxics inventory in the assessment area of interest may be beneficial for providing more accurate and precise risk assessment results and, consequently, a better basis for any air toxics risk- or airshed-program management decisions. Also, local emissions inventory work in specific areas of concern or study makes these air toxics efforts smaller and easier for agencies and participating facilities to manage and conduct, particularly in the shorter time frames commonly sought in local air toxics assessment projects.

The remainder of this chapter describes a process that can be used to develop an emissions inventory, including the general steps for developing an emissions inventory (Section 7.2), and data sources (Section 7.3)

7.2 Process for Developing an Emissions Inventory

There are eight steps for developing an emissions inventory:[3] (1) planning; (2) gathering information; (3) estimating emissions; (4) compiling data into a database; (5) data augmentation; (6) quality control/quality assurance; (7) documentation; and (8) access to data. Each is described in a separate subsection below.

The Emissions Inventory Improvement Program (EIIP)

To develop a systematic method for preparing an emission inventory, EPA's Emission Factor and Inventory Group (EFIG) has worked as a key member of the EIIP. The EIIP is a jointly sponsored effort of the State and Territorial Air Pollution Program Administrators/Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) and EPA. Both of these organizations are represented in the Standing Air Emissions Work Group (SAEWG), which endorsed the original EIIP plan. Funding is provided by S/L/T agencies through the Federal 105 grant programs. While EPA coordinates the EIIP efforts, all of the tasks are performed by working committees. The EIIP Steering Committee and technical committees are composed of S/L/T, industry, and EPA representatives. Membership on technical committees is open to any S/L/T agency representative, industry group, and the public; interested individuals can contact the appropriate committee co-chair for information.

7.2.1 Planning

Planning is the first stage in preparing an emissions inventory. Perhaps the most important activity in compiling an inventory, planning ensures a focused and streamlined process and avoids later costly and embarrassing mistakes. The Inventory Preparation Plan (IPP) is developed during the planning stage and is the overarching guidance document for the entire emission inventory development process.[4] First, the IPP identifies the end-use(s) of the inventory (e.g., to support a risk assessment) and subsequently, an acceptable data quality level for those uses. Once the end-use(s) are determined, the risk manager defines the inventory to be created, identifying the necessary components:

- The air toxics to be carried through the risk assessment (i.e., the COPCs);
- The specific sources or source categories to be assessed;
- The geographic area (scale) of the assessment area; and
- The time interval over which emissions are to be inventoried.

Generally, the IPP reflects the complexity of the risk assessment being conducted. That is, an assessment of a single stationary source with known pollutants and well-documented emissions would not require as elaborate a plan as would a risk assessment addressing multiple sources and source types affecting a broad community. Exhibit 7-1 lists the steps in developing an IPP.

Exhibit 7-1. Steps in Developing an Inventory Preparation Plan
• Identify the end-uses of the inventory • Determine Data Quality Objectives • Define the inventory to be created • Select an inventory data management and reporting system • Summarize data reporting and documentation • Establish QA/QC procedures • Determine staffing and resource requirements • Develop a schedule • Identify partners and develop a communication plan
Source: Pope, A. *Inventory Preparation for Toxics*.[3]

The level of precision for emissions data required may differ among different tiers of analysis. For example, screening-level risk assessments often incorporate conservative assumptions (e.g., all sources are co-located, all emissions are of the most toxic species of a particular chemical) in order to minimize the time and effort required to develop the emissions inventory. If the screening-level analysis indicates that there is a potential for a risk, then additional effort is made to characterize sources and emissions with greater precision. The IPP for a given risk assessment will identify the requisite level of precision for each potential tier of analysis.

7.2.2 Gathering Information

The next step in the development of an emission inventory is to gather the relevant information from existing sources. The information gathered should, at a minimum, include applicable pollutants, their sources, and emissions data (e.g., chemicals, emissions rates over time). If air quality modeling will be a part of the exposure assessment, the emissions inventory will need to include all of the source term data required by the model(s) to be used (e.g., latitude and longitude coordinates for each source, building size and shape for assessing downwash, chemical speciation).

A comprehensive information search may include guidance documents, existing emissions data, preliminary screening studies, emission factors, models, source characterization documents, and activity data references. A good starting point in this search is EPA's *Handbook for Air Toxics Emission Inventory Development*.[5]

7.2.3 Estimating Emissions

After gathering data from existing information sources, the analyst estimates the emissions to be reported in the inventory. There are two main approaches for estimating emissions: the top-down approach and the bottom-up approach.

- In the **top-down approach**, national- or regional data are allocated to a state or county based on a surrogate parameter such as population or employment in a specific sector. This approach typically is used for nonpoint sources when: (1) local data are not available, (2) the cost to gather local information is prohibitive, or (3) the end-use of the data does not justify the required cost. The top-down approach requires minimum resources, but at the expense of emissions accuracy.

- In the **bottom-up approach**, the inventory is developed from site-specific information on emissions sources, activity levels, and emission factors. This approach, typically used for point sources, requires more resources, but results in more accurate estimates than the top-down approach.

Exhibit 7-2 compares several methods for estimating point source emissions. Available methods for nonpoint sources include material balance, emissions factors, emissions estimation models (all listed in Exhibit 7-2), and surveys and questionnaires. Mobile source emissions estimates come from models, such as EPA's NONROAD[6] model for nonroad mobile sources (construction equipment, lawn mowers, airplanes, trains, and others) and MOBILE[7] for on-road mobile sources (automobiles, trucks). Section 7.3 below provides additional information on potential sources of emissions data.

Exhibit 7-2. Point Source Emission Estimation Methods		
Method	**Advantages**	**Disadvantages**
Continuous Emission Monitors (CEM)	• Measures actual emissions • Can be used to estimate emissions for different operating periods • Considered high quality data	• Often cost prohibitive
Source (Manual Stack) Testing	• Yields more accurate estimates than Emission Factors or Material Balance • Data can be used to develop emission factors • Data can be extrapolated to other representative (nonpoint) emission sources	• Cost prohibitive (especially if large number of pollutants to be tested) • Uncertainty issues due to representativeness of estimates over time • There may be no standardized testing reference methods
Material Balance	• Useful when other developed methods are not available or practical • Useful for sources resulting in evaporative losses	• Must have specific knowledge of all process parameters (amount of material entering and leaving the process, amount of material packaged as product itself)
Fuel Analysis	• Useful when other developed methods are not available or practical	• Estimates not as accurate due to inherent uncertainties in input parameters
Emission Estimation Models	• Useful for complex calculations	• Estimates not as accurate due to inherent uncertainties in input parameters
Emissions Factors	• Ease of availability	• Uncertain accuracy
Engineering Judgment	• Useful as a last resort when no other methods generate accurate emission estimates	• Estimates based on individual judgment and therefore not as defensible as more developed methods

Determining the best method for estimating emissions requires a trade-off between cost and the accuracy of results obtained. When estimating emissions, it is important to consider:

- Intended end-use of the inventory (as described in the IPP);
- Availability of data of the specified quality (preliminary screening can be helpful here);
- Practicality of the method for the specific source category;
- Source category priority; and
- Resources (time, staffing, funding) available to prepare the inventory.

The Emissions Inventory Improvement Program (EIIP) series of documents provides further guidance in choosing the most appropriate method for the specific inventory's needs.[1]

7.2.3.1 Direct Measurement

Direct measurement of source-specific emission rates is relatively infrequent except for certain permitted facilities with specific monitoring requirements written into their permits. For example, source monitoring is typically available for large point source releases at facilities covered under the Title IV emissions tracking system associated with the acid rain control program. Various state and local permitting programs that may also require intermittent or continuous monitoring, depending on the nature of the process.

In some instances, source testing is required as part of the process of obtaining a permit. For example, a hazardous waste incinerator must do stack testing during trial burns to ensure that the incineration units and air pollution control equipment meet the limits established in the permit before full operation is allowed to begin. Subsequent to full operation, the facility will usually be required to perform continuous monitoring of stack emissions to ensure continued compliance.

EPA's **Emission Measurement Center (EMC)** provides linkages to available source monitoring methodologies in five general categories (Exhibit 7-3).

7.2.3.2 Emission Estimation Models

Specific emission measurements are generally the best and most accurate method to quantify emissions; however, source data are not always available and/or practical to obtain. As an alternative, emission estimation software and accompanying models may be used to generate emissions data. Emission estimation models are used when a large number of complex calculations must be undertaken in order to estimate a given emission or when a combination of parameters has been identified that affect emissions but individually do not provide a direct correlation. EPA provides a variety of approved models that can be used to determine point, nonpoint, and mobile source emissions based on a variety of known input parameters. Some of these emission estimation models are discussed below.

CHEMDAT8

CHEMDAT8 is a Lotus®1-2-3 spreadsheet prepared by EPA's Emissions Standards Division that includes analytical models for estimating VOCs from treatment, storage, and disposal facility processes. The models cover releases from disposal impoundments, closed landfills, land treatment facilities, and aeration and nonaeration impoundment processes. Additional information is available for download from the CHIEF software index website at: http://www.epa.gov/ttn/chief/software/index.html.

Exhibit 7-3. Categories of Source Monitoring Methodologies
EPA has established the EMC (http://www.epa.gov/ttn/emc/tmethods.html), as part of its Technology Transfer Network, which is a collection of technical internet sites containing information about many areas of air pollution science, technology, regulation, measurement, and prevention. The EMC identifies five general categories of source monitoring methods: • **Category A: Methods Proposed or Promulgated in the Federal Register**. These methods have been proposed or promulgated in the Federal Register and codified in the Code of Federal Regulations (CFR). • **Category B: Source Category Approved Alternative Methods**. These methods are approved alternatives to the methods required by 40 CFR Parts 60, 61, and 63 as described by the General Provisions of the corresponding Parts. • **Category C: Conditional Methods**. EPA has evaluated these methods, and they may be applicable to one or more categories of stationary sources. EPA confidence for these methods is based upon review of various technical information including, but not limited to, field and laboratory validation studies, EPA understanding of the most significant quality assurance (QA) and quality control (QC) issues, and EPA confirmation that the method addresses these QA/QC issues sufficiently to identify when the method may not be acquiring representative data. The method's QA/QC procedures are required as a condition of applicability. • **Category D: Preliminary Methods**. The performance of these methods is not as well defined as that of the conditional methods of Category C. EPA is providing these as they may be useful in limited applications until more supporting information is available (i.e., can be '"gap filling'" methods). EPA expects the methods to work under the conditions of the applicability statement but is uncertain of the methods' applicability without additional data on broader application. EPA encourages submission of data to support broader applicability. • **Category E: "Idea box."** The idea box includes method concepts intended to promote information exchange only, and the concepts may not be used by sources to fulfill Federal requirements. These technical ideas have been provided to EPA for posting on the EMC web site. Concepts in the idea box generally have had little or no EPA review or analysis and are not technically supported by EPA. However, information that resides here may be considered for further assessment by EPA and non-EPA entities for the purposes of method development for placement into higher categories.

WATER9

WATER9 is a Windows-based computer program available for estimating air emissions of individual waste constituents in wastewater collection, storage, treatment, and disposal facilities. It also contains a database listing many of the organic compounds and describes procedures for obtaining reports of constituent fates, including air emissions and treatment effectiveness. WATER9 is a significant upgrade of features previously contained in WATER8, CHEM9 (a compound properties processor that can estimate compound properties that are not found in EPA's database of over 1000 compounds), and CHEMDAT8, and contains a set of models that can provide a holistic picture of emissions from a facility. The models produce emission estimates for each individual compound that is identified as a constituent of the wastes leaving

the facility based on the physical/chemical properties of the compound and its concentration in the wastes. Therefore, the analyst should be able to identify the constituent compounds and provide their respective concentrations. WATER9 has the ability to use site-specific compound property information and the ability to estimate missing compound property values. Estimates of the total air emissions from the wastes are obtained by summing the estimates for individual compounds. Program software may be downloaded from http://www.epa.gov/ttn/chief/software/water/index.html.

Landfill Gas Emissions Model v2.01

The Landfill Gas Emissions Model is a program specifically designed for use by state and local regulatory agencies to monitor the air emissions from landfills. The system allows the user to enter specific information regarding the characteristics and capacity of a landfill and to project the emissions of methane, carbon monoxide, nonmethane organic compounds, and individual HAPs over time using the Scholl Canyon decay model for landfill gas production estimation. The Scholl Canyon Model is a first-order decay equation that uses site-specific characteristics for estimating the gas generation rate. In the absence of site-specific data, the program provides default values for regulatory uses of the model and provides default values drawn from EPA's *Compilation of Air Pollutant Emission Factors* (AP-42) for inventory uses. For additional information, contact EPA's Air Pollution Prevention and Control Division, Office of Research and Development at (919) 541-2709. Program software may be downloaded from http://www.epa.gov/ttn/chief/software/index.html.

TANKS

TANKS is a Windows-based computer software program that estimates emissions of volatile organic compounds (VOCs) and hazardous air pollutants (HAPs) from fixed- and floating-roof storage tanks and is designed for use by S/L/T and Federal agencies, environmental consultants, and others who need to calculate air pollutant emissions from organic liquid storage tanks. The calculations are performed according to estimation procedures outlined in EPA's *Compilation of Air Pollutant Emission Factors* (AP-42). The user provides specific information concerning the storage tank and its contents, and the program then estimates annual or seasonal emissions and produces a report. The tank contents can consist of single or multiple liquid components. The program may be downloaded from http://www.epa.gov/ttn/chief/software/tanks/index.html.

MOBILE6 Vehicle Emission Modeling Software

MOBILE6 is an emission factor model for predicting gram per mile emissions of hydrocarbons (HC), carbon monoxide (CO), nitrogen oxides (NO_x), carbon dioxide (CO_2), particulate matter (PM_{10} and $PM_{2.5}$), and other toxics from cars, trucks, and motorcycles under various onroad conditions. The program is available for download from http://www.epa.gov/otaq/m6.htm.

NONROAD Model

The Draft NONROAD Model is a Windows-based software program intended for use by professional mobile source modelers for their use in estimating emissions specifically for emissions inventory development. The model is still in draft form, so EPA warns that some

emission rates and activity levels predicted from NONROAD may substantially change in future versions. The program is available for download from http://www.epa.gov/otaq/nonrdmdl.htm.

Please note that EPA's Office of Transportation and Air Quality is currently developing a new modeling system, Multi-scale mOtor Vehicles and equipment Emission System (MOVES) that will replace the existing MOBILE6 and NONROAD models. This new system will estimate emissions for onroad and nonroad sources, cover a broad range of pollutants, and allow multiple scale analysis, from fine-scale analysis to national inventory estimation. For further information on MOVES, visit http://www.epa.gov/otaq/ngm.htm.

7.2.3.3 Emission Factors

Emission factors are constants that assessors can use to relate release rates to the amount of specific activities that occur at a source. An emission factor is typically represented as a mass of chemical released per unit of activity. For example, releases from a coal burning combustion device are represented as pounds of pollutant emitted per BTU coal burned. Depending on the emission source, there may be a lot of emissions testing data, just one or two measurements (the usual case), or none. For a screening-level assessment it may be possible to obtain an estimate of maximum emissions in one of several ways.

- If sufficient data are available, the assessment could use the highest available value.
- If only one or two measurements are available, the assessment could assume that all the emissions occur in a short period of time (such as only for 8 hours a day) and/or assume that all sources of emissions are co-located.
- If no data are available, the assessor may need to rely on professional judgment based on similar types of sources.

Certain types of sources (e.g., incinerators) typically undergo various test or trial "burns" to establish emissions factors pursuant to RCRA permitting requirements. Data to support the development of emissions factors also may be collected to support compliance with maximum achievable control technology (MACT) standards or Toxics Substances Control Act (TSCA) permitting. For stable and well established processes, the emission factors are usually reliable estimates. However, for sources that are subject to different operational conditions, with limited testing, the emission factors may represent an estimate of a higher or lower release rate.

Frequently, emission factors contain an associated confidence level by species, which assists in determining the appropriate emission factor. Thus, the use of the emission factor for any specific source may over- or under-predict actual release rates. In some cases, accurate measurements of the activity rates are not available and estimates of activity rates can also contribute uncertainty to the release rate estimate for any particular source type. An example is for individual motor vehicles; this source model estimates an average emission factor for a fleet of vehicles in a particular location. Modeling approaches for traffic activity estimate the total amount of miles driven by vehicle class. Finally, multiplying the emissions factor by the number of vehicle-miles driven produces the total emissions. Thus, any individual motor vehicle may have a release rate significantly far removed from the average, but when averaged across the fleet, the release rate provides a more reliable estimate.

EPA suggests emission factors for criteria pollutants and HAPs in its national database, Factor Information Retrieval System (FIRE), which includes emission factors from EPA documents (such as *Compilation of Air Pollutant Emission Factors* (AP-42) and the *Locating and Estimating Air Emission* series) factors derived from state-reported test data, and factors taken from literature searches. FIRE is available for download at http://www.epa.gov/ttn/chief/software/fire/.

7.2.3.4 Mass Balance

Assessors can use the mass balance approach in complex processes in which a known amount of air toxics material is introduced to a process, and at the end of the process, a known amount of air toxics material is still retained in the final product. The difference between the two represents the production release. Engineering estimates can then suggest into what medium the process released the air toxic (e.g., to air or water, or as solid waste).

As an example, consider the use of a VOC as a carrier medium for a solid (e.g., paint particles). In this surface coating situation, the organic solvent that suspends the solids makes application of the coating possible. Once the mixture is exposed to the air, the solvent evaporates, leaving the solid coating film on the object. Mass balance techniques in this type of application may assume that 100 percent of the solvent is released to the air through evaporation. Other mass balance estimates may assume that some stable amount of the solvent is retained in the product that is shipped to customers. Mass balance estimates also may need to consider how much of the solvent is recycled at various stages in its life-cycle.

7.2.3.5 Engineering Judgment

With engineering judgment, users can estimate emission releases through engineering and operational observations about a process. For example, if a certain process must be operated at a set temperature and pressure to achieve the ideal result, engineers who understand the history of the process can often estimate how the release rate actually varies under changing operational conditions. Engineering judgment is a less desirable approach for estimating releases than actual measurements; however, it is often used because of a lack of any better information or options (e.g., it may not be possible to measure all fugitive leaks at a large facility with thousands of joints and valves).

7.2.4 Compiling Data Into a Database

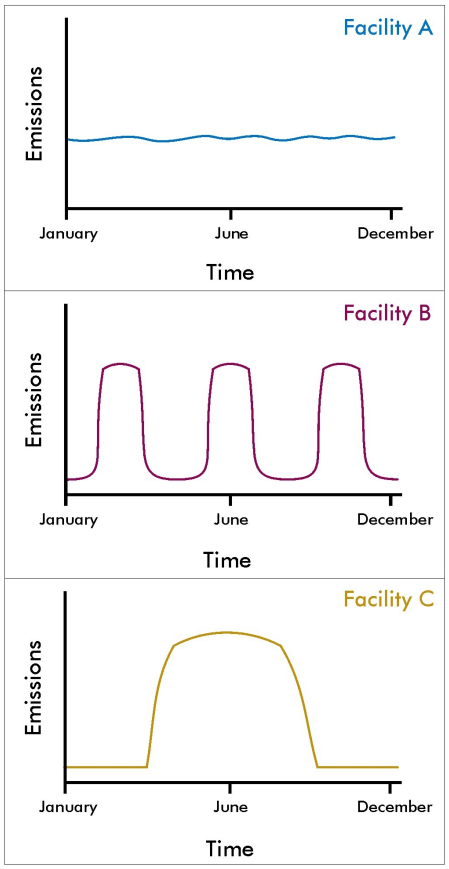
After estimating the applicable emissions from each source, the analyst compiles the data into the inventory database, based on the data management system delineated in the Inventory Preparation Plan. Three elements of data compilation are of note for a risk assessment: selection of production rates; unusual conditions; and how emissions are quantified for risk assessment purposes. Each is discussed in a separate subsection below.

7.2.4.1 Selection of Production Rates

The variability in a source's emissions rate can make it difficult to arrive at a single source-specific emissions level. Prior to collecting or reviewing data in support of a risk assessment, assessors will need to decide whether to use release data that reflects either annual average

emissions or "worst-case" operating conditions (or both). In some limited cases, it may be possible to obtain data on daily and seasonal variable emissions, although this is not common. Likewise, information on both the actual release rates and maximum permitted or allowable release or potential emission rate may be available. In addition to information on annual releases, a description of the release pattern over the year (see examples in Exhibit 7-4) and during the weeks of operation will be useful in characterizing the resultant ambient air concentrations over the exposure duration (e.g., is release occurring around-the-clock or only during the work week?).

Exhibit 7-4. Examples of Variable Patterns of Emissions



Emissions patterns may vary over time. In this hypothetical example, Facility A's emissions occur at a fairly constant rate. In contrast, Facility B's emissions levels fluctuate with spikes in their emissions evident at different times of the year. Facility C's emissions occur only during a specific part of the year.

Information on variability in operating conditions and the factors or conditions influencing that variability will be useful. This will assist in the selection of the release data for the scenario of interest in the assessment. For example, if the assessment is evaluating what may be released under current permit conditions, it may be appropriate to use release rate data corresponding to the maximum permitted release rate, regardless of reported actual rates. This method is best-suited for screening-level analyses, where the objective is to conduct a risk assessment for the purposes of screening out sources that pose negligible risk while efficiently conserving available resources (i.e., time and money), which may be needed for a more refined analysis of the remaining sources. However, use of reported release data (e.g., annual estimates) may be more appropriate for refined analyses of facilities with well-defined production capabilities and limited

operational variability. Note that more detailed information on variability may be needed for analysis of air concentrations (and resultant exposures) over shorter periods (e.g., acute analysis).

7.2.4.2 Unusual Conditions: Process Upsets, Accidental Releases, and Maintenance

Release characteristics frequently differ during atypical operations. Process upsets often result in the venting of large amounts of raw materials, intermediate products, finished products, or wastes to the air. Sources often flare organic releases during process upsets (i.e., burned as the chemicals are being released to the air) to reduce the mass of potentially toxic compounds, which can result in releases of particulate matter or other chemicals as a result of incomplete combustion. Shutting down and starting up processing equipment results in a period of time when the process is operating at less than ideal conditions, and release rates can change significantly during these shut down and start up procedures. Accidental releases associated with truck accidents, train derailments, or chemical spills from shipping operations can also cause significant releases that affect a local area for a short period of time.

Many operating permits require sources to report periods of process upset and maintenance activities, although assessors may not estimate release rates during these periods because measurement data are often unavailable. Local emergency authorities often possess information on accidental releases from trucking accidents and train derailments. These reports may be useful to provide modeling input data in subsequent acute risk assessment activities. Risk assessors can contact local HazMat Teams, and state or federal emergency response personnel to gather available information on accidental and upset releases. This type of information could be quite useful in local episodic acute risk analysis,[(a)] but may not be included in long-term risk evaluations.

Another source of startup/shutdown/malfunction data may be available in state/local/tribal permit files for the facilities. Specifically, many permitted facilities must file routine reports in which the provide information on spills, excursions, and other unusual circumstances where non-routine releases occur.

7.2.4.3 Quantifying Emissions for the Risk Assessment

Once the assessor has compiled the above information about the source in question, he or she would quantify the emission rate as the amount of pollutant released per unit of time. Most air toxics releases are expressed as tons of pollutants released per year in emissions inventories. However, as noted above, a yearly value may not provide the level of information required to evaluate the risk assessment questions, and more detailed information may be necessary. For example, are there seasonal fluctuations in emissions? Are the releases continuous around-the-clock, seven days a week, or more intermittent with a different schedule? The particular air dispersion model may require that emission rates be expressed in different units (e.g., pounds per

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[a]EPA's Chemical Emergency Preparedness and Prevention Program web page describes the development of emergency management plans relying on such acute risk analysis to assist in the response to accidental releases: http://yosemite.epa.gov/oswer/ceppoweb.nsf/content/RMPoverview.htm

Process Upset and Accidental Release Information Sources

The **National Response Center (NRC)** has an on-line query system that provides access to all non-Privacy Act data collected by the NRC since 1990. This information may be accessed at http://www.nrc.uscg.mil/foia.html.

The U.S. Chemical Safety and Hazard Investigation Board maintains a database of **Incident News Reports**, which may contain information on process upsets and accidental releases. The Incident News Reports database is available at http://www.chemsafety.gov/circ/.

RMP*Info is a national database that provides information on risk management plans (RMPs). Each RMP contains a hazard assessment that includes an accident history covering the facility's previous five years of operation. This information can be obtained by submitting a written request for the RMP database (without the Offsite Consequence Analysis data) to the RMP Reporting Center, P.O. Box 1515, Lanham-Seabrook, Maryland 20703-1515.

hour, grams per second). The NEI contains emission estimates of HAPs for periods of a year or less. Risk assessors generally consult the emission period table in the NEI and use the emission type field to determine the period for which emissions are reported. The EPA summarizes NEI data in summary files to annual emissions, but more detail on the reporting period is available in the NEI. The NEI also contains emissions estimates for actual, allowable, potential, and maximum emissions for the same emission release points.

7.2.5 Data Augmentation

If previous efforts at estimating emissions fail to obtain data to assemble an emissions inventory of sufficient quality or to provide the necessary inputs for an emissions model, the next step would be data augmentation. The analyst first identifies any missing information, most notably emission data, vent parameters, and location coordinates.

- **Emissions data**. When developing emission inventories for nonpoint sources, analysts sometimes find that no direct measure of activity exists at the local level. In cases where this occurs, national, regional, or state-level emission estimates already in existence may be allocated to the local level (i.e., a top-down approach). This practice is know as **spatial allocation** and is a common form of data augmentation. Similarly, emissions can be temporally allocated to the time period required by an emissions model. Other suggestions for filling emission data gaps include:
  - Additional searches of databases to identify appropriate surrogate data;
  - Extrapolation of emissions from other geographic areas; and
  - Estimation of emissions data from past inventories within the same geographic area.

- **Vent parameters**. Common vent parameters required for air quality modeling include height, diameter, temperature, exit velocity, and flow rate. If measures for any of these parameters are missing or incomplete, the NEI provides default lookup tables generated from Source Category Classification (SCC) and Standard Industrial Classification (SIC) codes.

  SCC codes serve as a primary identifying data element in the NEI (as well as other EPA databases) and many S/L/T agency emissions data systems. These codes are assigned to

specific release points within a facility based on the process to which the release point is linked and on various characteristics of the release point. A complete listing of SCC codes along with additional background information is available from EPA.[8]

SIC codes are numerical codes developed by the U.S. government as a means of consistently classifying the primary business of business establishments. A list of the industry groups that are required to report to the Toxics Release Inventory (TRI) is provided in Chapter 4 and also can be found at http://www.epa.gov/tri/report/siccode.htm.

For facilities that are regulated pursuant to a National Emissions Standard for Hazardous Air Pollutants (NESHAP), the MACT codes, based on the MACT source category into which a specific process falls, may provide additional information about the nature of the business, primary production processes, or activities related to the release of air pollutants.

If no SCC or SIC code is available for the emission source in question, the analyst may use the national default values for each parameter (see Exhibit 7-5).

Exhibit 7-5. National Vent Parameter Default Values

Parameter	Default Value
Height	10 ft.
Diameter	1 ft.
Temperature	72° F
Velocity	15 ft./sec.
Flow Rate	12 $ft.^3$/sec.

Source: Pope, A. *Inventory Preparation for Toxics*.[3]

- **Location coordinates** may be identified from the NEI (stationary sources) or topographic maps (discussed in Chapter 6).

7.2.6 Quality Assurance/Quality Control

Quality assurance and quality control (QA/QC) procedures are vital to the validity of the emissions inventory and ensure that the modeling input parameters derived from the inventory are of specified quality. The quality assurance plan (QAP) for the emissions inventory is usually a part of the quality assurance project plan (QAPP) for the overall risk assessment that is developed during problem formulation (see Chapter 6). The QAP documents the procedures of the QA/QC elements of the emissions inventory. Quality control measures include:

- Technical reviews;
- Use of approved standardized procedures for emissions calculations;
- Data verification procedures;
- Completeness checks;
- Consistency checks;
- Accuracy checks; and
- Reasonableness tests.

To the extent practicable, risk assessors have emissions data verified by external review and audit procedures conducted by a third party. Exhibit 7-6 identifies the typical errors that occur in developing an emissions inventory.

Exhibit 7-6. Typical Errors in Developing an Emission Inventory		
Facility Errors • Missing facilities • Duplicate facilities • Closed facilities • Improper facility locations	**Data Errors** • Missing operating or technical data • Erroneous technical data • Errors in calculations • Data entry and transposition errors • Data coding errors • Failure to identify all HAPs	**Double-counting Errors** • Overlap between point and nonpoint sources • Overlap between nonpoint source categories

7.2.7 Documentation

Documentation is the next step in developing an emission inventory. The key documents to be compiled into a final written report include:

- Inventory Preparation Plan (IPP);
- Quality Assurance Plan (QAP);
- Methods;
- Assumptions;
- Raw data (database); and
- Calculations.

7.2.8 Access to Data

The risk manager generally ensures appropriate access to the data compiled in the emission inventory. A key part of the planning and scoping process for the risk assessment is determining who needs access to the emissions data and how they will access the data. If it is necessary to report the results of the emission inventory to the EPA as part of a S/L/T agency's responsibilities under the Consolidated Emission Reporting Rule, data preparation and submission procedures prepared by EPA for HAP data should be followed.

7.3 Data Sources

The two data sources for emissions inventory information that are most applicable to air toxics risk assessments are S/L/T agencies and the NEI. The TRI can provide some helpful information about the types of emissions from sources, but TRI data have not been collected to support air toxics risk assessments and therefore may be of limited value. The following subsections describe several other sources of information that may provide information to assist in developing an emissions inventory for the risk assessment.

7.3.1 Permit Files

Most stationary sources (especially large sources) are subject to one or more emissions limitation standards to control criteria emissions and/or HAP emissions. These sources are usually subject to a Title V operating permit that will include all of the operating and emissions limit requirements subject to that facility. In addition, they may be subject to additional S/L/T regulations. Operating permits require routine reporting to confirm that the operating conditions and emission limits are being met. Frequently, these reports are based on some kind of monitoring information that is directly related to the release process(es). In most cases, actual release rates are reported. Therefore, permit compliance reports represent an excellent source of information that will provide the actual release rate directly through continuous emissions monitoring, or they will provide sufficient information to estimate the release rates with a fairly high level of reliability.

Unfortunately, using the permit compliance system is not always an attractive source for data on release rates that are suitable for risk assessment activities. EPA does not maintain a central database of Title V permit or compliance information. Therefore, gathering data from the permit program can be a time-consuming task if many sources are needed for the risk analysis. The reports will also be represented in terms that match the requirements of the permit (e.g., if the permit conditions specify an annual release limit, release rates may be presented as an annual average; if the permit conditions specifies a maximum release rate for any hour, then the compliance report will document the maximum hourly rate observed at the facility). Therefore, some adjustments and assumptions may be necessary. In addition, the permit compliance report will only include the specific pollutants named in the regulations to which the permit applies. For example, for NESHAPs that are applicable to the source, only HAPs specifically listed in the rule may be included on the permit; other HAPs may also be emitted which are not required to be reported. Additionally, not all important HAP sources are required to have a Title V permit, and even small annual release rates of certain highly toxic HAPs may post significant risk.

In general, EPA has made an effort to include permit data in the NEI database (via data submissions from S/L/T offices) where appropriate and has taken steps to review the data. In many cases, it may be more reasonable to consult the NEI prior to attempting to gather release rates directly from permit files.

7.3.2 Regional Inventories

Several regional organizations provide emission data specific to their geographic area of concern. For example, the Great Lakes Commission (a partnership among EPA, the eight Great Lakes states, and the province of Ontario, Canada), with funding from EPA and the Great Lakes Protection Fund, have developed the Regional Air Pollutant Inventory Development System (RAPIDS). This ongoing initiative seeks to provide researchers and policy makers with detailed, basin-wide data on the source and emission levels of toxic contaminants. Originally focused on 49 toxic air pollutants, the inventory database has been expanded to include 82 toxic air pollutants which have been identified as significant contributors to the contamination of the Great Lakes. RAPIDS uses the FIRE database to estimate emissions for both point and nonpoint sources. The software may be downloaded from http://www.glc.org/air/rapids/.

Additionally, EPA provides funding to five regional planning organizations throughout the U.S. to address regional haze and visibility impairment issues. These organizations exist to evaluate technical information to better understand how their states and tribes impact national park and wilderness areas (Class I areas under the CAA) across the country and to then pursue the development of regional strategies to reduce emissions of particulate matter and other pollutants contributing to regional haze. To this end, each regional planning organization assesses its member states' emission inventories, and some provide funding through EPA for the development of regional emission inventories. Information regarding regional emission inventorying activities may be found at the organizations' respective websites as listed below:

- Central Regional Air Planning Assocation (CENRAP) – http://www.cenrap.org/
- Western Regional Air Partnership (WRAP) – http://www.wrapair.org/
- Midwest Regional Planning Organization (Midwest RPO) – http://64.27.125.175/
- Mid-Atlantic/Northeast Visibility Union (MANE - VU) – http://www.manevu.org/index.htm
- Visibility Improvement State and Tribal Association of the Southeast (VISTAS) – http://www.vistas-sesarm.org/

7.3.3 Industry Profiles

To help assessors understand the nature of releases from sources, EPA has compiled a variety of guidance documents and information resources that explain how various industries operate and the types and locations of emissions that commonly are associated with their processes. Two key groups of these documents are the "Sector Notebooks" and the TRI Facility Specific profile.

The sector notebooks are a series of profiles or notebooks containing information on selected major industries. These notebooks, which focus on key indicators that holistically present air, water, and land pollutant release data, have been thoroughly reviewed by experts from both inside and outside EPA. Each notebook provides:

- A comprehensive environmental profile;
- Industrial process information;
- Pollution prevention techniques;
- Pollutant release data;
- Regulatory requirements;
- Compliance/enforcement data;
- History government and industry partnerships;
- Innovative programs contact names;
- Bibliographic references; and
- Description of research methodology.

The notebooks cover a wide variety of activities, including:

- Agricultural chemical, pesticide and fertilizer industry;
- Dry cleaning industry;
- Ground transportation industry;
- Inorganic chemicals industry;
- Fossil fuel electric power generation industry;
- Metal fabrication industry; and

- Organic chemical industry.

Regarding TRI resources, the TRI website provides a number of very industry-specific and chemical-specific guidance documents that were developed to help stakeholders understand the nature of major industrial process and how emissions may occur from those processes (see http://www.epa.gov/tri/guide_docs/index.htm#industry_sp). Example titles include:

- Presswood and Laminated Products Industry;
- Coal Mining Facilities;
- Electricity Generating Facilities;
- Petroleum Terminals and Bulk Storage Facilities;
- Rubber and Plastics Manufacturing;
- Printing, Publishing, and Packaging Industry;
- Textile Processing Industry;
- Leather Tanning and Finishing Industry; and
- Semiconductor Industry.

Assessors can take advantage of these materials to help them better understand the nature of potential risk posed by facilities on local populations.

7.3.4 AP-42 Emissions Factors

Emission factors and emission inventories have long been fundamental tools for air quality modeling. The Emission Factor and Inventory Group (EFIG) in EPA's Office of Air Quality Planning and Standards (OAQPS) develops and maintains emission estimating tools. The AP-42 series is the principal means by which EFIG can document its emission factors. It is available from EPA online.[9] These factors are cited in numerous other EPA publications and electronic databases, but without the process details and supporting reference material provided in AP-42. Information about emission factors for mobile sources can be found on EPA's Office of Transportation and Air Quality website (http://www.epa.gov/otaq/).

So just what is an AP-42 Emission Factor? It is a representative value that attempts to relate the quantity of a pollutant released to the atmosphere with an activity associated with the release of that pollutant. These factors are usually expressed as the weight of pollutant divided by a unit weight, volume, distance, or duration of the activity emitting the pollutant (e.g., kilograms of particulate emitted per megagram of coal burned). Such factors facilitate estimation of emissions from various sources of air pollution. In most cases, these factors are simply averages of all available data of acceptable quality and are generally assumed to be representative of long-term averages for all facilities in the source category (i.e., a population average).

7.3.5 Factor Information Retrieval System

The Factor Information Retrieval (FIRE) Data System is a database containing EPA's recommended release rate estimation factors for criteria and hazardous air pollutants. FIRE 6.24 (released March 2004) is a Windows-based program. Users can browse through records in the database or select specific emission factors by source category, source classification code (SCC), pollutant name, chemical CAS number, or control device. FIRE 6.24 contains emission factors from the Compilation of Air Pollutant Emission Factors (AP-42 Fifth Edition) through March

2004, the Locating and Estimating (L&E) series of documents, and the retired AIRS/Facility Subsystem Emission Factors (AFSEF) and Air Toxic Emission Factor Database Management System (XATEF) documents. FIRE can be accessed at: http://www.epa.gov/ttn/chief/software/fire/index.html.

7.3.6 Locating and Estimating Documents

This report series characterizes some of the source categories for which releases of a toxic substance have been identified. These volumes include general descriptions of the emitting processes, identifying potential release points and emission factors. Some of the locating and estimating documents were prepared as early as 1984 and the information may be dated. Others have been developed since 1994 and will provide more up-to-date information (see http://www.epa.gov/ttn/chief/le/index.html). EPA does not maintain L&Es and has not published new L&Es since the mid 1990s.

7.3.7 RCRAInfo

RCRAInfo is EPA's comprehensive information system providing access to data supporting the Resource Conservation and Recovery Act (RCRA) of 1976 and the Hazardous and Solid Waste Amendments (HSWA) of 1984. The RCRA law is the primary statute under which EPA monitors and regulates the management of nonhazardous and hazardous solid waste by entities that produce, store, treat, transport, or otherwise manage such wastes (all of which are potential sources of air toxics emissions in a community). This RCRAInfo replaces the data recording and reporting abilities of the Resource Conservation and Recovery Information System (RCRIS) and the Biennial Reporting System (BRS).[10]

RCRIS was the national program management and inventory system of facilities that handle RCRA hazardous waste.[11] Facilities fit one or more of the following categories: treatment, storage, and disposal facilities (TSDFs); large quantity generators (LQGs); small quantity generator (SQGs); and transporters. RCRIS contains the following information:

- General information on all handlers (e.g., name, address, activity type);
- Permitting and corrective action program status, and Standard Industrial Classification (SIC) code information for TSDFs only; and
- Enforcement and compliance actions for specific facilities, regardless of type, which have been subject to inspections or other enforcement activity.

States and regions populated RCRIS with data necessary for their program implementation. Those portions of the data that were relevant for national program oversight and management were contained in a RCRIS national database.

The **BRS** was the national system that collected data on the generation, management, and minimization of hazardous waste. BRS captured detailed data on the generation of hazardous waste from large quantity generators and data on waste management practices from treatment, storage, and disposal facilities. These data were collected every other year, providing the ability to perform trend analyses. The data were reported by the facilities to EPA on even years regarding the hazardous waste activities of the previous year. EPA produced a report on hazardous waste generation and management activity that included the data files. The BRS can

be queried to identify facilities treating hazardous wastes with technologies that may generate air toxics emissions. BRS reports are available from EPA through 2003.[12]

RCRAInfo data is made available to the public through EPA's Envirofacts Data Warehouse[13] through monthly extracts or through the Right to Know Network.[14] The same files that are provided to Envirofacts and the Right to Know Network are also available for downloading from EPA's publically accessible FTP server.[b]

The RCRAInfo system that is replacing the RCRIS and the BRS allows tracking of many types of information about the regulated universe of RCRA hazardous waste handlers. RCRAInfo characterizes facility status, regulated activities, and compliance histories and captures detailed data on the generation of hazardous waste from large quantity generators and on waste management practices from treatment, storage, and disposal facilities. Although the BRS does not contain emissions monitoring data, it does identify hazardous waste constituents, quantities managed, and other facility information. For example, the RCRA files include trial burn data for hazardous waste incinerators, certification of compliance test data, and facility plot plans, all of which could be useful in risk assessments of air toxics.

7.3.8 Emissions and Dispersion Modeling System (EDMS)

For aircraft emissions, the Federal Aviation Administration has developed an emission estimation method model, Emissions and Dispersion Modeling System (EDMS), Version 4.0.[15] This model can be applied to specific airports and used to develop air toxics emissions for both commercial and general aviation emissions. The primary basis for estimating emissions is based on landing and take off data available from FAA's airport activity statistics database. EDMS includes emissions and dispersion calculations, the latest aircraft engine emission factors from the International Civil Aviation Organization (ICAO) Engine Exhaust Emissions Data Bank, vehicle emission factors from EPA's MOBILE5a, and EPA-validated dispersion algorithms.

7.3.9 Summary

Exhibit 7-7 lists the different data sources that provide information on air toxics emissions that are being used or can be adapted for air toxics risk assessments.

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[b]The server is available at: ftp://ftp.epa.gov/rcrainfodata/brfiles/. A comprehensive web-enabled help module (RCRAInfo_Flat_File_WebHelp.zip) is also available to explain the flat file specifications and data element values (see ftp://ftp.epa.gov/rcrainfodata/rcra_flatfiles/).

Exhibit 7-7 Summary of Emissions Inventory and Related Information				
Data Source	**Maintained By**	**Sectors Covered**	**Comments**	**Address**
S/L/T Inventories	Individual S/L/T agencies	Large point sources; nonpoint sources; mobile sources from selected S/L/T agencies; coverage is variable	Many S/L/T agencies have specific information collected for special studies; attempts have been made to include most of the S/L/T-level data into the NEI, but higher resolution data may be available	Various S/L/T-specific and other web pages http://www.cleanairworld.org/
National Emissions Inventory (NEI)	U.S. EPA	Point sources; nonpoint sources; on-road and nonroad mobile sources	Point sources are reported for individual release points (includes other modeling data); nonpoint and mobile sources are reported at the county level	http://www.epa.gov/ttn/chief/net/index.html
Title V Permit Conditions	States/EPA	Large stationary point sources and limited coverage of nonpoint sources; only HAPs greater or equal to 10 tons/25 tons per year covered	Source-specific operating conditions to achieve permitted emissions levels; actual emissions reported for compliance in many cases; includes MACT requirements	Generally available in paper format only; some regional offices maintained databases
EIIP	States/EPA	Large point sources; nonpoint sources; mobile sources	Series of reports with recommended and alternative emissions estimation methods, and recommended emission factors	http://www.epa.gov/ttn/chief/eiip/index.html
Clearinghouse for Inventories and Emission Factors (CHIEF)	U.S. EPA	Collection of information, tools, and guidance on emissions from all sectors	EPA's main web page for emissions inventories and related data	http://www.epa.gov/ttn/chief/
Emissions Tracking System (ETS)	U.S. EPA	Large electric generating units	Annual reports of actual monitored emissions of SO2, NOx and CO2 from Title IV affected facilities, no toxics reported	http://www.epa.gov/airmarkets/emissions/index.html
RCRAInfo	U.S. EPA	Generally point sources; does include information on waste transporters	Reporting of releases from Hazardous Waste Treatment Storage and Disposal Facilities (TSDF); includes data from Biennial Reporting System (BRS) and Resource Conservation and Recovery Information System (RCRIS)	http://www.epa.gov/epaoswer/hazwaste/data/index.htm#rcra-info
Toxic Release Inventory (TRI)	U.S. EPA	Generally only point sources; includes only those sources that are subject to reporting thresholds	Self reported information at facility level; no other data necessary for modeling are reported (e.g., vent characteristics); updated annually; source and pollutant coverage can be limited by reporting thresholds; generally not recommended for modeling	http://www.epa.gov/tri/

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Chapter 8 Quantification of Exposure: Dispersion, Transport, and Fate of Air Toxics in the Atmosphere

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8.1 Introduction

This chapter describes the major physical processes that affect the movement of air toxics through the atmosphere. Section 8.1 describes the mechanisms through which sources release air toxics into the air and how specific release characteristics and meteorological factors affect air toxics dispersion and transport. Section 8.2 discusses the major physical and chemical processes that affect the fate of air toxics, including deposition and chemical reaction. The discussion of air toxics fate in this chapter is focused on describing the presence of air toxics in the atmosphere and processes that influence this presence. The fate of deposited air toxics in other media and ecosystems is included in Chapter 17.

The atmosphere and atmospheric processes is a complex and expansive subject. An understanding of at least the rudiments of this subject is central to an understanding of how air toxics disperse and persist or are removed once released to the air. Appendix G provides an overview of atmospheric and meteorological concepts and terms relevant to this chapter. Appendix G also provides information on sources of meteorological data for modeling air toxics dispersion and transport. Whenever possible, it recommended that a meteorologist be part of the risk assessment technical team.

8.2 Dispersion and Atmospheric Transport of Air Pollutants

Several characteristics of the source can affect the movement of air toxics while they are still close to the source (e.g., source height, gas exit temperature). Once air toxics are transported beyond the immediate vicinity of the source, atmospheric and meteorological factors (particularly wind speed and direction) govern air toxics dispersion and transport. This section describes how the movement of air toxics is affected by source characteristics, chemical properties, and atmospheric processes.

Dispersion, Transport, and Fate: What's the Difference?

Dispersion is a term applied to air toxics releases that means to spread or distribute from a source, with (generally) a decrease in concentration with distance from the source. Dispersion is affected by a number of factors including characteristics of the source, the pollutants, and ambient atmospheric conditions.

Transport is a term that refers to the processes (e.g., winds) that carry or cause pollutants to move from one location to another, especially over some distance.

Fate of air pollution refers to three things:
- Where a pollutant ultimately ends up (e.g., air distant from the source, soil, water, fish tissue);
- How long it persists in the environment; and
- The chemical reactions which it undergoes.

The fate of an air pollutant is governed both by transport processes and by the characteristics of the pollutant (e.g., its persistence, its ability to undergo reaction, and tendency to accumulate in water or soil, or to concentrate in the food chain).

8.2.1 General Types of Releases

The discussion of air toxics sources in Chapter 4 described air toxics emissions from a regulatory perspective (e.g., "stationary" versus "mobile" sources). This chapter focuses instead on emissions from the perspective of the primary types of industrial or physical processes through which sources release most pollutants to the air. The distinction between the major types of releases is not always clear, and the same air toxic can often be released in more than one way from a single source or process. Section 8.2.2 below discusses how the characteristics of these different types of release affect dispersion and transport of air pollutants.

The following terms are routinely used to generally describe or categorize emissions at a facility:

- **Stack or Vent Emissions**. These emissions are how most people envision air pollution. Stacks and vents include "smokestacks" that emit combustion products from fuel or waste combustion, as well as vents that carry air toxics away from people or industrial processes. The major characteristics that stack and vent emissions share are that the release is intentional, they remove airborne materials from specific locations or processes, and they channel the releases through dedicated structures designed specifically for that purpose. Often, stack and vent releases involve the active "pumping" of pollutant-laden air to the external atmosphere by using fans or the "draft" associated with the tendency of hot gases to rise rapidly through cooler, denser air. For many industrial operations, stack and vent emissions account for the bulk of releases (according to the most recent TRI reports from large industrial sources, about 86 percent).[1] For this reason, firms often install pollution control equipment in stacks or vents to reduce the concentration of potentially toxic pollutants released to the environment.

- **Fugitive Emissions**. "Fugitive" emissions are uncontrolled air pollutant releases that "escape" from physical, chemical, or industrial processes and activities, and which do not travel through stacks or vents. Examples include dust or vapors that are generated by the transfer of bulk cargo (e.g., coal, gravel, occasionally organic liquids) from one container to another (e.g., from a tank or hopper car to a storage silo, tank, or bin). Another example includes leaks from joints and valves at industrial facilities and evaporative emissions of fuel from mobile sources.

  "Fugitive dust" emissions often occur when quarrying, earth moving, construction, or excavation activities produce particulates. Such emissions are often called "fugitive" because they are uncontrolled (though this is not always the case). Historically, EPA has regarded fugitive emissions as being less important than stack and vent emissions; this is because either the amount of material released was relatively small or the characteristics of the release (large particle size, for example) precluded transport over large distances. However, the combined fugitive emissions from intensive or widespread industrial activities can be as important a contributor to risk as stack emissions.

The following terms are routinely used to describe processes that generate emissions.

- **Particle Suspension and Entrainment**. Particle suspension refers to a set of physical release mechanisms, without reference to specific types of sources and can overlap with the

previous definition of fugitive emissions. Suspension and entrainment refers to any process that results in the release of particles into the air from soils or other surfaces. Suspension and entrainment can occur as a result of artificial soil disturbance; or the action of wind on loose soil, sand or dust. Depending on the nature of the material and atmospheric conditions, suspended particles transport only a few feet, or may transport very long distances before redepositing (for example, dust storms that originate in the Sahara Desert may blow across the Atlantic and impact Central and North America). In some sections of the western United States, the majority of particulate matter detected in air is "crustal material" (soils and fine rock particles) suspended and transported by the wind, rather than human-made pollutants.

- **Volatilization/Vapor Release**. Many organic compounds and some inorganic compounds may "volatilize" to some extent; this means that these compounds tend to evaporate at normal atmospheric temperatures and pressures when not contained. Volatilization can occur for chemicals contained in mixtures as well as from concentrated or pure forms. Common examples include the lighter components of gasoline such as benzene, which volatilize to a sufficient degree that they can be smelled (and sometimes seen) when cars are refueling at filling stations without vapor control systems. Sources can release vapors when handling highly-concentrated or pure organic compounds, as well as when solids and liquids with low levels of organic contamination are exposed to the atmosphere. Volatilization releases are common from chemical manufacturing and processing operations, from metal cleaning and dry cleaning operations that use organic solvents, and from waste management facilities. Volatilization also is important for many natural sources of organic emissions. For example, in heavily forested areas, terpenes (volatile chemicals emitted from pines and other tree species) can account for a large proportions of total organic air pollution.

  Volatile organic compounds (VOCs) are not the only types of substances that vaporize. Some metals (e.g., elemental mercury), organometallic compounds, and other inorganic substances (e.g., ammonia and chlorine) have a high vapor pressure. Many semivolatile organic compounds (SVOCs) also volatilize relatively quickly, albeit at a slower rate than VOCs. Some solids also have a high vapor pressure (mothballs are a common example).

Common Measures of Chemical Volatility

Henry's Law Constant. The ratio at equilibrium of the gas phase concentration to the liquid phase concentration of a gas. Note that the Henry's Law constant can be defined in several ways and expressed using different units.

Vapor pressure. The pressure exerted by a vapor, either by itself or in a mixture of gases; often taken to mean saturated vapor pressure, which is the pressure of a vapor in contact with its liquid form.

8.2.2 Characteristics of Releases that Affect Dispersion and Transport

EPA and others have developed several air "dispersion" models to predict the often-complex behavior of air pollution releases. Most air dispersion models take into account a number of characteristics of the source and pollutants released. The most common of these characteristics are described below.

- **Release Rate and Volume**. The rate of release (exit velocity) strongly influences the behavior of the pollutant **plume** as it moves through the atmosphere. In the case of stack and

vent releases, sources can release pollutants as pure vapors, as dilute solutions of vapor in air or other gases, or as suspended particles. Large volumes are often released at a relatively high velocity from stacks or vents, which can also serve to drive pollutants higher in the atmosphere. Air quality models often calculate volume from data on exit area and exit velocity. In the case of fugitive releases or volatilization, the "volume" of release has less meaning, and often does not receive explicit consideration in fate and transport modeling.

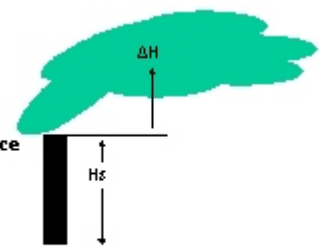
- **Concentration**. Concentration (the mass of pollutant per unit volume of released gases) is the other half of the equation that determines the amount (mass) of pollutant released. Pollutants at higher concentrations may also be more likely to condense onto particles or liquid droplets.

- **Temperature**. The temperature of a plume emitted from a stack or vent influences the dispersion and transport of pollutants. A plume that is warmer than the surrounding air will generally rise, which tends to increase the distance over which pollutants will be transported. The combination of temperature and vertical velocity of stack emissions combine to affect the height to which the plume will rise and the layer of the atmosphere in which it will initially be transported. As with concentration, the temperature of the plume also affects the physical form of pollutants, with less volatile pollutants condensing faster from cooler plumes.

- **Height**. Pollutants may also be released into the atmosphere at different heights, and the height of release can strongly affect dispersion and transport. Greater release heights generally result in increased pollutant dilution in the atmosphere, lower ground-level concentrations, and a greater distance to peak ground-level concentrations. Release height also is important in evaluating local effects on air transport, such as building downwash. While power generation or industrial activities may release combustion products from stacks that are hundreds of feet tall, volatilization releases or suspension of particulate pollutants often occur at or near the ground surface.

Source Characteristics Affecting Dispersion

- Release rate
- Plume height = Hs + ΔH
  - *Physical release height (Hs)
    - From a stack
    - From an area/volume source
    - From the ground
  - *Plume rise (ΔH)
    - Exit velocity
    - Stack temperature
    - Wind speed



- **Timing and Duration**. Multiplying the release duration by the release rate produces the total mass of pollutant released. The timing of release relative to specific meteorological conditions determines the particular dispersion and transport of pollutants. Unfortunately, only total annual or average daily release data are available for most sources, making it difficult to fully characterize time varying releases. Fortunately, chronic exposure assessments usually focus on the average long-term (annual) concentrations. Acute exposure assessments, however, usually focus on the maximum short-term (24-hours or less) concentration. Acute exposures are derived from conservative meteorological factors that

lead to the highest short term peak values for a screening exercise; for a more detailed exercise, the actual meteorology should determine the short term peaks.

- **Physical Form**. The physical form of pollutant releases greatly affects the dispersion, transport and chemical reactions that pollutants undergo. Generally, pollutants are characterized as being **vapors** (not bound to particles, but existing as single molecules or very small aggregates "dissolved" in air – also called **gaseous**), **particle-bound** (reversibly absorbed or condensed onto the surface of particles), or **particulate** (irreversibly incorporated into airborne particles). The distribution of pollutants in these three "phases" is known as **partitioning**. Partitioning is a function of the chemical and physical properties of the pollutants and the temperature and pressure of the atmosphere into which the chemicals have been released (e.g., the partitioning behavior of pollutants can vary greatly with temperature). As noted above, sources can emit chemical pollutants in the vapor phase at relatively high temperatures, and these pollutants can condense into or onto particulates as the emitted gases cool in the atmosphere. Sources generally emit most metals (with the important exception of mercury) as particles in the atmosphere.

- **Particle Size**. When sources release pollutants as particles (or if released as gases, if these pollutants condense into particles or absorb onto the surface of existing particles), the rate of pollutant removal from the atmosphere to surfaces (e.g., plants, soils, surface water) depends upon particle size. The typical size of particles that different activities and processes emit into the air can vary by many orders of magnitude (powers of ten). As the size of particles increases, the rate at which particles fall due to gravity (the settling velocity) increases. Thus, fine particles (approximate diameter less than a few microns)[(a)] may remain suspended in air indefinitely, but particles larger than about 20 microns in diameter settle rapidly and may not transport far from sources of release.

  For purposes of air toxics risk assessment, particles less than 10 microns in diameter are of primary concern because they are small enough to be taken into and deposited in the lung after inhalation. These particles are divided into two size ranges: "fine" particles less than 2.5 micrometers in size ($PM_{2.5}$), and "coarse" particles covering the range from 2.5 to 10 micrometers in diameter (PM_{10}). (Thus, monitoring analyses for metals in particulates, for example, would commonly collect particulate samples of $PM_{2.5}$ and PM_{10} for analysis, not total suspended particulate (TSP), because such samples contain particles that are too large to be effectively respired – thereby leading assessors to overestimate inhalation risk).

  Particles emitted from combustion and high-temperature chemical processes can be very fine, on the order of 0.01 to 1.0 microns in diameter. Such fine particles tend to condense to form larger aggregates up to the limit of perhaps a few microns, and participate in a wide range of chemical reactions.

[a]One micron is one one-millionth of a meter, or about 0.00004 inches.

Aerosols and Particulate Matter

Aerosols are mixtures of fine solid or liquid particles in a gas. They can be emitted directly as particles or formed in the atmosphere by gas-to-particle conversion processes. The terms dust, smoke, fume, haze, and mist all describe different types of aerosols. Dust refers to solid particles produced by disintegration process; smoke and fume are particles formed from the gas phase. Mists are composed of liquid droplets. Some aerosols occur naturally, originating from volcanoes, dust storms, forest and grassland fires, living vegetation, and sea spray. Human activities, such as the burning of fossil fuels and the alteration of natural surface cover, also generate aerosols.

Particulate matter is the term given to the tiny particles of solid or semi-solid material found in the atmosphere. Particulates less than about 50 micrometers in size are called total suspended particulates (TSP). Particles larger than that range tend to quickly settle out of the air. Particulate matter 10 micrometers in diameter and smaller (PM_{10}) is considered inhalable. These particles are divided into two size ranges: fine and coarse.

"Fine" particles less than 2.5 micrometers in size ($PM_{2.5}$) are responsible for causing the greatest harm to human health. 1/20th the width of a human hair, these fine particles can be inhaled deep into the lungs, reaching areas where the cells replenish the blood with oxygen. They can cause breathing and respiratory symptoms, irritation, inflammation, damage to the lungs, and premature deaths. Some $PM_{2.5}$ are released directly to the atmosphere from industrial smokestacks and automobile exhaust, but a large percentage is actually formed in the atmosphere from other pollutants such as sulphur dioxide, nitrogen oxides, and volatile organic compounds.

"Coarse" particles covering the range from 2.5 to 10 micrometers in diameter are also known to cause adverse health effects, such as aggravation of respiratory disease. When inhaled, particles larger than 10 micrometers tend to be deposited in the upper parts of the respiratory system, from which they can be eventually expelled back into the throat. Coarse particles generally remain in the form in which they are released into the atmosphere without chemical transformation, eventually settling out under the influence of gravity. While some of these coarse particles are generated naturally by sea salt spray, wind and wave erosion, volcanic dust, windblown soil, and pollen, they are also produced by human activities, such as construction, demolition, mining, road dust, tire wear, and grinding processes of soil, rocks, or metals.

- **Chemical Form**. Chemical form is generally more of a concern for inorganic pollutants, because organic chemicals tend to have well-defined chemical compositions and properties. The most important chemical properties of inorganic metal compounds, for example, include the **oxidation** or **valence state** of the **cationic metal**, the identity of the **anionic counterion**, and the chemical and physical properties of the compound that the cation and anion comprise. As an example of the importance of valence state, consider the metal chromium. When emitted in the *hexavalent* form (with six positive charges – Cr^{6+}), chromium is highly reactive chemically and is readily reduced under certain conditions to the *trivalent* form, which is Cr^{3+}. Cr^{6+} can cause respiratory irritation and cancer in humans. Cr^{3+}, on the other hand, is much more stable, is much less toxic to humans and animals (and is actually an essential mineral), and is not thought to cause cancer.

Available air pollution dispersion models differ in the ways in which they use these characteristics. While Chapter 9 presents a general discussion of these, users can find specific details in the documentation for the various models at EPA's (Support Center for Regulatory Air Models) SCRAM website.[2]

8.2.3 Physical and Meteorological Factors Affecting Air Toxics Dispersion and Transport

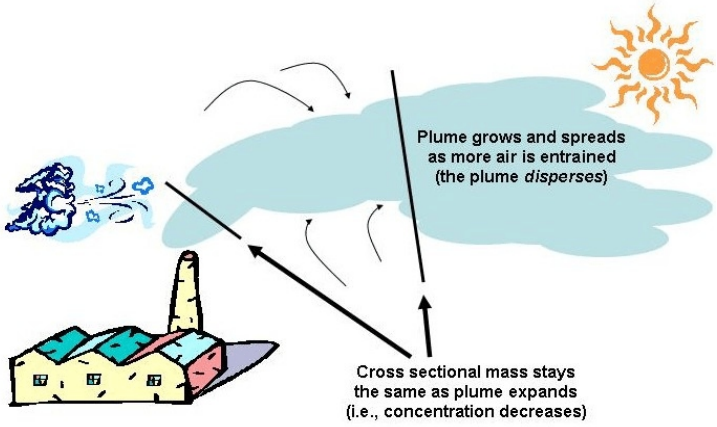
This section describes some of the most important physical and meteorological factors that affect the movement of air pollutants after their release. For definitions of and further details about the atmospheric and meteorological terms this section uses, refer to Appendix G.

Wind Speed and Direction Affect Plume Dispersion

The wind will determine which direction the plume goes and how fast it gets there. To look at long-term impacts (chronic exposure) a wind-rose (a distribution of winds around a compass) can be used to determine the areas of persistent wind; downwind of the largest persistent winds will generally be the areas to expect the maximum long-term impacts.

Although this section focuses on releases from stationary point sources (i.e., stacks), most of the factors may apply to releases from other source types as well. Stacks come in all sizes, from a small vent on a roof to stacks hundreds of feet in height. The function of a stack is to remove pollution of high concentration and to discharge it to the atmosphere for dispersion and transport. Stacks release pollutants high enough above the earth's surface that pollutants can sufficiently disperse in the atmosphere before reaching ground level. All else being equal, taller stacks disperse pollutants more effectively than shorter stacks because the pollutants release into higher wind speeds and travel through a greater depth of the atmosphere before reaching ground level.

Concentrations of Air Toxics in a Plume Decrease With Distance



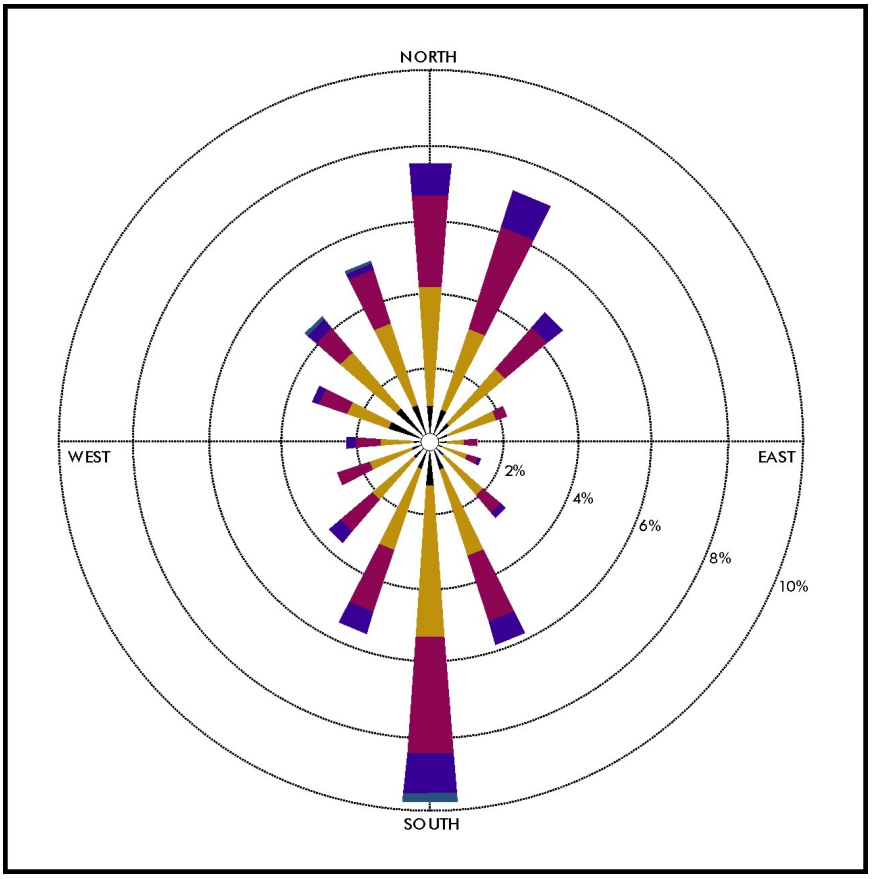
As a plume grows, it entrains clean ambient air and disperses. In other words, the amount of pollutant mass at any given cross section in the plume is generally the same; thus, as the plume spreads, its concentration goes down.

The air space the stack pollutant occupies can be described as a **plume**. As the plume travels, it spreads and disperses, reducing ambient pollutant concentrations even though the cross sectional mass of the plume remains the same. Eventually, the plume may intercept the ground. The combination of emission velocity, emission temperature (see below), vertical air movement and horizontal airflow all influences how high a plume will rise and how fast and far it travels. Another factor is wind meander (i.e., changes in wind direction during light wind speed

conditions), which can cause the plume to deviate in the horizontal direction due to turbulence and wind fluctuation.

As the gases exit the stack, they mix with ambient air. This mixing of ambient air into the plume is called **entrainment**. The plume grows in volume as it entrains ambient air and travels downwind. Because stack gases are often warmer than the ambient outdoor air, the gases may be less dense and than the outdoor air and are therefore buoyant (like a helium filled balloon). Gases that stacks emit are often pushed out by fans giving the gas momentum as it enters the atmosphere. The combination of this momentum and the buoyancy of the stack gases that are warmer than the ambient air cause the gas to rise.

Example of a Wind Rose



A wind rose illustrates, for a given locality or area, the frequency and strength of the wind from various directions for a selected time period, typically a year or longer. In this example, the length of the bars indicates the percentage of the year the wind blows in each of 16 directions and the colors indicate the percent of time at that wind speed for each of these directions.

This plume rise allows air toxics emitted in this stack stream to be lofted higher in the atmosphere. Since the plume is higher in the atmosphere where the winds are generally stronger, the plume will generally disperse more before it reaches ground level. Plume rise depends on the stack's physical characteristics and on the effluent's exit temperature and velocity.

Vertical Air Motions

When air is displaced vertically, atmospheric behavior is a function of atmospheric stability. A stable atmosphere resists vertical motion, and air that is displaced vertically in a stable atmosphere tends to return to its original position. This atmospheric characteristic determines the ability of the atmosphere to disperse pollutants. To understand atmospheric stability and the role it plays in pollution dispersion, it is important to understand the dynamics of the atmosphere as they relate to vertical atmospheric motion.

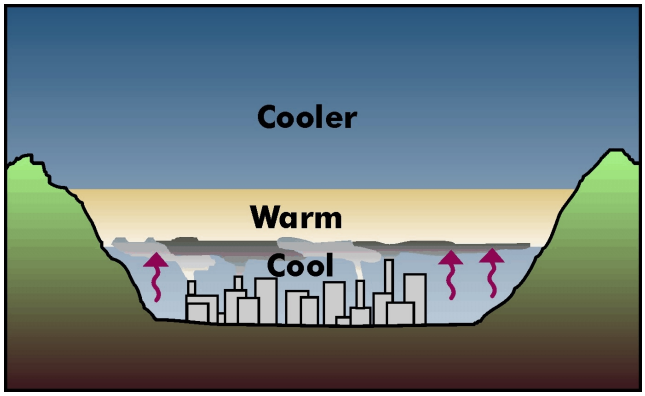
The degree of stability of the atmosphere is determined by the temperature difference between an air parcel and the surrounding air. This difference can cause the parcel to rise or fall. There are three general categories of atmospheric stability.

- In **stable** conditions, vertical movement tends not to occur. Stable conditions occur at night when there is little or no wind. Air that lifts vertically will remain cooler, and therefore denser than the surrounding air. Once the lifting force ceases, the air that has lifted will return to its original position.

- **Neutral** conditions ("well mixed") neither encourage nor discourage air movement. Neutral stability occurs on windy days or when there is cloud cover such that there is neither strong heating nor cooling of the earth's surface. Air lifted vertically will tend to remain at the higher level once the lifting force ceases.

- In **unstable** conditions, the air parcel tends to move upward or downward and to continue that movement. Unstable conditions most commonly develop on sunny days with low wind speeds where strong solar radiation is present. The earth rapidly absorbs heat and transfers some of it to the surface air layer. As warm air rises, cooler air moves underneath. The cooler air, in turn, may be heated by the earth's surface and begin to rise. Such conditions enhance vertical motion in both directions and considerable vertical mixing occurs.

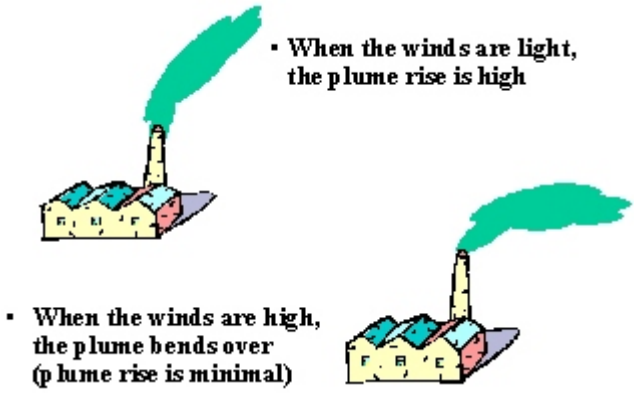
- **Inversions** occur whenever warm air over-runs cold air and "traps" the cold air beneath. Within these inversions there is little air motion, and the air becomes stagnant. High air toxic concentrations can occur within inversions due to the limited amount of mixing between the "trapped" air and the surrounding atmosphere. Inversions can limit the volume of air into which emissions are dispersed, even from tall stacks.



The condition of the atmosphere (i.e., the vertical profile of the winds and temperature) along the path of the plume also determines how far the plume rises in the atmosphere. As described in Appendix G an **inversion layer** (formed when a layer of warm air "traps" a layer of cold air beneath) may act as a barrier to vertical mixing. The height of a stack in relation to the height of the inversion layer may often influence ground-level pollutant concentrations (Exhibit 8-1).

The initial velocity of the plume (stack exit velocity) reduces quickly as the plume entrains ambient air and acquires horizontal momentum from the wind. This momentum causes the plume to bend over. The greater the wind speed, the more horizontal momentum the plume acquires. Wind speed usually increases with height above the earth's surface. Therefore, as the plume continues upward the stronger winds tilt the plume even further. This process continues until the plume may appear to be horizontal to the ground. The point where the plume looks level may be a considerable distance downwind from the stack (Exhibit 8-2).

Wind Speed Affects Plume Rise

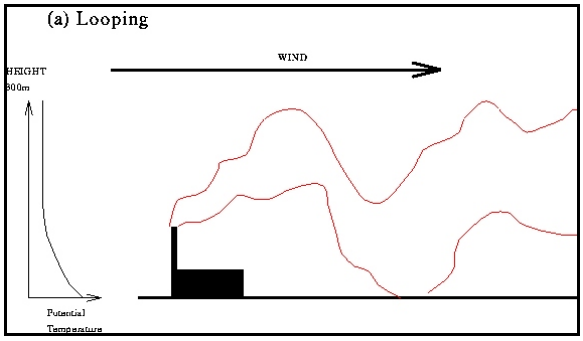


The strength of the wind will help determine how high the plume rises; a strong wind will "knock-over" the plume right away, while a light wind will allow a plume to rise from its own buoyancy and initial inertia.

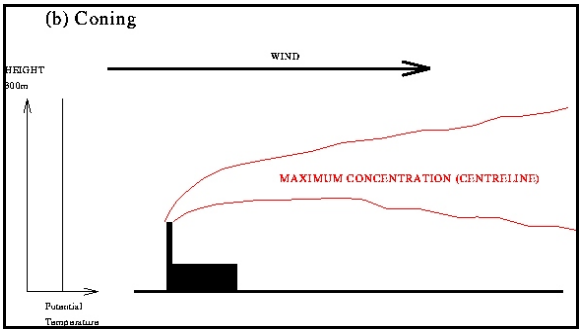
Due to configuration of the stack or adjacent buildings, the plume may not rise freely into the atmosphere. The way in which the wind moves around adjacent buildings and the stack can force the plume toward the ground instead of allowing it to rise in the atmosphere. Stack-tip downwash can occur where the ratio of the stack exit velocity to horizontal wind speed is small. In this case, low pressure in the wake of the stack may cause the plume to draw downward behind the stack. Pollutant plume rise reduces when this occurs and elevates pollutant concentrations immediately downwind of the source. As air moves over and around buildings and other structures, it forms turbulent wakes. Depending upon the stack height, it may be possible for the plume to be pulled down into this wake area. The reduction in plume height is known as **aerodynamic or building downwash** (Exhibit 8-3).

Once air toxics have equilibrated with ambient conditions (e.g., temperature, velocity), atmospheric and meteorologic factors primarily influence dispersion and transport of air toxics. In particular, the rate of dispersion is influenced by both the thermal structure of the atmosphere and mechanical agitation of the air as it moves over the different surface features of the earth (see Appendix G). As the next section describes, exposure to solar radiation and moisture, as well as other properties in the atmosphere, complement the factors above and contribute to the eventual fate of the air toxics.

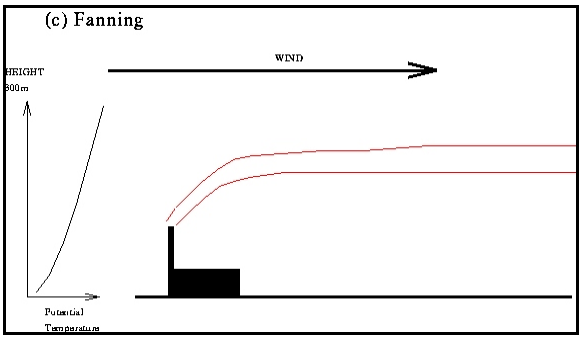
Exhibit 8-1. Effects of Boundary Layer Conditions on Plume Dispersion



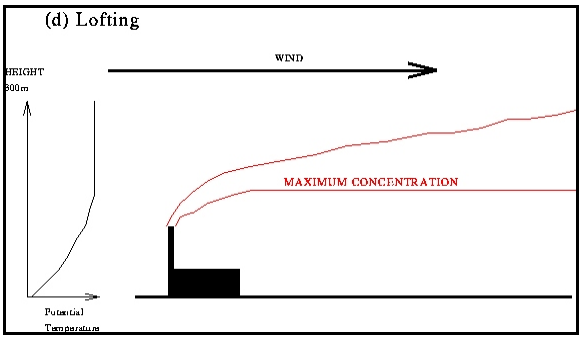
(a) Looping. When the atmosphere is very unstable through a deep layer, convective currents carry the plume up and down, forming a looping pattern and rapidly diluting the plume through intense vertical mixing.



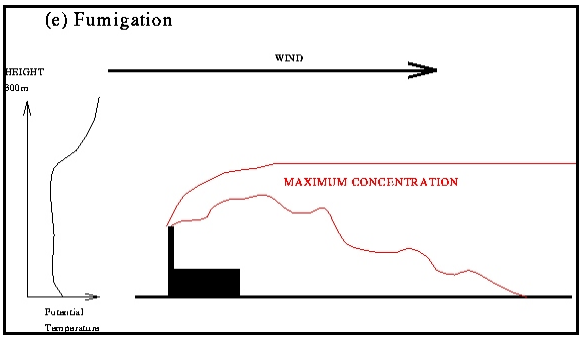
(b) Coning. Under neutral conditions, the vertical mixing also transports freely, but the turbulent motions that irregularities of the ground and shearing of the wind introduce are about equal, and the plume resembles a cone.



(c) Fanning. When the plume rises into an inversion layer, the stability limits diffusion up or down, so that the only spreading of the plume is sideways and when viewed from above has a fanning appearance.



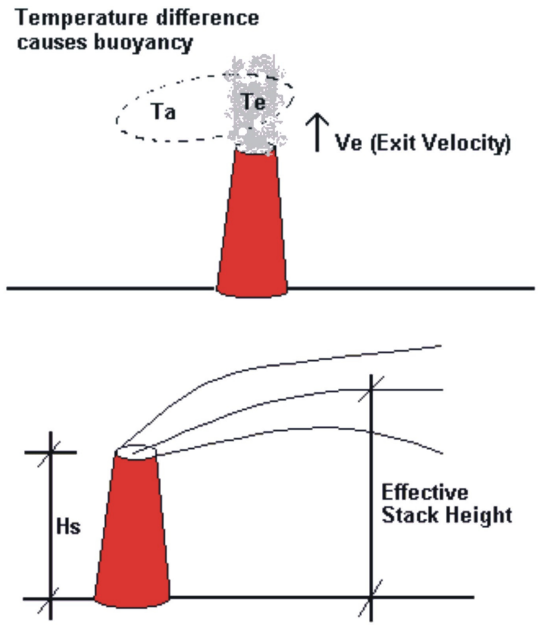
(d) Lofting. When conditions are unstable or neutral above an inversion, the release of a plume above the inversion is more likely to result in effective dispersion and lower ground-level concentrations around the source



(e) Fumigation. If the plume is released overnight just under an inversion layer, it can become trapped. As solar radiation warms the ground in the morning, the air below an inversion layer becomes unstable. If the unstable conditions then extend upwards and reach the plume that is still trapped below the inversion layer, the pollutants can be rapidly transported down toward the ground. Ground-level pollutant concentrations can be very high when fumigation occurs.

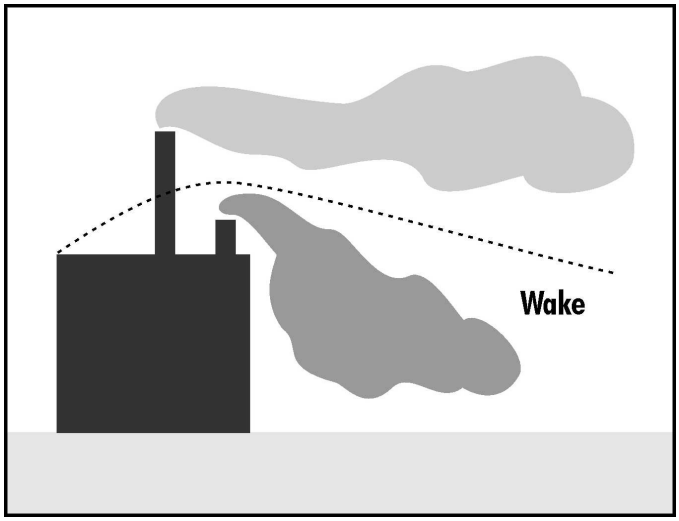
Graphics courtesy of Doug Parker, University of Leeds, and available at: http://www.env.leeds.ac.uk/envi1250/lectures/lect11.html.

Exhibit 8-2. Plume Rise Schematic



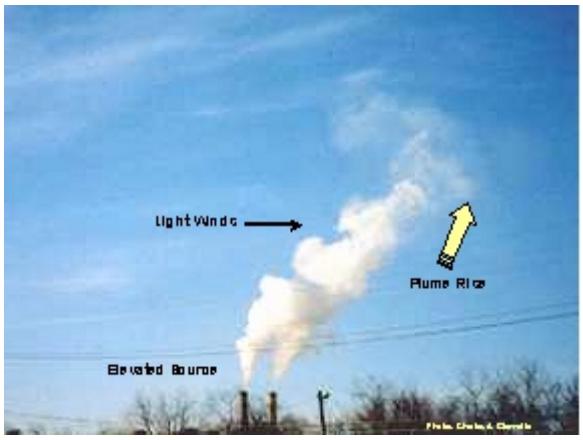
As emissions exit a stack, they can be lofted higher into the atmosphere as a result of plume rise. Plume rise is caused by (1) buoyancy resulting from emissions with higher temperatures than ambient air (i.e., Te > Ta) and (2) the initial momentum (i.e., exit velocity) of the emissions leaving the stack. The effective stack height of a stack is equal to the actual physical height of the top of the stack (Hs) plus the plume rise, minus any downwash associated with wake turbulence behind objects on the ground (see Exhibit 8-3).

Exhibit 8-3. Aerodynamic or Building Downwash



Nearby structures can disturb the horizontal flow of the wind (indicated by the dashed line) and cause a plume to get "downwashed" to the ground quickly. This is how a snow fence works.

Examples of Plume Rise



The picture on the left is an example of an elevated point source that probably has a hot plume or high exit velocity, as the plume rise indicates. Because of the light wind and neutral or unstable atmospheric conditions, there are essentially no impacts at ground level near the source. The picture on the right is another example of elevated point sources, but this time with higher winds. There is little plume rise, and the plumes fan straighter out from the stacks, resulting in narrower plumes.

8.3 Fate of Air Toxics in the Atmosphere

This section discusses the major physical and chemical processes that affect the fate of air toxics in the atmosphere. The scope of this section is limited to processes that remove air toxics from the atmosphere. Part III of this reference manual discusses the fate and transport of air toxics in other environmental media and the ecosystem once a chemical has been removed from the air.

8.3.1 Physical Processes Removing Air Toxics

A number of important physical processes (processes that do not alter the chemical nature of pollutants) affect how air toxics move in and out of the atmosphere. In particular, this section discusses how gravity and precipitation remove air toxics from the atmosphere. The process through which particulates fall (or settle) to the surface in the absence of precipitation is known as **dry deposition**, and the removal of pollutants from the air through precipitation events is called **wet deposition**.

- **Dry Deposition**. As the previous section noted, dry deposition is the settling of particles due to gravity. The maximum speed at which a particle will fall in still air is known as the **settling velocity (settling rate)**. A particle's settling velocity is a function of its size, density, and shape. Larger, denser particles settle more rapidly, and particles with more irregular shape settle more slowly (Exhibit 8-4). For particles smaller than a few microns in diameter (fine and ultrafine particles), the gravitational settling rate is so slow that other forces, such as local air currents and collisions with gas molecules, tend to offset it. Thus, in the absence of other removal mechanisms (e.g., condensation and/or aggregation to form larger particles, wet deposition), particles in this size range tend to remain suspended in the

air for long periods of time. Depending on the conditions, fine particles may persist in the atmosphere for days or weeks and travel hundreds or thousands of miles from their source. At the other extreme, coarse dust particles (> 50 microns in diameter), such as those generated while handling materials, have large settling velocities. Under normal conditions, such particles generated near the ground will deposit on the surface within a few seconds or minutes, generally within less than a kilometer of the source. Particles in between these two extremes in the size distribution will settle at intermediate velocities, and will distribute at intermediate distances from their sources.

Exhibit 8-4. Approximate Settling Rates for Typical Particles in Air

Equivalent Diameter* (microns)	Settling Rate (cm/sec)
0.01	0.00001
0.1	0.0002
1.0	0.01
10	0.6
100	40

* Diameter of a sphere that is approximately equivalent to a particle's diameter

In typical air dispersion models, the modeler must specify a particle size distribution, classifying what proportion of the emitted particles are within particular size ranges. In initial screening-level analyses of pollutant levels in air, users assume that particulate settling does not occur. This is conservative relative to the air concentration - if the amount deposited to the ground is the key issue of concern, then a high removal rate from the atmosphere would be "conservative." Users can assess dry deposition for low-volatility pollutants that partition out of the air primarily onto airborne particles in the same fashion as non-volatile particulates. Volatile chemicals that exist primarily in the vapor phase have negligible settling velocities, and modelers generally need not consider dry deposition for these pollutants. In the case of pollutants whose vapor-particle partitioning is unclear, it is common to run air dispersion models assuming a range of partitioning behavior from fully particle-bound to fully vapor phase.

- **Wet Deposition**. Wet deposition involves the "washing out" of pollutants from the atmosphere through precipitation events (including rain, snow, and in some cases hail). Wet deposition affects both particulate and vapor-phase pollutants. For larger particles and vapor phase pollutants that are soluble in water, precipitation is very efficient at removing pollutants from the air and depositing them on the earth's surface. Wet deposition may be less efficient at removing fine particulates, and has limited effect on the levels of gaseous pollutants with high Henry's Law constants (indicating low solubility in water compared to vapor pressure). Because wet deposition depends on the occurrence of precipitation events, it is best characterized over long periods (e.g., seasons or years). The relative importance of precipitation in removing pollutants from the air depends on the climatic conditions in the areas affected by pollution.

Transport and Deposition of Mercury

Mercury is a natural trace element in nearly all coal, and the large quantities burned in major electric power plants can release considerable mercury. In both municipal and medical incinerators the variety of waste materials burned can include mercury. Some mercury remains in the ash-materials, some may be captured by pollution controls on exhaust, and the rest is emitted to the air in three forms or chemical "species:" gaseous elemental mercury (Hg(0)), gaseous ionic or "inorganic" mercury (Hg(II)), and particle-bound mercury (Hg(p)). Elemental mercury gas is nearly insoluble in water and rather inert chemically, so it can be transported up to thousands of miles while gradually being converted to other forms and deposited. The ionic form, Hg(II) or Hg (2+), is soluble in water and thus incorporated into rain, fog, and snow. Also, Hg(II) is both physically and chemically active and is known as "reactive gaseous mercury" or RGM. Most of the Hg(II) emitted is deposited via both precipitation and dry gases within about 30 to 60 miles from a stack. In many cases, this "local" deposition can be the most important impact of mercury from combustion sources. The fate of particle-bound mercury depends on the size of the particles, though generally they deposit to earth within a few hundred miles of the emitting stack.

8.3.2 Chemical Reactions that Remove Air Toxics

In addition to deposition, chemical reactions may occur that reduce air toxics concentrations. Air toxics may be destroyed through the action of sunlight, through reactions with atmospheric chemical pollutants, or through a combination of these pathways. In estimating the ambient air concentration associated with air toxics releases, it is therefore necessary to consider chemical reactions as well as deposition. As will be discussed in the next section, not all chemical reactions result in the destruction of air toxics, or their conversion to less harmful products. Potentially harmful pollutants may also be formed as a result of atmospheric chemical reactions (a process that is called **secondary production** or **secondary formation)**. This section, however, focuses on atmospheric chemical reactions which are known or believed to destroy air toxics (i.e., resulting in less toxic forms).

Chemical Transformations Can Occur in the Atmosphere

$$X + Y \xrightarrow{\text{light}} Z$$

Numerous complex chemical transformations may occur in the atmosphere, some of which are photochemical in nature (i.e., reactions in the presence of light to form new chemicals).

- **Major Chemical Reactions of Air Toxics**. Generally, organic compounds are much more susceptible to chemical reactions in the atmosphere than metals or other inorganic contaminants. The major chemical reactions undergone by organic chemicals in the atmosphere include:

  – Photolysis (destruction by sunlight alone);
  – Reactions with the hydroxyl radical (OH•);

- Reactions with the nitrate radical (NO_3•); and
- Reaction with ozone (O_3).

Often these reactions occur in combination with reactions that are strongly affected by sunlight. While reaction rates vary widely for pollutants, under typical atmospheric conditions, reactions with the hydroxyl radical are the most rapid, and account for a large portion of pollutant degradation during daylight hours. Reactions with nitrate radical occur primarily during the night, and reactions with ozone occur both day and night. Except in the case of a few pollutants, "pure" photolysis is a relatively minor reaction process. Other reactive species such as the hydroperoxide radical (OOH•) may also participate in pollutant degrading reactions under some conditions. The relative importance of these reactions is dependent not only on climatic factors (e.g., duration and intensity of sunlight), but also on the overall concentrations of pollution present. For example, high levels of nitrogen oxide (NO_x) emissions and emissions of VOCs increase the levels of nitrate radicals and ozone in the atmosphere, thereby increasing reaction rates for subsequent reactions where these species are involved.

8.3.3 Chemical Reactions that Result in the Secondary Formation of Pollutants

As noted previously, not all chemical reactions result in the destruction of pollutants or in reaction products that are of less concern than the pollutants from which they derive. In some cases, the immediate reaction products result in products that are more toxic and/or more persistent than the chemicals that were originally released into the atmosphere.

Examples of large-scale chemical reactions that result in products that can be hazardous to health include the generation of acid particulate through photo-oxidation after the release of sulfur dioxide (SO_2) and NO_x from combustion sources (i.e., to make sulfuric acid and nitric acid), and the formation of ozone and photochemical oxidant in areas with high levels of NO_x and volatile organic emissions. In addition, there are many reactions of specific organic pollutants that generate air toxics of concern, as Exhibit 8-5 shows. The extent to which these reactions are important at any given location depend, of course, on the emissions and resulting concentrations of the precursor materials. In addition, many of these reactions are catalyzed directly and indirectly by sunlight, so weather and climatic factors are important in judging the importance of secondary formation. While it is difficult to generalize, the secondary formation of formaldehyde and acrolein are thought to be important in many regions of the country with significant industrial and mobile source emissions.[3]

Exhibit 8-5. Examples of Secondary Pollutants

Pollutant	Formed From
acetaldehyde	propene, 2-butene
acrolein	1,3-butadiene
carbonyl sulfide	carbon disulfide
o-cresol	toluene
formaldehyde	ethene, propene
hydrogen chloride	nitric acid, chlorinated organics
methylethyl ketone	butane, branched alkenes
N–nitroso-N–methylurea	N–methylurea
N–nitrosodiethylamine	dimethylamine
N–nitrosomorpholine	morpholine
phosgene	chlorinated solvents
propionaldehyde	1-butene

Source: Rosenbaum et al., 1998[3]

8.3.4 Overall Persistence of Air Toxics in the Atmosphere

In analyzing the potential impacts of air toxics releases, it is necessary to combine considerations of all the above processes to characterize the overall pattern of air toxics concentrations and estimate the time periods and distance scales over which air toxics impacts need to be evaluated.

Detailed quantitative comparisons of removal pathways may be too complex and expensive to include in most risk assessments. However, air pollution scientists have developed a number of simple models and gathered data on a large number of pollutants that enable them to assess the relative impacts of different physical processes and chemical reactions on single chemicals under typical conditions. The most common model uses the simplifying assumption that pollutant removal through each chemical and physical processes can be approximated using processes that have characteristic **half-lives** and **atmospheric lifetimes** (Exhibit 8-6).

Under the most commonly used approach (many variations exist), the overall lifetime of a pollutant in the environment is:

$$\frac{1}{r_{overall}} = \frac{1}{r_{physical}} + \frac{1}{r_{chemical}} \qquad \text{(Equation 8-1)}$$

That is, the overall lifetime ($1/r_{overall}$) of a chemical in the environment is equal to the sum of the atmospheric lifetime when considering only physical processes ($1/r_{physical}$) plus the lifetime when considering only chemical processes ($1/r_{chemical}$). This equation is the same as saying that the overall rate constant for pollutant removal/destruction ($r_{overall}$) is equal to the sum of the rate constant for physical removal ($r_{physical}$) plus the rate constant for chemical reaction ($1/r_{chemical}$). This relationship follows from the nature of first-order reaction kinetics, and is known to be only an approximate description of actual physical processes (see Exhibit 8-5). It is a useful approximation, however, that can be used to evaluate the importance of atmospheric processes for many pollutants.

As noted in Section 8.2.2, organic chemical pollutants can undergo a number of chemical reactions that may be important under different sets of conditions. Thus, the atmospheric lifetime for chemical reactions in the above equation is often broken down to consider contributions from each important reaction:

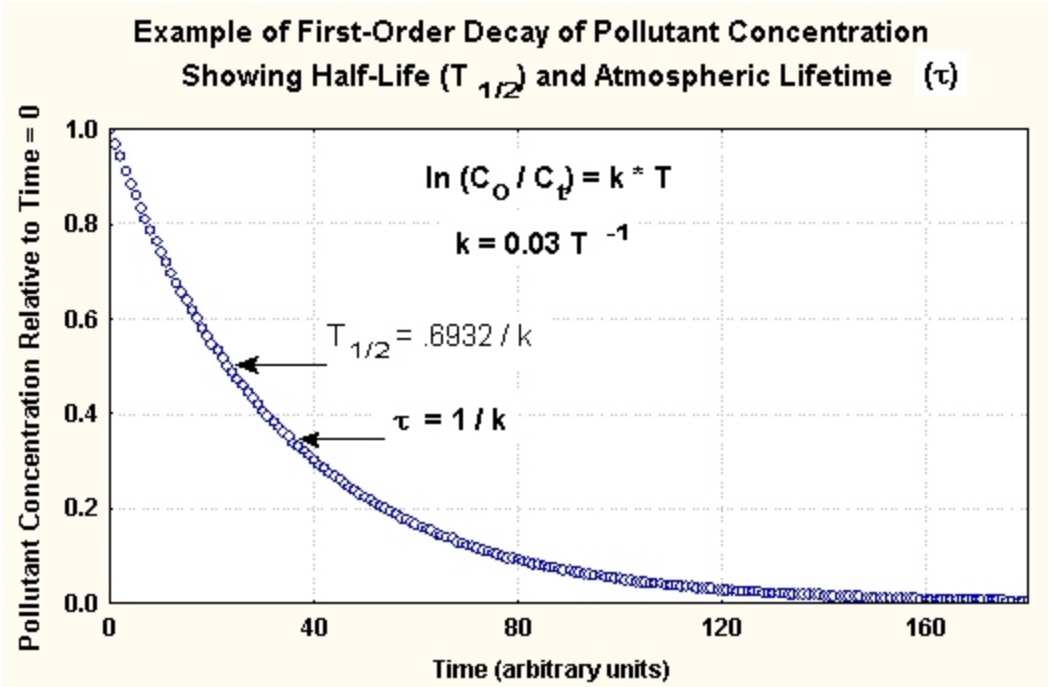
$$\frac{1}{r_{chemical}} = \frac{1}{r_{OH}} + \frac{1}{r_{NO3}} + \frac{1}{r_{O3}} + \frac{1}{r_{photolysis}} \qquad \text{(Equation 8-2)}$$

where the terms on the right side of the equations represent the rates of pollutant removal through the reactions with hydroxide radical, nitrate radical, ozone, and photolysis, respectively.

For any given air toxic, overall persistence in the atmosphere depends on particle-vapor partitioning behavior, particle size distribution (if the material is non-volatile), and susceptibility

to various types of chemical reactions. Atmospheric half-lives due to deposition (wet and dry) tend to be highly variable depending on particle size, ranging from a few minutes for coarse particles to many days for very fine particles. Most fine particles (less than a few microns) are removed from the troposphere (the lower level of the atmosphere where most weather takes place) with an average lifetime of between 5 and 15 days.

Exhibit 8-6. Example First-Order Decay of Pollutant Concentration



Simple physical and chemical reactions often proceed according to what are called "first-order kinetics." In a first-order reaction, the rate of the reaction at any given time is proportional to the concentration of one reactant (in this case, the air toxic that is being destroyed). The overall rate of the reaction is governed by the first-order (or "pseudo first-order") rate constant, "k." A higher rate constant implies a higher reaction rate for a given concentration of reactant. First-order reactions have the properties that the "half-life" of the reaction (the time in which one-half of the original concentration of reactant is destroyed) is the same no matter what the initial concentration. Air pollution scientists also measure the "atmospheric lifetime" of pollutants, which is abbreviated as the Greek letter τ (tau) or the letter "r," which is equal to 1/k. In this example, the rate constant (k) represents the sum of both physical and chemical removal.

Exhibit 8-7 presents estimated *chemical* half-lives for a few example chemicals based on measured reaction rates. Estimated atmospheric lifetime for chemical reactions ranges from many thousands of hours for the least reactive chemicals to only a few hours for chemicals that are more reactive. As noted above, the lifetimes for reactions with the hydroxide radical (r_{OH}) are the shortest, indicating that this pathway is the most important for most of the chemicals in the table, at least during daylight hours. Reactions with ozone and nitrate radicals are much slower

for most of the chemicals. "Pure" photolysis is not important for most chemicals, with the notable exceptions of the two aldehydes, where it is a major degradation pathway.[4]

Exhibit 8-7. Typical Atmospheric Half-lives for Chemical Reactions (hours) for Selected Pollutants for Reactions with Hydroxide, Nitrate, Ozone, and for Photolysis

Compound	r_{OH}	r_{O3}	r_{NO3}	$r_{photolysis}$
methane	28,000	$2x10^8$	$2x10^6$	–
ethane	8,40	$3x10^7$	$1x10^5$	–
benzene	180	$4x10^6$	$4x10^6$	–
toluene	37	$3x10^5$	$3x10^5$	–
1-butene	7.4	26	93	–
isoprene	2.3	20	1.4	–
formaldehyde	19	–	–	5.5
acetaldehyde	12	5,600	–	2.7

Source: California Air Resources Board Toxic Air Contaminant Fact Sheets[4]

Data such as those in Exhibit 8-7 are available to some degree for many chemicals, and can help assessors to judge the distance scales over which to analyze air toxics impacts. As noted above, persistence on the order of less than a day suggests transport of about ten miles, while persistence for several days suggests regional transport (500-1,000 miles) before being substantially degraded. Atmospheric reactivity is not well-studied for some chemicals, requiring the use of assumptions about persistence that span a reasonable range of reactivity. For non-volatile air toxics that partition primarily into particles, physical processes (wet and dry deposition) may be the most important in determining overall atmospheric lifetimes.[4] Some chemicals that are very persistent in the atmosphere and in terrestrial and aquatic systems may require special consideration, as described in Chapter 17. Chapter 9 builds upon the discussion above and identifies how well available dispersion models address chemistry/physical removal.

References

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2. U.S. Environmental Protection Agency. 2004. Technology Transfer Network. *Support Center for Regulatory Air Models.* Updated February 23, 2004. Available at: http://www.epa.gov/ttn/scram/. (Last accessed March 2004).

3. Rosenbaum, A.S., Ligocki, M.P., and Wei, Y.H. 1998. *Modeling Cumulative Outdoor Concentrations of Hazardous Air Pollutants, Volume 1: Text*. SYSAPP-99-96/33r2, Prepared for U.S. Environmental Protection Agency, Office of Policy, Planning and Evaluation, by Systems Applications International, Inc., San Rafael, CA.

4. California Air Resources Board. 1998. *Toxic Air Contaminant Fact Sheets*. Available at: http://www.arb.ca.gov/toxics/tac/tac.htm. (Last accessed March 2004).

Chapter 9 Assessing Air Quality: Modeling

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9.1 Introduction

Models have been used for decades to approximate physical systems and make estimates about the nature of the system under study. The types of models most frequently used in air toxics exposure assessments are mathematically-based models, which attempt to approximate all of the important physical and chemical processes affecting contaminant fate and transport within the environment. The physical and chemical processes are described as a set of mathematical expressions which characterize the behavior of contaminants released into the environment.

One specific type of model, called an **air quality model**, is used by EPA to understand the impact of pollution on air quality for a variety of purposes. For example, under the Clean Air Act (CAA), EPA uses air quality models to facilitate the regulatory permitting of industrial facilities, demonstrate the adequacy of emission limits, and project conditions into future years. For several of the criteria pollutants, regulatory requirements call for the application of air quality models to evaluate future year conditions as part of State Implementation Plans to achieve and maintain the National Ambient Air Quality Standards (NAAQS). Model simulations are also used to assist in the selection of monitoring locations.

Air quality models, when combined with emissions inventory and meteorological data, can be used as part of risk assessments that may lead to the development and implementation of regulations or voluntary reduction measures. For example, under National Air Toxics Assessments (NATA), EPA has conducted a national-scale assessment using air quality models for some 33 priority air toxics (see Chapter 2) to identify broad national air toxics issues and to help focus efforts. This Chapter provides an overview of air quality modeling used in air toxics risk assessments.

9.2 Air Quality Modeling

A variety of methods, data, and tools used for modeling the fate and transport of air toxics released to the environment have been developed; for a summary of methods, the reader can refer to Chapter 3 and other parts of EPA's *Residual Risk Report to Congress*.[1] While the Report to Congress is oriented toward assessment of residual (i.e., post-Maximum Achievable Control Technology [MACT]) risks from facilities regulated by the Clean Air Act, it also provides a good, general overview of general modeling procedures for air toxics assessments at the local scale. Another key reference for air quality models is the EPA's Support Center for Regulatory Air Models (SCRAM) website (http://www.epa.gov/ttn/scram/).[2]

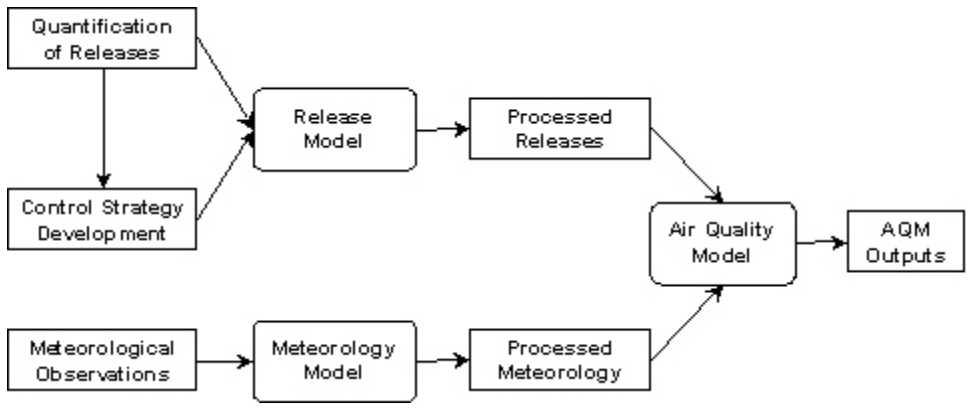
9.2.1 The Overall Structure of an Air Quality Model

Air quality models provide estimates of ambient air concentrations and/or deposition rates for one or more chemicals emitted from one or more sources. All air quality modeling systems are comprised of three major components (see Exhibit 9-1) which, when combined, provide a picture of predicted fate and transport of air toxics once released into the environment:

- An emissions (release) model (Chapter 7 discusses developing the emissions inventory);
- A meteorology model (Chapter 8 discusses atmospheric phenomena and physical properties that affect the fate and transport of air toxics after release); and

- An air quality model that predicts the movements of chemicals through the atmosphere along with any physical and chemical changes that may occur (e.g., chemical reactions that degrade the pollutant).

Exhibit 9-1. Basic Components of an Air Quality Modeling System



Specifically, the emissions and meteorology data are fed into the model (or the various components of the model) which are then run through various algorithms that simulate the physical and chemical processes in the atmosphere to provide estimated concentrations of chemicals (e.g., for inhalation exposure assessment, the exposure concentration at the point of exposure). Depending upon the specific model application being used, the release and meteorological data may simply be input to a single air quality model that includes both release and meteorological modules or the release and meteorological modules may be separated initially to "pre-process" the data and subsequently combined for the remaining calculations.

Air quality models provide estimates of ambient air concentrations at specific points distant from the source(s) being modeled. These are either predetermined within the model or selected by the analyst. In the simplest models (e.g., SCREEN3), the points are laid out along a vector (straight line) from the source. Many other models use a grid system to calculate ambient concentrations at specific exposure points at specified "nodes"(see Exhibit 9-2). The model does not always automatically provide an estimate of concentration at every desired location, and extrapolation to desired locations is often required. A discussion of where and how to choose exposure points is provided in Chapter 11.

Air Toxics Modeling Issues

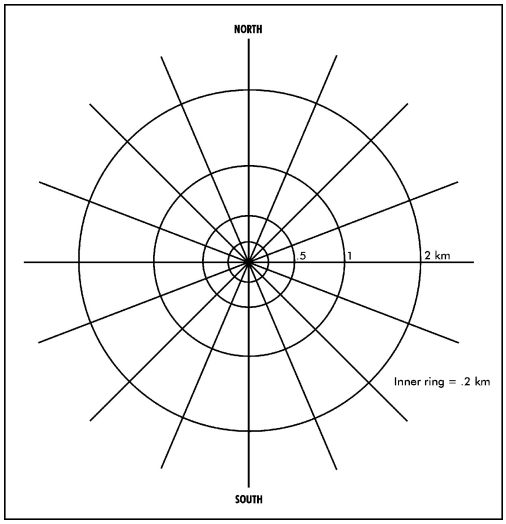
A recent study identified several issues that affect uncertainties associated with air toxics modeling, including:

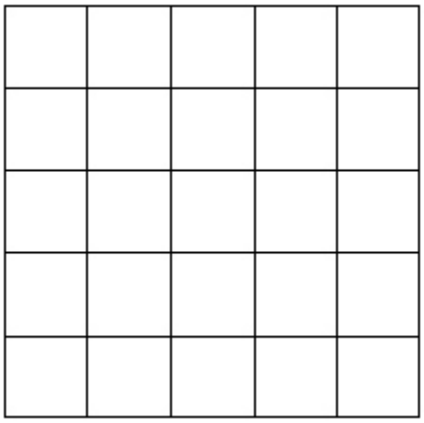
- Uncertainties associated with emissions;
- Meteorological conditions that are difficult to simulate (e.g., calm conditions, complex terrain, land/sea breezes, precipitation events);
- Spatial coverage, temporal resolution, and detection limits in monitoring data;
- Chemical transformations in the atmosphere;
- Removal via dry and wet deposition;
- Indoor sources; and
- Population activity patterns.

The study recommended a combination of modeling and monitoring for air toxics exposure assessments. For further information, see:

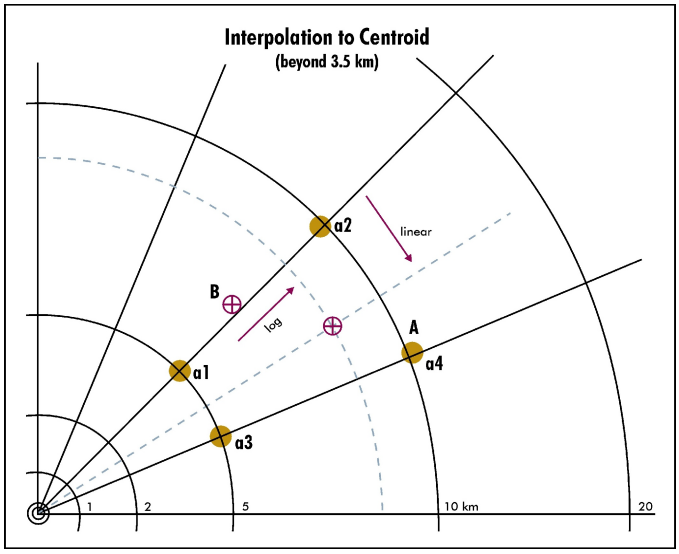
Coordinating Research Council and U.S. Department of Energy. 2002. *Critical Review of Air Toxics Modeling*, August 2002. CRC Project Number A-42-1, available at: http://www.crcao.com.

Exhibit 9-2. Model Grids and Interpolation





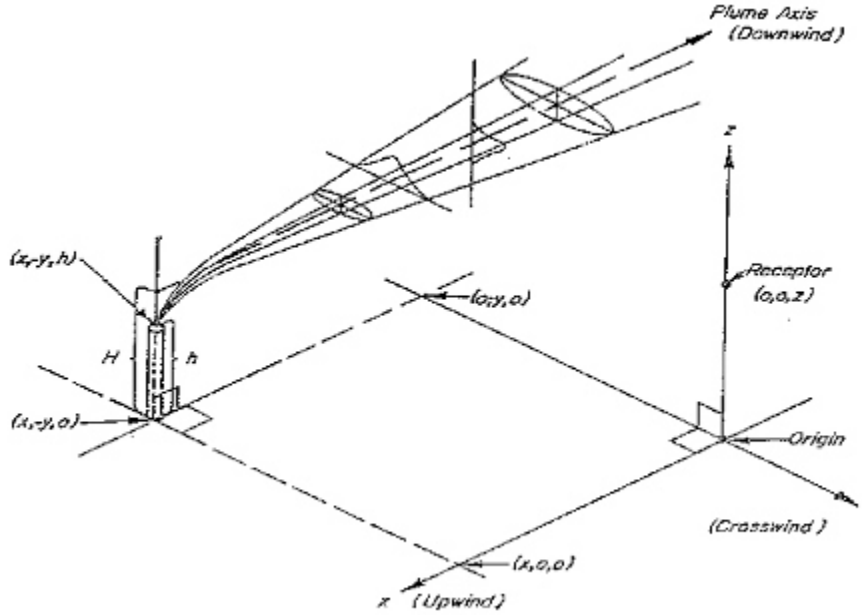
Many air quality models calculate ambient concentrations at specific exposure points at specified "nodes" using either a polar coordinate grid system (i.e., the intersections of a series of concentric circles and radial lines [above, left]) or on a standard Cartesian coordinate system (above, right). (Note that the nodes, in both of these types of grids, are simply the points where two lines intersect.) The locations of these nodes often do not fall precisely on the locations of interest for a given risk assessment.



In cases where the nodes and locations of interest do not align, a process of interpolation is used to estimate the ambient air concentration at the location. For polar grids, a two-step interpolation is used, starting with the modeled concentrations at the nearest locations (e.g., a1, a2, a3, and a4 in the graph to the left). The first interpolation is in the radial direction (i.e., along the two adjacent radial lines [a1,a2] and [a3, a4] in the graph). The concentration is estimated at the intersection of each radial line with the concentric circle that intersects the receptor location (at the same radial distance from the source as the internal point). This interpolation is performed under the assumption that the logarithm of the concentration decreases in proportion to the increase in the logarithm of the distance from the source (i.e., a log-log interpolation). The second interpolation is in the azimuthal direction (i.e., along the concentric circle that intersects the internal point). This interpolation is performed under the assumption that the change in concentration is proportional to the distance around the circle between the two radial lines (i.e., linear interpolation).

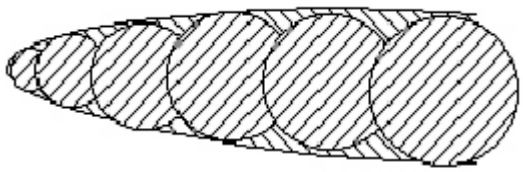
Illustrations of Three Common Types of Air Quality Models

Gaussian Plume Models: Model a continuous release downwind from a source

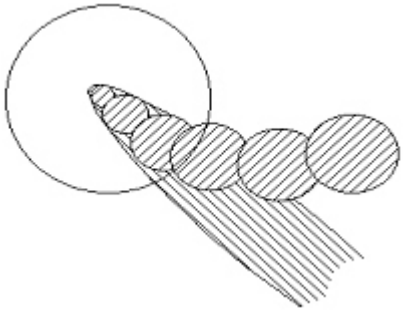


Gaussian plume models estimate the transport and mixing of pollutants in the dispersing plume as it moves downwind from the source. They assume that dispersion in the vertical and lateral dimensions will take the form of a normal Gaussian curve, with the maximum concentration at the center of the plume.[a]

Gaussian Puff Models: Model either Steady-state or Non-steady state releases



Steady-State Approach: Plume = Puff



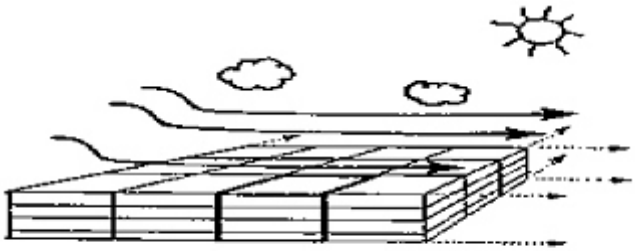
Non Steady-State Approach: Puffs follow Air

Puff models use a series of overlapping puffs to represent emissions. As shown by the illustration of the non-steady state approach, changes in wind direction over time and through space bring about changes in the plume's shape.[b]

Illustrations of Three Common Types of Air Quality Models (continued)

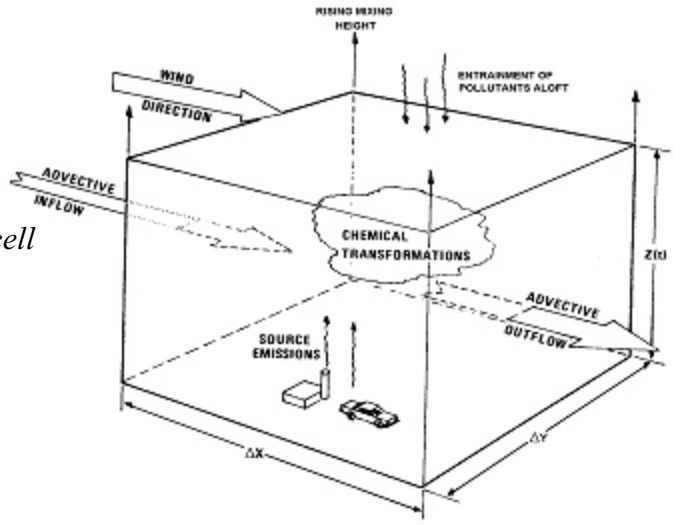
Numerical Grid Models: Model reactive pollutants in complex topography

Modeling Domain



Numerical grid models assume that emissions from area and line sources are mixed throughout the volume of each surface cell within the modeling domain. Emitted species react with each other and the incoming solar radiation with resulting chemical reactions taking place. Point source emissions, typically emitted from elevated stacks, are emitted into upper layers of the modeling domain based on a plume rise calculation. The point source emissions are then mixed throughout the volume of the elevated layer. Some models may modify this widespread dispersal by including a plume in grid module which acts to minimize the instantaneous mixing across the grid cell volume. These reactions are simulated to generate volume-average concentrations as a function of time within each cell.[c] The cells of the grid, representing discrete portions of the atmosphere, are superimposed on the modeling domain. [d]

Individual surface cell



[a] U.S. Environmental Protection Agency. 1970. Office of Air Programs, prepared by Turner, D.B. *Workbook of atmospheric dispersion estimates*. Publication AP-26. NTIS PB 191 482.

[b] National Oceanic and Atmospheric Administration. 2003. Prepared by Irwin, J.S. *Modeling Air Quality Pollutant Impacts*. Research Triangle Park, NC, 15 Oct. 2003. Available at: http://www.meteo.bg/EURASAP/40/paper1.html .

[c] U.S. Environmental Protection Agency. 1984. Office of Research and Development, prepared by Schere, K.L. and Demerjian, K.L. *User's guide for the photochemical box model (PBM)*.. Research Triangle Park. EPA-600/8-84-022a

[d] Systems Applications International. 1991-1993. Urban Airshed Modeling National Training Workshops.

Results from air toxic modeling are highly dependent upon the quality of data used as input to the models. The degree to which a user has reliable information on releases, meteorology, and setting will determine the accuracy of the modeled concentrations. Because model inputs are only estimates, even the most sophisticated models will have inherent uncertainties and will have the potential to underestimate or overestimate actual concentrations. (Monitoring data can assist in this regard as a way of evaluating the modeled results and to look for important gaps in the emissions inventory – see Chapter 10).

The uncertainty associated with the meteorology data includes measurement of key variables of wind speed/direction and atmospheric stability, and to a lesser extent, temperature and precipitation. Uncertainty is also associated with the terrain specification. Use of a model designed for flat terrain will likely provide inaccurate estimates of concentrations if the terrain is actually more complex (e.g., a facility located in a river valley modeled as being located on flat terrain).

In addition to the model inputs, uncertainties also arise from the model formulation used to describe the physical and chemical processes that take place in the atmosphere. In general, models are most accurate in simulating long-term averages of ambient concentrations and deposition rates in settings with simple topography.

9.2.2 Types of Models: Scientific Principles

In general, air quality models can be categorized as one of two types: **steady-state** and **non-steady state** models. The movement of mass away from the source (i.e., **advection**) and **turbulent diffusion** (e.g., dispersion) are modeled in both types of models. The steady-state model assumes that no variations occur over a certain time period (typically, one-hour); the non steady-state allows time-varying changes, but this capability imposes the need for additional model inputs, increased computation resources, and increased model formulation complexities. For additional information on air dispersion modeling, refer to NOAA's Real-time Environmental Applications and Display sYstem (READY) website.[3]

- **Steady-state models** are models which assume no time-varying processes occur over the period of interest. Hence, material released travels infinitely in only one direction over the time period (e.g., one hour). Often, these models assume that the material is distributed normally (also termed a "Gaussian distribution") and are thus called "Gaussian plume" models (see illustration above). The steady-state model typically uses meteorological information obtained near the source and assumes it holds true throughout the modeling region (e.g., a 50 kilometer radius). Wind direction, wind speed, and atmospheric stability are used to predict concentrations. This type of model is most widely used for stationary sources and for non-reactive pollutants (although models can take into account deposition and simple linear decay). The models are least applicable in areas with rapid time-varying conditions, over spatially varying terrain and land use, over large spatial scales (> 50 km), and where complex atmospheric chemistry takes place.

- **Non-steady state models** are models which can simulate the effects of time- and space-varying meteorological conditions on pollutant transport, transformation, and removal. The modeling region is typically divided into grid cells, and the model simulates movement of pollutants between cells by taking into account advection, degradation, and other physical

and chemical processes. These models are often used for chemically reactive pollutants or where there is complex topography or meteorology (e.g., complex sea breeze circulation). They require complex wind flow characterization and other detailed meteorological information for dispersion. For chemical transformation, they require information on the important chemical compounds as well as chemical kinetics to properly characterize the transformation and removal of air toxics. These models often take the form of grid models with the calculation of the physical and chemical processes taking place at each grid location. Other model types include "puff models" (illustrated above), which use a series of overlapping puffs to represent emissions. The calculations of the physical and chemical processes are made for each "puff."

Another type of non-steady state model, the atmospheric trajectory model, uses meteorological data and mathematical equations to simulate transport in the atmosphere. The position of a parcel of air with time are calculated based on externally provided meteorological data such as wind speed and direction, temperature, humidity, and pressure. Model results depend on the spatial and temporal resolution of the meteorological data used, and also on the complexity of the model itself. Simpler models may deal with only two-dimensional transport by winds assuming the material emitted into the parcel stays at the same level, while more complex models may include 3-dimensional chemical and thermodynamic processes such as aerosol formation, convection, and turbulent diffusion.

9.2.3 Modeling Deposition

Deposition is the transfer of chemicals from the plume to the earth's surface (i.e., to soil, water bodies, or living organisms such as plant surfaces). Although the primary route of exposure for many air toxics is inhalation of ambient concentrations, deposition rates can be important for the multimedia fate and transport assessments required for persistent bioaccumulative hazardous air pollutant (PB-HAP) substances (see Chapter 18). Air quality models all simulate ambient air concentrations, and many also simulate deposition. Based on the simulated ambient air concentration at a location, the **deposition flux** (i.e., mass of pollutant deposited per unit area) can be simulated based on a number of assumptions (see Chapter 8 for a discussion of mechanisms of deposition). Two types of deposition are usually modeled:

- **Dry deposition** is determined from the ambient air concentration and the deposition velocity. Particle-phase air toxics are the principal pollutants removed through dry deposition by particle settling. In addition, semi-volatile toxics (air toxics that exist both in the gas and particle phases) can also be removed through dry deposition. Dry deposition of some vapor-phase air toxics is also possible for some chemicals (e.g., divalent mercury).

- **Wet deposition** is determined from a combination of the ambient concentration and a **scavenging ratio**. The scavenging ratio accounts for the propensity of the modeled chemical to partition into precipitation in the atmosphere, based on physical and chemical characteristics of the pollutant, the nature of the precipitation (liquid or frozen), and the precipitation rate. The term "scavenger" is a general term that can apply to anything chemical or physical that removes a pollutant from the atmosphere. In this example, rain is a scavenger because it is removing (by dissolution) an air toxic from the atmosphere and transferring it to a surface.

9.2.4 Screening vs. Refined Models

The overall accuracy and precision of results determined by a model is generally proportional to the complexity of the model, which in turn affects input data requirements and overall resources.

- **Screening-level models** are designed to provide conservative (i.e., high) estimates, and are useful for applications such as identifying facilities and/or air toxics that appear likely to contribute the greatest risk among a group of sources and chemicals released. Data requirements are generally low (e.g., emission rates, some stack parameters), and running the models is generally easy and requires few resources.

- **Refined models** take into account more complex chemical behavior and a greater degree of site-specific information, generally producing more accurate results. Data requirements are higher (e.g., site-specific meteorology, terrain, chemistry data), and application of more refined models may require expert judgment in developing model inputs and setting model options. Some models can be used both as a screening model and refined model if additional site-specific information is used in the application.

The selection of a model for a specific application depends on a number of factors, including:

- The nature of the pollutant (e.g., gaseous, particulate, reactive, inert);
- The meteorological and topographic complexities of the area of concern;
- The complexity of the distribution of sources;

Exposure Concentrations: Units are Important

Air toxics exposure concentrations (ECs) should in general be reported as $\mu g/m^3$. Dose-response values often are reported as parts per million (ppm), parts per billion (ppb), or mg/m^3. In the risk characterization step, ECs are compared to dose-response values, and therefore the units for the EC must match the units for the dose-response values.

The conversion from mg/m^3 to ppm can be expressed as:

Concentration [ppm] = Concentration [mg/m^3] × 24.45 [L/mole] / MW

and the conversion from ppm to mg/m^3 is:

Concentration [mg/m^3] = Concentration [ppm] × MW / 24.45 [L/mole]

where MW is the molecular weight of the air toxic in g/mole and 24.45 is the volume in liters of one mole of an ideal gas at 1 atmosphere and 25 degrees Celsius.

Note also that ppb = 1,000 × ppm and that here, ppm is volume-based. Also, $\mu g/m^3$ = 1,000 × mg/m^3.

Tip: In the development of the analysis plan, stipulate that all laboratory and modeling results be reported in $\mu g/m^3$. This will save time (and reduce computational errors) in the remaining phases of the risk assessment.

- The spatial scale and temporal resolution required for the analysis;
- The level of detail and accuracy desired for the study and the amount of uncertainty that the analyst/risk manager is willing to accept; and
- The technical expertise of user.

For example, steady-state models are not considered appropriate for downwind distances beyond a 50 km range, primarily because the steady-state wind speed and direction over that distance become unrealistic over the typical one-hour simulation period. This is especially true where complex terrain or meteorology is present.

Because screening models are applied with fewer resources and data to provide conservative estimates of concentrations, screening models are often applied prior to any refined modeling in order to narrow the set of sources or air toxics to be modeled. Such an iterative approach is generally recommended by EPA, where screening results are used to generate a subset of potentially higher-risk sources or chemicals for more refined assessment. General guidance on screening-level modeling has been published by EPA.[4] Additional guidance on air modeling is incorporated into EPA's Guideline on Air Quality Models.[2]

Risk assessors generally work out the development of a modeling protocol to be used in the assessment during the planning/scoping and problem formulation phase of the assessment. Providing this protocol will help establish the modeling approach for not only review and comment by interested parties up front, but will help to establish technical credibility and provide for consensus building among all interested parties.

9.2.5 Specific Data Required for Modeling

As described above, meteorology, terrain, and emissions data are processed and used as primary input data for air quality models. Depending on the level of refinement of the model, the required input data for an air quality model will include (but not necessarily be limited to) the following parameters:

- **Emission rate**. In general, the rate at which emissions are released into the atmosphere are specified as a rate of release for each chemical in units of mass per unit time.

- **Physical/chemical characteristics of emissions**. These data are closely related to emission rates (i.e., from measurements and/or emission factors; see Chapter 7). For some models, the phase of emission must be specified (e.g., gas, particulate, or semi-volatile). For chemicals present as particulate matter or as semi-volatile substances, particle size distribution and fraction of particle phase as a function of temperature, for each chemical, may be necessary inputs. In some cases, information may only be available on the basis of total volatile organic compounds or total particulates. This information may be speciated based on the emissions source type through the use of sources such as EPA's SPECIATE database. (The most recent version of SPECIATE, Version 3.2, was last updated with new profiles in October 1999.) [5]

- **Type of release point**. The required input data, modeling approach, and model selected for assessment can depend on the type of release being modeled. Chapter 4 discussed types of sources from a regulatory perspective (e.g., stationary, mobile). The following discussion is focused on types of sources from a modeling perspective.

- **Point sources** (modeling sense) are releases from stacks and isolated vents, and typically have plume rise associated with the release due to the buoyancy or momentum of the effluent.
- **Area sources** (modeling sense) are sources which are usually low level or ground level releases with no plume rise (e.g., fugitive emissions from the summary of equipment leaks across a facility; uncontrolled emissions that escape from the windows along a building wall; releases of dust from a road or work site; slag dumps; storage ponds). Depending on the type of area source, the modeler may opt to evaluate it as emissions occurring from a two-dimensional surface (i.e., an area source in the modeling sense) or as a three-dimensional volume source (see below). If a large number of sources are to be modeled, a common approach is to spread these sources uniformly across the modeling domain if no appropriate spatial surrogate is available. Alternatively, these sources may be allocated based on spatial surrogates. Typical examples include census tract population and commercial, residential and industrial land-uses.
- **Volume sources** are releases that are modeled as emanating from a 3-dimensional volume (such as a box) . Examples include releases from conveyor belts or the collective releases from the gas pumps at service stations. Volume sources differ from area sources in that they have a vertical dimension to their release. Like area sources, they do not have plume rise.
- **Line sources** are releases that are modeled as emanating from a two-dimensional area. Examples include rail lines and roadway segments. Line sources differ from area sources in that they have aspect ratios (length to width) much higher than 10:1. Like area sources, they do not have plume rise.
- **Specialized release types** include multiple parallel release lines that result in increased buoyant dispersion (e.g., coke ovens, aluminum smelters); dense gas release; and exothermic gas release, jet-plume release and horizontal venting that may be defined and modeled using special techniques or models depending on the characteristics of the emission source.

- **Release point parameters**. Depending on the type of source being modeled, the user may need to specify the physical characteristics of the release point. Key parameters may include the following:
  - Release height above ground level (e.g., stack height, average height of fugitive emissions).
  - Area of the release point (for point sources, stack diameter; for area sources, length and width of the area across which releases occur).
  - Other stack parameters of the release stream for point sources that can alter the effective release height, which include temperature, stack orientation, the presence of obstructions to flow (i.e., rain caps), and exit velocity or flow rate. Flow rate is expressed in terms of the total volume of material released per unit of time. In general, most of the flow rate is made up of nontoxic exhaust gases, with a small fraction being composed of chemical contaminant.
  - Facility building dimensions, if building downwash (i.e., the effects on plume dynamics due to structures located near the source) is modeled.

- **Location of special receptors**. The location of known sensitive receptors (e.g., a school or day-care center) may be a critical input when determining where to model ambient concentrations. If these special receptor locations are not identified, the model will only

provide concentration estimates at the nodes of the modeling grid that is initially laid out around the source.

- **Information on the surrounding land-use and terrain heights**. For dispersion models, classification of the surrounding area as urban or rural is usually required (this classification can affect the rate of dispersion). In addition, more refined modeling that takes into account complex terrain (e.g., ground surfaces higher than release height elevation) will require terrain elevation data.

- **Chemical-specific data**. If transformation/removal is being modeled, rates of transformation or removal for the chemicals being modeled are required (transformation processes are discussed in Chapter 8).

- **Boundary or background concentrations**. Ideally, emissions from modeled source(s) are responsible for the modeled concentrations. However, background concentrations, or boundary conditions in the case of grid models, may be important contributors to the total concentrations. This is particularly relevant where modeled concentrations are compared to observed concentrations. There are three basic approaches to estimating background concentrations:

  – Default values based on supporting documentation from the literature (this is the simplest approach);
  – Data collected from monitoring stations within the study area; and
  – Estimates made from larger regional scale models that cover the study area.

  For grid type models, users should be aware that with a smaller modeling domain, there is more potential for the boundary concentrations to play a more important role in determining the total concentration.

In general, air quality modeling results will be most sensitive to the emission rate when studying a single or few release points. However, when studying multiple release locations over a broad area, source location becomes the most important parameter. For a Gaussian-type dispersion model (e.g., ISC3, AERMOD; see Section 9.2.7 below), the ambient concentration will be directly proportional to the emission rate (enabling the use of unit emission rates). Other inputs, especially stack height and distance to fenceline, can also affect the results because these parameters can have a direct impact on the location of higher ambient chemical concentrations and potential off-site receptors. In general, however, the sensitivity of air modeling results to specific input parameters can vary widely according to site-specific and chemical-specific factors. Site-specific analyses are generally required to derive accurate sensitivity results for a specific air modeling application. Additional discussion on sensitivity analysis can be found at the EPA Region 6 Air Modeling for Combustion Risk Assessments website.[6]

9.2.6 Sources of Air Quality Models and Information

Numerous models (both screening and refined) have been developed by EPA, other government agencies, and private sources. EPA models in particular undergo extensive evaluation and statistical measures of performance. Some private industry models are also available to the user at little or no charge. (If a public domain model is not available and a private model must be

used, the user should request information about the theoretical basis for the model and the result of any peer review.) Important sources of information include EPA's *Guideline on Air Quality Models*[2] and *Dispersion Modeling of Toxic Pollutants in Urban Areas: Guidance, Methodology and Applications*.[7] Both are available at EPA's SCRAM website (http://www.epa.gov/ttn/scram/), EPA's primary resource for Agency air modeling information.[2] At the SCRAM site, EPA maintains an up-to-date collection of the executable files, source codes, and user guidance for EPA air quality models. The EPA Office of Air Quality Planning and Standards maintains an on-line Air Pollution Training Institute (APTI) that is managed by the Education and Outreach Group (EOG) and offers additional information and training opportunities for air quality modelers.[8]

9.2.7 Examples of Air Quality Models

A variety of models are available for air toxics risk assessments, with some models having been designed for specific air toxics application. The SCRAM website provides detailed information regarding individual models, including software/code for each model, user's manuals, and other support documentation.

The extent to which a specific air dispersion model is suitable for the evaluation of air toxic source impacts depends upon several factors, such as the nature of the pollutant (e.g., gaseous, particulate, reactive, inert), the meteorological and topographic complexities of the area, the complexity of the source distribution, the spatial scale and resolution required for the analysis, and the level of detail and accuracy required for the analysis. For example, steady-state Gaussian plume models are not considered appropriate for downwind distances outside of the 0.1 km to 50 km range. Because of the assumption in Gaussian models of a steady wind speed and direction over the entire modeling domain for each hour, a > 50 km distance may be inappropriately long in many areas, especially where complex terrain or meteorology is present. In such cases, a non-steady state model would be more appropriate.

Exhibit 9-3 provides an overview of the key physical processes simulated in the most widely used air quality models oriented toward assessment of risks from facilities. Exhibit 9-4 shows the spatial and temporal scales over which these air quality models are typically applied. Exhibit 9-5 identifies some common applications for these air quality models.

> The Draft Guidance on the Development, Evaluation, and Application of Regulatory Environmental Models recommends best practices to help determine when a model, despite its uncertainties, can be appropriately used to inform a decision. The Knowledge Base (KBase) is a web-accessible database of information on some of EPA's most frequently used models. The draft guidance recommends what information about models to document, while the Knowledge Base is the repository where this information is documented. Both products are available at the CREM internet site at http://www.epa.gov/crem.

Finer scale models, such as CAL3QHC and CALINE4, are most typically applied to exposure studies from mobile sources. The UAM-TOX and CMAQ models are examples of models which can simulate photochemically active air toxic species, including secondary formation of pollutants like formaldehyde. Because the complex secondary formation processes are nonlinear and can occur at locations distant from the emission source, these models are designed to be applied to an exhaustive set of sources over a large region, rather than to individual facilities or small groups of facilities. The models more typically applied to single or

multiple facilities include SCREEN3, ISCST3, ISCLT3, AERMOD, ASPEN, CALPUFF, and UAM-TOX. Brief descriptions of these models are provided below. Some modeling studies have combined the application of a regional model with a neighborhood-scale model in order to address secondary and background concentration contributions, while capturing finer spatial resolution for primary pollutant predictions.

Community Multi-scale Air Quality (CMAQ) Modeling System

The CMAQ modeling system has been designed to approach air quality as a whole by including state-of-the-science capabilities for modeling multiple air quality issues, including tropospheric ozone, fine particles, toxics, acid deposition, and visibility degradation. In this way, the development of CMAQ involves the scientific expertise from each of these areas and combines the capabilities to enable a community modeling practice. CMAQ was also designed to have multi-scale capabilities so that separate models were not needed for urban and regional scale air quality modeling.

The target grid resolutions and domain sizes for CMAQ range spatially and temporally over several orders of magnitude. With the temporal flexibility of the model, simulations can be performed to evaluate longer term pollutant climatologies as well as short term transport from localized sources. With the model's ability to handle a large range of spatial scales, CMAQ can be used for urban and regional scale model simulations. By making CMAQ a modeling system that addresses multiple pollutants and different spatial scales, CMAQ has a "one atmosphere" perspective that combines the efforts of the scientific community. Improvements will be made to the CMAQ modeling system as the scientific community further develops the state-of-the-science. Additional information about CMAQ can be found at: http://www.epa.gov/asmdnerl/models3/cmaq.html.

SCREEN3

- Screening-level Gaussian dispersion model that estimates an hourly maximum ambient concentration based on an average, constant emission rate (concentration results can be scaled up to annual average using simple conversion factors as specified in EPA guidance;[4] results are not direction-specific (i.e., wind direction is not taken into account).

- Data requirements are relatively low; uses site-specific facility data (e.g., stack height, diameter, flow rate, downwash); does not use site-specific meteorology data.

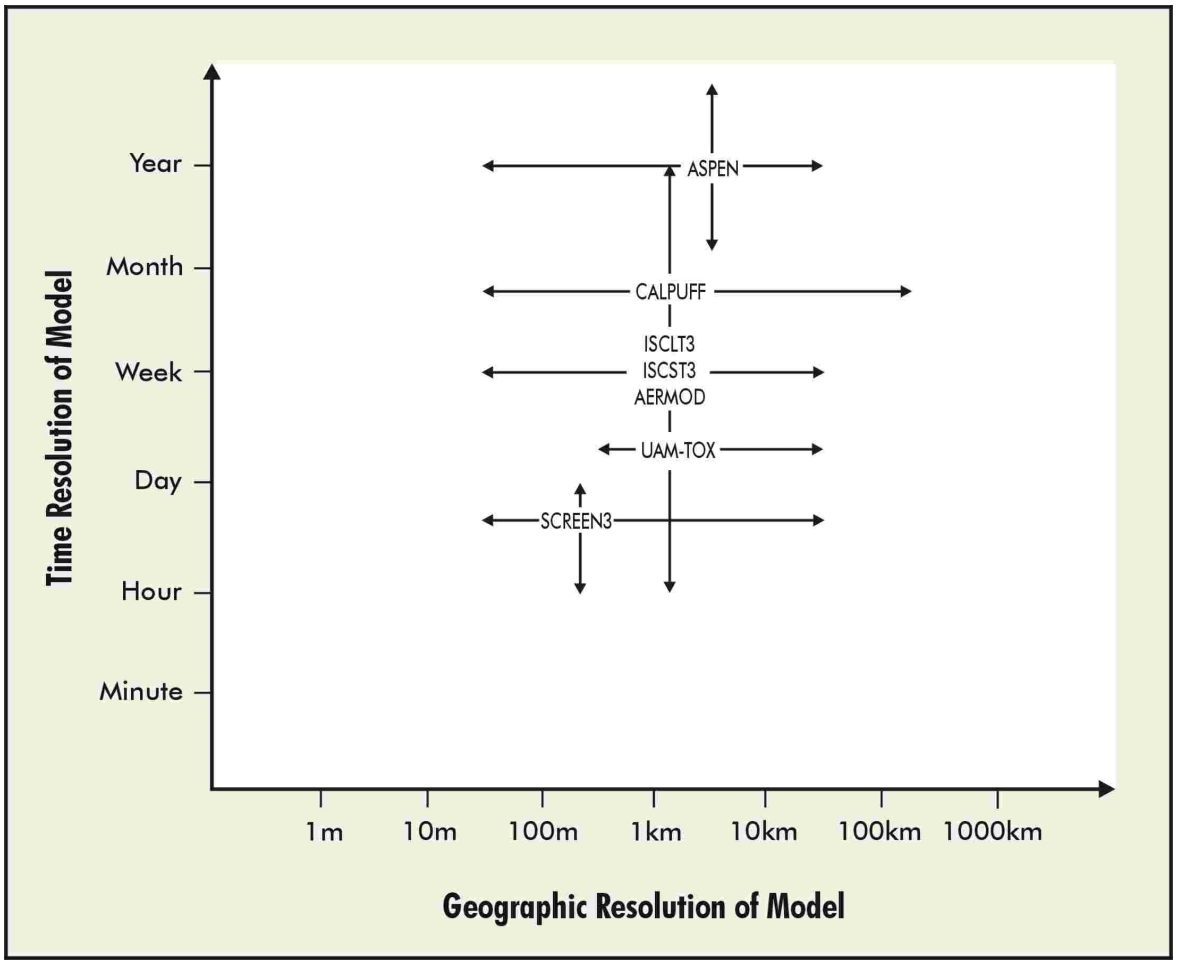
- Data processing requirements are low; easy to use for quick assessment of a single facility.

- Model does not estimate deposition rates.

Exhibit 9-3. Key Modeling Attributes of Some Widely Used Air Quality Models for Residual Risk Assessment							
Modeling Attribute	**SCREEN3**	**ISCST3**	**ISCLT3**	**AERMOD**	**ASPEN**	**CALPUFF**	**UAM-TOX**
Point	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Volume	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Area	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Meteorology	Built-in worst-case meteorology	Hourly (National Weather Service) or site-specific equivalent	Frequency array of meteorology data	Hourly (National Weather Service) or site-specific equivalent	Multiple hourly observations (National Weather Service or site-specific equivalent	Hourly user-defined 3-D fields, usually from a meteorological model with multiple meteorological stations	Hourly user-defined 3-D fields, usually from a meteorological model with multiple meteorological stations
Wet Deposition	No	Yes	No	Yes*	Yes	Yes	Yes
Dry Deposition	No	Yes	Yes	Yes*	Yes	Yes	Yes
Complex Terrain	Yes	Yes	No	Yes	No	Yes	Yes
Overwater Effects	No	No	No	No	No	Yes	No
Vertical Wind Shear	No	No	No	Yes	No	Yes	Yes
Building Downwash	Yes	Yes	Yes	Yes	Yes	Yes	No
Model Formulation and Plume Distribution	Steady-state, Gaussian	Steady-state, Gaussian	Steady-state, Gaussian sector average	Steady-state Gaussian stable & neutral conditions, bi-Gaussian in unstable conditions	Steady-state, Gaussian sector average	Non-steady-state, Gaussian puff	Non-steady-state grid model
Chemical Transformation	None	Simple decay	Simple decay	Simple decay (SO_2)	Difference between precursor inert and precursor decay	Simple psuedo-first-order effects	Complete chemical mechanism for most gas-phase toxics
Relative Complexity	Simple	Moderate	Moderate	Moderate	Moderate	Complex	Complex

*AERMOD version 02222 is now available for review and comment on EPA's SCRAM website (http://www.epa.gov/scram001/).
This version includes algorithms for dry and wet deposition as well as an improved downwash algorithm known as PRIME.

Exhibit 9-4. Spatial and Temporal Scales of Widely Used Air Quality Models



This figure illustrates the geographic and temporal resolution of several widely used air quality models. For example, the screening-level model SCREEN3 has a spatial resolution of 50 m to 50 km, but a temporal resolution of 1-24 hours. In contrast, ISCST3 has the same spatial resolution (50 m to 50 km), but has a temporal resolution from 1 hour to 1 year.

Industrial Source Complex - Short Term (ISCST3)

- Gaussian dispersion model (more advanced than SCREEN3); estimates average annual ambient concentration by modeling hourly emissions, and meteorology includes removal effects for wet and dry deposition flux for any locations specified by the user.

- Data requirements are higher than for SCREEN3; requires hourly, site-specific, processed meteorological data, physical characteristics of emissions, and terrain information. Model can accommodate variable emission rates.

- More expertise is required to use model (compared to SCREEN3); user should possess specific technical and computer skills.

Exhibit 9-5. Typical Applications for Common Dispersion Models						
	Averaging Period	**Terrain Type**	**Single Source**		**Multiple Sources**	
			Rural	**Urban**	**Rural**	**Urban**
Screening Models	Short Term (1-24 hour average)	Simple	SCREEN3	SCREEN3	ISCST3, AERMOD	ISCST3, AERMOD
		Complex	SCREEN3, ISCST3	SCREEN3, ISCST3	ISCST3	ISCST3
	Long Term (Monthly-Annual)	Simple	ISCLT3	ISCLT3	ISCLT3, ASPEN	ISCLT3, ASPEN
		Complex	ISCST3	ISCST3	ISCST3	ISCST3
Refined Models	Short Term (1-24 hour average)	Simple	ISCST3, AERMOD	ISCST3, AERMOD	ISCST3, AERMOD	ISCST3, AERMOD, UAM-TOX
		Complex	AERMOD, CALPUFF	AERMOD, CALPUFF	AERMOD, CALPUFF	AERMOD, UAM-TOX, CALPUFF
	Long Term (Monthly-Annual)	Simple	ISCST3, AERMOD	ISCST3, AERMOD	ISCST3, AERMOD	ISCST3, UAM-TOX, AERMOD
		Complex	CALPUFF, AERMOD	CALPUFF, AERMOD	CALPUFF, AERMOD	CALPUFF, UAM-TOX, AERMOD

Industrial Source Complex - Long Term (ISCLT3)[(a)]

- Similar to ISCST3, but uses seasonal frequency distribution of meteorological inputs rather than hourly data; runs more rapidly than ISCST3, but can only produce concentrations averaged over a relatively long period of time; not considered as accurate as ISCST3.

- Unlike ISCST3, it cannot simulate wet deposition or complex terrain (terrain higher than the stack height).

[a]EPA is no longer actively updating the model with improvements or additional capabilities. It still is one of EPA's preferred models and can be used in appropriate situations. For most single or limited source applications, the ISCLT3 model can be used without any overwhelming computational burden.

AMS/EPA Regulatory Model (AERMOD)

- Replacement model for ISCST3 using new or improved algorithms on the parameterization of the earth's boundary layer turbulence and state-of-the-science dispersion modeling; deposition algorithms should be available soon.

- Like ISCST3, is a Gaussian formulated model.

- Similar to ISCST3, but includes dispersion algorithm for both convective and stable boundary layers and allows plume penetration into elevated inversions.

- Incorporates new algorithms for building downwash.

- Unlike ISCST3, it simulates vertical profiles for wind, turbulence, and temperature.

- No wet or dry deposition (although planned future improvement).

- Requires surface characteristics as inputs (e.g., albedo, Bowen ratio, surface roughness), which allow user to differentiate between different types of terrain.

ASPEN

- A Gaussian dispersion model used to estimate toxic air pollutant concentrations over a large scale domain from regional to continental scale. (This is the model used for NATA risk characterization analyses.)

- Employs a dispersion algorithm similar to ISCLT3.

- However, unlike ISCLT3, it includes treatment of wet deposition for particles, and more detailed treatment of chemical transformation than ISCLT3 or ISCST3, although less detailed than UAM-Tox.

- In contrast to ISCLT3, ASPEN can utilize meteorological information from several locations, and includes a simplified treatment of secondary formation of gaseous air toxics.

CALPUFF

- A Gaussian puff model designed for long-range transport (> 50km) assessment, but may also be applied for near-source in situations with complex meteorology. As described previously, a puff represents a continuous plume as a number of discrete packets of pollutant material.

- Has all the functional capabilities of ISCST3, but also includes capabilities for including 3-dimensional wind fields, vertical wind shear, and overwater effects.

- Not as extensively evaluated and tested as ISCST3 model.

- Requires a substantially higher level of air quality modeling expertise to use the model (compared to ISCST3).

UAM -Tox (Urban Airshed Model - Toxics Version)

- A three-dimensional, grid-type model used to model pollutants in urban areas. Derived from the Urban Airshed Model (UAM), designed to calculate ozone concentrations under short-term, episodic conditions lasting three to four days resulting from emissions of oxides of nitrogen (NOx), volatile organic compounds (VOC), and carbon monoxide (CO).

- Simulates the most photochemically active air toxics (i.e., acetaldehyde, 1,3-butadiene, and formaldehyde), as well as secondary formation of acetaldehyde and formaldehyde, tracking primary and secondary fractions separately.

- Requires a substantially higher level of air quality modeling expertise to use this model (compared to ISCST3).

9.2.8 Emissions from Soil

In addition to the air quality models described above, it is sometimes necessary to model emissions of chemicals from soil. Emissions from soil may occur as a result of the volatilization of chemicals from contaminated soil or as a result of the resuspension of study area soils. Models that predict emission rates for volatile chemicals or dust require numerous input parameters, many of which are study area-specific. For volatile chemicals, emissions models are available from several EPA sources.[9] Emissions due to suspension of soils may result from wind erosion of exposed soil particles and from vehicular disturbances of the soil. To predict soil or dust emissions, a number of modeling approaches have been developed. These include EPA's fugitive dust model for a site-specific assessment.[10] For road dust, other techniques are generally used.[11] After emissions have been estimated or measured, air dispersion models can be applied to estimate air concentrations receptor points.

In addition, chemicals in contaminated soils and groundwater may also evaporate into homes and buildings through cracks in the floor. The models used to assess these types of exposures (often called "basement models" because this type of problem can be exacerbated when a room is buried in the contaminated medium) are commonly used by hazardous waste site cleanup risk assessors to determine whether people living on or near contaminated sites are being adversely affected by chemicals evaporating into their living or working spaces. This type of analysis is less common for ambient air toxics risk assessment of the type that will generally be performed in an urban setting or in the evaluation of source impacts on nearby populations. However, this issue does come up on occasion and the topic is mentioned here for completeness.

One of the primary vapor intrusion models is the Johnson and Ettinger model (http://www.epa.gov/oerrpage/superfund/programs/risk/airmodel/johnson_ettinger.htm), and EPA has developed a users guide for evaluating vapor intrusion into buildings through the use of this model (http://www.epa.gov/superfund/programs/risk/airmodel/guide.pdf).

Another chemical, radon, is also an issue for homes and buildings in certain parts of the country (see Chapter 2). EPA's Indoor Environments Division (http://www.epa.gov/iaq/) provides a comprehensive set of informational materials on risks associated with radon and mitigation methods (see http://www.epa.gov/iaq/radon/pubs/).

9.3 Air Quality Modeling Examples

EPA's Air Toxics Community Assessment and Risk Reduction Projects Database has been compiled to provide a resource of planned, completed, and ongoing community-level air toxics assessments across the country. The projects included in the database provide examples of the applications of air quality modeling at real-world sites. Project descriptions and related information can be obtained from the database website at: http://yosemite.epa.gov/oar/CommunityAssessment.nsf/Welcome?OpenForm.

Additional Reference Documents

Although the list of following documents are now somewhat dated in terms of computational limitations for application of the models, the documents do provide overall methodology and guidance on procedures to consider when conducting air toxic modeling:

Guidance on the Application of Refined Dispersion Models for Hazardous/Toxic Air Releases, USEPA/OAQPS, Research Triangle Park, NC, EPA-454/R-93-002, May 1993.

Air/Superfund National Technical Guidance Study Series, Volume V - Procedures for Air Dispersion Modeling at Superfund Sites, EPA/OAQPS, Research Triangle Park, NC, February, 1994.

Dispersion Modeling of Toxic Pollutants in Urban Areas, Guidance, Methodology And Example Applications, EPA/OAQPS, Research Triangle Park, NC, EPA-454/R-99-021, July 1999.

Guidelines on Air Quality Models. 40 CFR Part 51 and Part 52, Appendix W; Environmental Protection Agency, AH-FRL-5531-6.

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Chapter 10 Assessing Air Quality: Monitoring

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10.1 Introduction

In environmental investigations, the term "monitoring" describes the collection of actual samples of environmental media and then subjecting those samples (usually) to chemical analysis to determine the identity and concentration of the various pollutants in the sample. A distinction may also be made between sampling (i.e., stack testing) and monitoring (i.e., for ambient concentrations). In air toxics risk assessment, this process commonly consists of collecting air samples and either evaluating the samples at the monitoring station itself, or sending them to a laboratory for evaluation.

For air toxics risk assessments, monitoring and analysis can help determine the concentration of both those pollutants in air and those that have migrated into other media, such as soil, water, sediments, and biota. This chapter discusses the use of monitoring to evaluate pollutants in air. Chapter 19 discusses the use of monitoring in media other than air.

Many aspects of a monitoring program will depend on the spatial scale of the assessment being supported by the measurement program:

- **Micro-scale** – highly localized regions up to 100 meters in size; these might reflect city blocks or individual households.

- **Middle-scale** – regions of several blocks with sizes of 100 to 500 meters.

- **Neighborhood-scale** – an extended area with uniform land use (and, hence, relatively homogeneous receptor population), extending up to several kilometers in size.

- **Urban-scale** – overall city or county conditions, perhaps up to 50 km in size.

- **Regional- or national-scale** – a state, several states, or the entire nation.

Air toxics risk assessments often examine exposure to relatively large numbers of people over relatively large geographic areas (e.g., a neighborhood or urban area, county, or larger). In these instances, the risk managers and analysts must carefully use their planning and scoping activities to develop the questions they want to answer and identifying the types of data they will need to answer those questions. For some questions and data needs, monitoring is the preferred tool for estimating inhalation exposure concentrations for air toxics risk assessment, either as the primary way of determining concentrations in air or as a way to test and normalize model results (and look for gaps in the emissions inventory).

This chapter provides an overview of monitoring, including recent advances by EPA (Section 10.2); the reasons for monitoring (Section 10.3); how to plan a monitoring program (Section 10.4); implementation (Section 10.5); available air monitoring methods (Section 10.6); archiving monitoring data (Section 10.7); and using monitoring data to evaluate source contribution (Section 10.8).

10.2 Air Toxics Monitoring: Recent Advances

EPA recently published a draft *National Air Toxics Monitoring Strategy* that describes the structure of the national air toxics monitoring program, including its history, status, and expected products.[1] At the start of the program, EPA's focus was on "nationally pervasive" priority pollutants. In recent years, EPA has initiated local scale monitoring studies to address potential air toxics problem areas.

EPA's Ambient Monitoring Technology Information Center (AMTIC)

AMTIC (http://www.epa.gov/ttn/amtic/welcome.html) is centered around the exchange of ambient monitoring related information. Established in 1991 as an electronic Bulletin Board System (BBS), AMTIC has evolved with changing technology into a page on the World Wide Web. AMTIC is operated by EPA's Office of Air Quality Planning and Standards (OAQPS) through the Monitoring and Quality Assurance Group (MQAG). AMTIC contains information on all the Reference and Equivalent methods for the Criteria pollutants, the toxic organics (TO) Methods for air toxics and other noncriteria pollutant methodologies, Federal Regulations pertaining to ambient monitoring, ambient monitoring quality assurance/quality control (QA/QC) related information, information on ambient monitoring related publications, ambient monitoring news, field and laboratory studies of interest, and updates on any new or developing EPA Ambient Air standards.

EPA's air toxics monitoring is structured into four groups – national level, local scale, persistent bioaccumulative toxics (PBTs), and "other" EPA-specific programs.

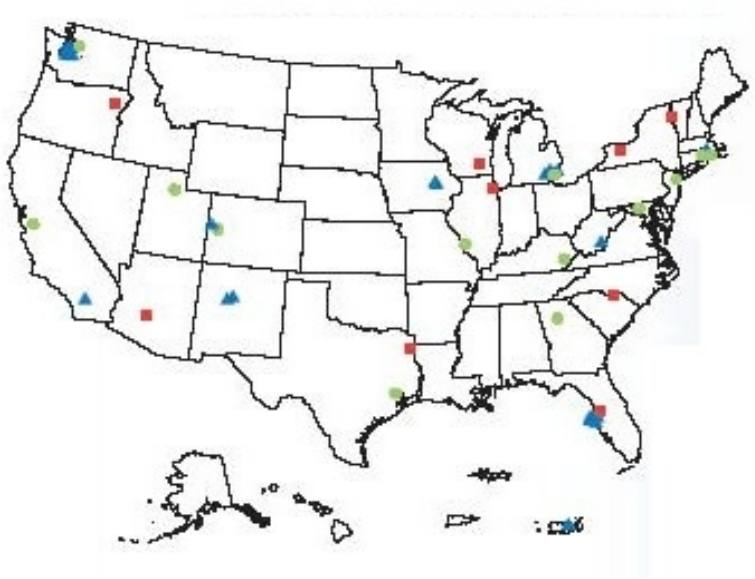
- The National Air Toxics Trends System (NATTS) program is a network of monitoring stations at 22 urban or rural locations across the country (see Exhibit 10-1). The focus for these sites is on seven "nationally pervasive" priority pollutants (formaldehyde, arsenic, chromium, benzene, 1,3-butadiene, acrolein, and light absorbing carbon). All of the stations are expected to become operational in early 2004.

- Local scale monitoring studies are designed to complement NATTS, but they are shorter-term (less than 2 years) and have more flexible study requirements to go beyond the scope of the NATTS. Local-level studies provide information of urban/local interest that is not achievable with a single monitoring site at a city. For example, these studies may address specific source categories or better characterize pollutant levels associated with different locations in a metropolitan area. EPA plans to implement 10 to 15 local scale monitoring projects that are implemented by state, local, and tribal (S/L/T) air pollution control agencies.

- Programs that monitor atmospheric deposition of PBTs include (1) the National Atmospheric Deposition Program – Mercury Deposition Network (NADP – MDN), a multi-agency program with approximately 90 monitoring sites; (2) the Integrated Atmospheric Deposition Network (IADN), a partnership between EPA and Canada, which is measuring PBTs in the Great Lakes Region; and (3) the National Dioxin Air Monitoring Network (NDAMN), a 30-site research program.

- A variety of EPA Regional air toxics monitoring activities that existed prior to NATTS continue.

Exhibit 10-1. National Air Toxics Trends Stations (NATTS) Sites



January 2003 Startup ●	January 2004 Startup ■	Pilot Programs ▲
Providence, RI	Chittenden County, VT*	Barcelona/San Juan, PR
Roxbury, MA	Rochester, NY	Providence, RI
New York, NY	Tampa, FL	Keeney Knob, WV*
Washington, DC	Chesterfield, SC*	Tampa, FL
Decatur (Atlanta), GA	Chicago, IL	Detroit, MI
Hazard, KY*	Mayville, WI	Rio Rancho, NM
Detroit, MI	Harrison County, TX*	Cedar Rapids, IA
Deer Park (Houston), TX	Phoenix, AZ	San Jacinto, CA
St. Louis, MO	La Grande, OR*	Grand Junction, CO*
Bountiful, UT		Seattle, WA
Grand Junction, CO*		
San Jose, CA		
Seattle, WA		* rural site

Source: EPA's *Latest Findings on National Air Quality*[2]

EPA has encouraged a significant effort over the past few years to increase reporting of air toxics sampling results to EPA's AirData database website (http://www.epa.gov/air/data). For example, the Lake Michigan Air Directors Consortium (LADCO), the Northeast States for Coordinated Air Use Management (NESCAUM), and the California Air Resources Board (CARB) "mined" existing data from approximately 300 existing monitoring sites across the U.S. to provide information about the spatial pattern, temporal profile, and general characteristics of air toxics compounds. EPA collected additional data for this analysis from a year long monitoring study carried out in four urban areas and six smaller city/rural areas. A number of reports, newsletters, and related documents describing EPA's air toxics monitoring efforts are available at EPA's Ambient Monitoring Technology Information Center website.[3]

10.3 Monitoring for Air Toxics Risk Assessments: Why Monitor?

Air toxics programs have long used monitoring to evaluate the concentration of chemicals in air. In general, monitoring (sampling and analysis) results may help:

- Identify and estimate current exposures to ambient concentrations of air toxics (outdoor and/or indoor) at a specific location of concern (e.g., a school or neighborhood). As an example, EPA tracks ozone concentrations at numerous locations around the country, with results available over the Internet (http://www.epa.gov/airnow/) for many locations, virtually in real-time. As another example, air toxics monitoring can be used to evaluate the impacts of a specific source on a nearby receptor ("source-oriented" monitoring).

- Develop or refine values for specific parameters needed by air dispersion models (for example, study-specific release data, meteorological conditions).

- Validate the predictions of a model in specified circumstances (e.g. validate that the location of highest exposure predicted by the model is correct, which increases confidence that a maximally exposed subpopulation has been identified – may be difficult to do without a very dense monitoring network).

- Track trends in air quality levels (e.g. to determine whether air pollution programs have generally been effective at reducing exposures).

- Identify gaps in emissions inventories (e.g., monitoring identifies an airborne chemical that is not reported in existing emissions inventories) or close gaps that might be present in existing data (e.g., concentrations of specific air toxics in specific releases).

- Determine compliance with air toxics legal requirements (e.g., permit limits at a factory, emissions limitations on motor vehicles).

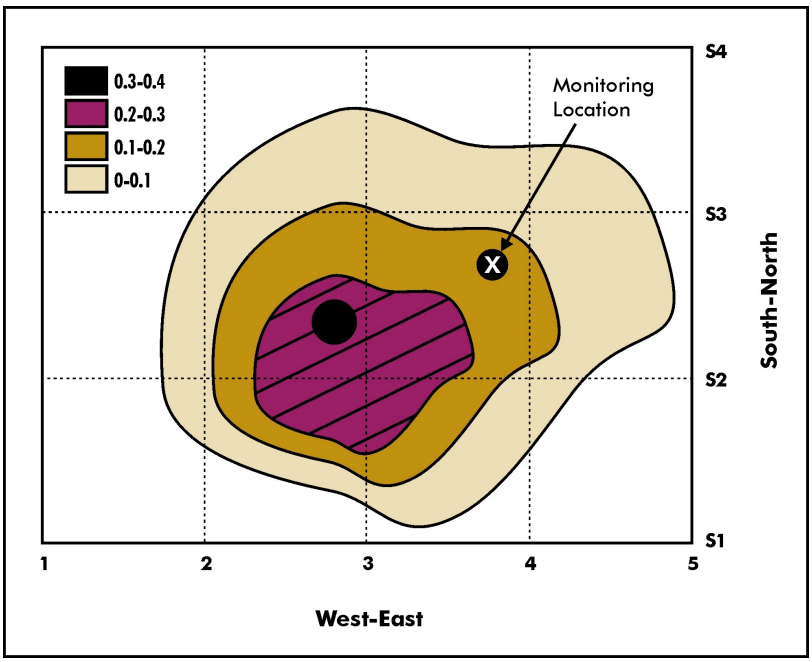
- Gather data in support of enforcement actions.

Ultimately, the choice of whether to monitor or model (or both) depends on the goals of the assessment, the exposure setting, other specific project circumstances (e.g., many communities want monitoring as part of a risk assessment), and the assessing entity. For example, to understand the exposure an actual individual receives as they move about their daily activities, personal monitoring is the best option because it reflects the pattern of this movement. However, such studies are rarely done outside of research settings. As another example, compliance with a permitted release rate may also require monitoring as the preferred method of measurement. Exhibit 10-2 provides a brief comparison of modeling versus monitoring.

Exhibit 10-2. Comparison of Modeling and Monitoring Approaches for Estimating Ambient Air Exposure Concentrations (ECs)	
Modeling	**Monitoring**
Modeling is relatively fast and inexpensive compared to monitoring. Many screening-level models can be run in spreadsheet formats and require relatively simple input parameters. Many dispersion models, along with technical reference manuals and other support documents, are available for free download from EPA's Support Center for Regulatory Air Models (SCRAM) website (http://www.epa.gov/ttn/scram/). Resources normally need to be expended to enhance the local air toxics emission inventories to make air toxics modeling more precise.	With monitoring, it takes time to build data, and there are methodological limits and logistical issues. How expensive monitoring is depends on what you are trying to do and how much you are willing to pay. Monitoring does not always require equipment purchase, and some states and local areas already have equipment. Some less expensive monitoring techniques are now available (e.g., passive samplers).
Modeling results can estimate concentrations over a large spatial area (e.g., a 50-km radius from a source) and can provide a "big picture" view of the assessment area. Modeling also allows for analysis of EC at multiple points throughout the assessment area. The downside of modeling, however, is that these are predicted concentrations.	Monitoring results provide actual measured concentrations. Multiple locations may be required to characterize concentrations over an area, although Geographic Information Systems (GIS) methods facilitate interpolation between locations. The downside is that the monitoring may not be representative of a large geographic area.
Screening-level models can provide a predicted estimate of whether significant concentrations are likely. A simple screening analysis may be sufficient to make a risk management decision that no action is required.	Monitoring can be used to identify and measure exposures for specific individuals at a specific location of concern (e.g., a school). This data can provide a quick screen to determine whether more extensive monitoring is needed.
Models can be used to identify areas where maximum concentrations are likely to occur, and thus where to focus efforts for additional tiers of the assessment. Uncertainties in model parameters and the discrete division of the wind field used in models (often with only eight wind directions) can result in incorrect identification of the locations of maximum concentration.	Monitoring can identify areas and actual levels of exposure occurring at the monitoring sites. Monitoring can also be used to indicate the point of maximal exposure if the monitoring is designed for that purpose. The selection of the monitoring locations is critical; if placed in the wrong locations, monitors can provide incorrect and misleading information about maximal exposures.
Models can be used to identify the subset of chemicals of potential concern (COPCs) and exposure pathways/routes that have the greatest contribution to risk. This can be helpful in focusing efforts for additional tiers of the assessment as well as determining appropriate risk management actions.	Monitoring can be used to confirm significant exposure pathways and routes. (Measured concentrations can be compared to risk-based screening levels). It also can be used to identify compounds that may not have been suspected and, hence, were not included in models (i.e., monitoring allows identification of gaps in the emissions inventory).
Models allow "what if" scenarios to be evaluated (e.g., what if a permitted emission were doubled?).	Monitoring can only evaluate current conditions.
More complex modeling may allow explicit predictions and estimates of variability in exposure.	A large number of samples generally is needed to characterize variability; this may be prohibitively expensive. Monitoring, however, provides a direct and reliable means to characterize variability.
Models often use simplifying assumptions and data inputs that may or may not be representative of the specific assessment area. This introduces uncertainty into model predictions.	Monitoring can be used to confirm actual exposure levels, to investigate assumptions or calibrate models to site-specific conditions, and to close gaps in data, reducing uncertainties.

Air toxics risk assessments, however, tend to examine potential exposures to hazardous air pollutants (HAPs) and other air toxics for a relatively large number of people over relatively large geographic areas (e.g., a neighborhood or urban area, county, or larger). In these instances, the risk managers and analysts must carefully use their planning and scoping activities to develop the questions they want to answer and to identify the types of data they will need to answer those questions. For some questions and data needs, monitoring is the preferred tool. For others, modeling is better. In general, most air toxics risk assessments will benefit from some combination of both modeling and monitoring to provide the depth and breadth of information that will be necessary to answer the assessment questions (see hypothetical example in Exhibit 10-3).

Exhibit 10-3. Hypothetical Example of a Combined Modeling and Monitoring Program



This figure illustrates a hypothetical set of isopleths for annual average air concentrations that a dispersion model predicted, assuming a single source (black dot) near the center of the geographic region. Note that the model predicts the point of maximal exposure to be somewhere within the area bounded by grid points 2, 4, S1, and S3, based on the existing information on release rate, wind direction, and effective release height. In this hypothetical example, a monitoring station was used to measure ambient concentrations as a means of evaluating the model predictions. Note that the monitoring location is not in the area of estimated highest concentration and, therefore, might not provide a better estimate of maximum exposure.

Indeed, most air toxics risk assessments that evaluate exposures to populations receiving impacts from one or more sources should generally consider using modeling as their primary tool to evaluate and characterize exposures and risks. In certain instances, assessors may use monitoring as the primary tool to evaluate exposure concentrations for potentially exposed populations. The utility of modeling for neighborhood and larger scale analyses is that it provides a better picture of the variation of exposure conditions over the assessment area domain (i.e., modeling provides spatial resolution) and allows a more straightforward approach to source allocation (i.e., what portion of the risk is caused by each of the modeled sources).

Monitoring, on the other hand, only provides estimates of concentrations at the point at which samples are taken, and it is often difficult to clearly define the spatial coverage that those measured concentrations represent. In addition, it is often difficult to use monitoring data for source allocation (especially for chemicals emitted by numerous sources). Monitoring plays a crucial role in identifying important chemicals that the emissions inventories may not have captured. In rarer instances, assessors can use monitoring as the primary tool to evaluate exposures for potentially exposed populations; however, this method carries a corresponding increase in the uncertainty of the results (see Section 10.4 on how to use ambient monitoring data to develop estimates of exposure concentration). (Note that, in limited circumstances, geostatistical techniques such as kriging are sometimes applied to estimate concentration variation between a set of monitors. This topic is beyond the scope of this reference manual; however, assessors are encouraged to carefully consider the uncertainties associated with this type of approach and whether alternate tools, such as air dispersion modeling, would provide a better understanding of concentration gradients across the study area. In addition, the average concentration of atmospheric pollutants across a study area is sometimes estimated by averaging the results of all the monitors in the area. However, since pollutant concentration can change rapidly across space and time, combining data across monitors may "average out" very important information about exposure at a particular monitoring location. It is for this reason that combining data across monitors is not commonly performed and assessors are encourage to carefully consider the pros and cons of attempting such an analysis. If monitors are combined, the results should, nevertheless, be reported alongside the results of each of the individual monitors.)

If assessors make the choice to implement a monitoring program, it is important to carefully design the sampling and analysis approach to provide meaningful input into the risk management decision. Because sampling and analysis are relatively expensive and time consuming, a well-designed monitoring program can ensure the efficient use of resources. Well designed and implemented monitoring programs quantify not only the concentrations but also information related to the associated data uncertainty. The study-specific conceptual model and analysis plan that assessors develop during the planning and scoping phase help ensure a well-designed sampling and analysis program that will yield results suitable for decision-making purposes. Monitoring programs are commonly designed to:

- Use a sampling methodology that results in scientifically defensible data and that meets regulatory criteria or other concerns – it is important to utilize methodologies that are scientifically defensible and acceptable within a regulatory context;

- Identify and quantify air toxics (or their breakdown products) of interest with respect to contribution to risk in all media of interest (including, in some cases, non-air media; see Chapter 19);

- Attain quantitation requirements (e.g., quantitation limits) sufficient to compare to dose-response values (e.g., the sensitivity should be sufficient to allow reliable measurements below concentrations anticipated to produce adverse health effects);

- Demonstrate acceptable confidence in the data set to be used for decision-making based on quality assurance benchmarks including benchmarks for precision, accuracy, representativeness, completeness, and comparability; and

- Provide for a clear and unambiguous data validation and reporting methodology so monitoring results can be tracked, verified, and validated when they are used in decisions.

The design of a monitoring program that meets data quality objectives (DQO) and quality assurance project plan (QAPP) requirements depends on the answers to four questions:

1. **What is the risk management decision to be made, and how will assessors use monitoring results in that decision?** Monitoring programs typically are a component of risk assessments that support risk management decisions; these decisions normally focus on how best to reduce risks from exposure to air toxics through reducing or otherwise limiting emissions.

Quality Assurance Project Plan (QAPP) and Data Quality Objectives (DQO) Process

As Chapter 6 introduced, a QAPP is part of the overall risk assessment analysis plan that ensures the quality of data used in decisions. Generally included in the data quality program is the DQO process, which establishes the criteria that must be met if data are to meet the needs of a decision-maker (e.g. it establishes the error bounds on data, which are related in turn to the uncertainties a decision-maker, can tolerate in reaching a defensible decision). Assessors can accomplish this goal through the following seven steps:[a]

1. State the problem.
2. Identify the decision to be made.
3. Identify inputs to the decision (i.e., which data are needed).
4. Define the study boundaries (i.e., what factors, scenarios, etc., will be included in the study to produce these data).
5. Develop a decision rule (i.e., how the data will relate to a specific decision to be made).
6. Specify limits on decision errors (i.e., how much uncertainty can exist and still allow a defensible decision to be made).
7. Optimize the design of the study to ensure the data quality meets the decision rule.

The QAPP specifies precisely how to collect and analyze the data to meet the goals established by the DQO process. The QAPP establishes specific procedures that assessors follow to meet DQOs. These DQOs include procedures for identifying reliable methods, choosing sample locations and frequencies, handling samples, calibration of equipment, recording and archiving of data, and analysis of the data. The DQO goal is to ensure that all members of the project team understand, and follow, procedures that will ensure the results of the study meet the data quality needs of a decision. Once these DQOs have been established, it is necessary to develop a plan as to how the participants will meet them in practice while collecting the data for the study.

[a]U.S. Environmental Protection Agency (EPA). 1994. *Guidance for the Data Quality Objectives Process*, EPA QA/G-4, Office of Research and Development, EPA/600/R-96/055; available at http://ww.epa.gov/swerust1/cat/epaqag4.pdf.

2. **How accurately must the results be to be useful in these decisions?** The reliability of monitoring program results must be adequate for the needs of the risk management decision. For example, risk assessors need to quantify air concentrations and/or exposures within some bounds of accuracy and/or precision. It is important to meet these criteria of accuracy and precision, but not necessarily to exceed them. As noted in Appendix H, the data quality objectives must provide results that allow reliable decision-making. However, resources that participants devote to one aspect of a monitoring program, such as choosing a larger number of sampling sites, will draw resources away from another aspect of the program, such as sampling for a larger number of air toxics. This is why it is essential to understand fully the decision that the given set of results will support, other results that assessors will need to support that same decision, and how participants can balance monitoring results across these different data needs to reduce the levels of uncertainty to acceptable levels. Assessors can achieve this goal by conducting a **sensitivity analysis**[a], which determines what aspects of a full monitoring program will require the greatest attention and resources; monitoring results that play the most significant role in a decision may require the greatest allocation of resources.

3. **What methodologies are available to monitor at a particular level of quality?** The choice of monitoring method depends on the specific air toxic(s) to be analyzed, the objective of the monitoring (as the DQOs specified), the time over which a result is to apply, and available resources. It is important to note here that there do not currently exist valid methods (either field, lab, or both) for a large number of chemicals that may be of interest; for methods that do exist, the achievable sensitivity may not match the DQOs (this is another reason that modeling is often used as the primary decision making tool since these issues are irrelevant to models).

4. **What resources are available for the monitoring program?** The choice of a monitoring strategy often depends primarily on available resources (e.g., time, money). These factors are of particular concern in air toxics monitoring because most studies of chronic exposure generally require a minimum of one full year of data to characterize chronic exposure. It is not uncommon to have a lag time of two years or more from the beginning of a monitoring study to a final report when one considers the time it takes to plan the monitoring study, obtain access to land, build the monitoring structures, run the study, analyze the samples, validate the results, and write the data report.

10.4 Planning for Air Toxics Monitoring

As noted above, planning is a critical part of any air toxics monitoring program. The discussion of planning below first describes a recommended general approach (Section 10.4.1) and then outlines several specific planning issues (Section 10.4.2). EPA has developed resources that provide additional details on operating procedures, with discussions of data quality issues, definitions, and applications to specific methodologies.[4]

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[a] A sensitivity analysis shows the relative effect of uncertainty in each aspect of an assessment on the overall uncertainty in that assessment. Ideally the data quality objectives will be more stringent for those measurements that play a larger role in the final decision, since narrowing the uncertainty in these measurements significantly reduces uncertainty associated with the decision.

10.4.1 General Planning Approach

Planning an air toxics monitoring program involves a step-wise integration of sampling protocols with data quality criteria and data analysis processes that are consistent with the study-specific conceptual model (CM), QAPP, and DQO processes. Although presented step-wise, the process is actually iterative, and decisions at one step may require verification or modification of assumptions or decisions made at previous steps.

1. **Understand the problem**. As noted above, assessors may design monitoring programs to support a number of different types of management decisions. For risk assessments, the CM can focus participants' understanding of both the scope and the breadth of the problem that the sampling and analysis are to address. The ***most important questions to answer*** immediately are: whether assessors will use monitoring results to characterize exposure and risk, whether they will use results to evaluate air quality model performance and look for gaps in the emissions inventory, or whether they will use results for both reasons. This is a ***critical question for participants to answer***, because the data needs can be drastically different, depending on how the assessors will use the monitoring data.

2. **Identify existing data**. Sampling and analysis for risk assessment may not be necessary if the information to be developed is already available from other sources and meets the quality requirements for decision making. The data sources discussed in Chapter 4 may provide sufficient information for the risk management decision.

Examples of Study-Specific Questions

- What is the maximum plausible value of EC for the population in a geographic region, taking into account spatial and temporal variability and uncertainty?
- What is the location of this maximal value within the geographic region?
- Which air toxics are found at the highest concentrations with respect to their dose-response values (e.g., which air toxics have the greatest potential to produce a hazard quotient above one)?
- Do monitoring results generally agree or disagree with the value of air concentrations identified by existing models?

3. **Itemize data needs**. Where existing data are insufficient to answer the study-specific questions, it will be necessary to obtain new data through monitoring. Potential data needs include: filling gaps in emissions inventory data; providing input data for models and validating modeling results; generating new data to more fully characterize exposures in areas, populations, or pathways; establishing trends over time; or supplementing a body of data to increase their quality for the risk management decision. The process for itemizing data needs includes articulating critical decision criteria (which may drive data quality needs and/or selection of specific methods), applying these criteria to determine areas where existing data are insufficient, and identifying the manner in which new data can supplement existing data to meet the decision criteria. In many ways, the identification and enumeration of data needs acts a bridge between the conceptual model and the DQO process.

4. **Define data quality needs**. The reliability (e.g., accuracy and precision) of monitoring results must be adequate to meet the needs of the risk management decision. However, given finite resources, even well-designed studies may not be able to achieve all quality criteria. That limitation makes it important to determine which criteria are essential for addressing the

study-specific decision problem and for focusing resources on meeting (and not necessarily exceeding) those criteria.

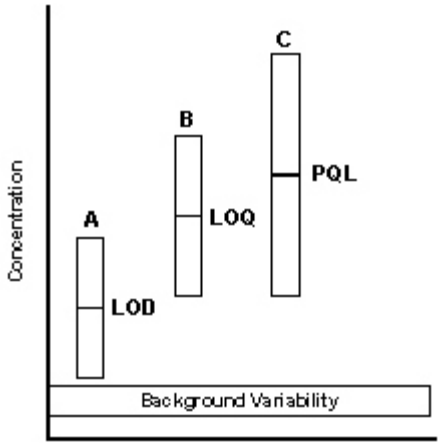
The DQO process determines general data quality objectives to meet specific needs. This process can be informed both by a well specified decision statement and by a sensitivity analysis to determine which aspects of a full monitoring program will require the greatest attention and resources to support that decision. Identification of data quality needs at this level is targeted on the specific problem identified in Step 1, but is independent of the specific methods to be applied. It is important to base data quality criteria at this step on what is required to answer the problem identified in Step 1, not on impressions of best available analytical methods, approaches used in the past, or consideration of questions that might be of general scientific interest but are not of direct use in the decision problem. A common approach is to consider all aspects of sample and data handling from collection to data report writing, as these affect the confidence with which decisions can be made through the introduction of random or systemic errors. A number of factors affect data quality, including bias related to sampling error (e.g., taking only a single sample at one location, which may or may not be representative of actual ambient concentrations) and relative precision related to analysis methods.

5. **Select monitoring methods to meet data quality needs**. The choice of monitoring method depends on the scale of the assessment, specific contaminant(s) to be analyzed, the sampling time over which the result is derived (e.g., a sample collected over 15 minutes versus a sample collected over 24 hours), the decision criteria or other reporting limit needs, and the resources available (see Section 10.3). Methodologies include the sampling methods and techniques, sampling program design (i.e, sampling frequency, coverage, and density), as well as analytical methods. The data quality needs identified in Step 4 represent the total data quality requirements of all aspects of the sampling and analysis process necessary to support risk-based decision-making. Therefore, evaluation of all aspects of sampling and analysis with respect to data quality needs is necessary for proper method selection.

   The QAPP process involves balancing decisions for method selection to meet data and quality needs. Selection of the methods for both sampling and data analysis defines the approach and defines what is termed the **measurement quality objectives**. Although there is a natural tendency to select sampling and analysis methods based on previous data, it is important that the benefit of consistency and likely improved comparability are not outweighed by data gaps that Step 3 identified. For example, in a risk assessment for chlorinated volatile solvents, the presence of fluorinated volatile solvents may cause assessors to overestimate chlorinated concentrations due to analytical interferences. The method selection generally takes into account the known or suspected presence of other chemicals having similar toxic effects, symptoms, and mechanisms, and/or that which otherwise may affect sampling and analysis results. To take this into account, the study may require adding chemicals to the target analyte list, selecting a method where these compounds are not potential interferents, or limiting the scope of the study with stated assumptions about contributions from these undefined factors (e.g., stating only that the measured concentration is the sum of a defined set of analytes and not applicable to any one analyte in the mixture).

Detection Limits and Limits of Quantitation

The **detection limit** is the minimum concentration that an analyst can reliably expected to find (i.e., detect) in a sample, if it is present. For any given method (e.g., the method to analyze for volatile organic compounds [VOCs] in air), this limit is established in each lab for each instrument and is called the **method detection limit** or **MDL**. An MDL of 1µg/m^3, indicates that a field sample that contains 1 µg/m^3 or below of contaminant will probably not be detected by the instrument in question. The **limit of quantitation (LOQ)**, on the other hand, is the minimum concentration for which the analyst can reliably say that the substance is present in the sample and at a specific concentration within some pre-established limits of precision and accuracy. If the limit of quantitation is 2 µg/m^3, then measurement results above 2 µg/m^3 may be reported as not only indicating the presence of the substance in the sample, but as indicating the specific concentration measured (i.e., positive identification, certain concentration). Measurements between the MDL and the LOQ , indicate the presence of the substance in the sample, but analysts can only make an estimate of the concentration (i.e., certain identification, uncertain concentration). NOTE: It is common (but incorrect) to refer to the quantitation limit as the detection limit. The LOQ, practical quantitation limit (PQL), estimated quantitation limit (EQL), and sample quantitation limit (SQL; see below) are all limits of quantitation, not detection. Thus, when one says "benzene was not detected at a detection limit of 5 µg/m^3," this most likely actually means "benzene was not detected; the limit of quantitation was 5 µg/m^3." Likewise, when a lab reports a measurement as "<5 µg/m^3," this most likely means "not detected; the limit of quantitation was 5 µg/m^3." There is much confusion on this point and analysts must clarify with the laboratory exactly what they mean in their lab reports (and what the analyst needs to have reported to them for their risk assessment activities). For air toxics risk assessments, the MDL is largely irrelevant for purposes of estimating exposure and the limit of quantitation is the critical information that needs to be reported (see Chapter 7).



In establishing limits of detection and quantitation, it is necessary to give the confidence level associated with the detection limit and the limit of quantitation. In this figure, the confidence level is 99 percent. The *Limit of Detection* (LOD) is then the minimum concentration that has a 99 percent probability of producing a result above background noise (background is shown in the figure as a horizontal bar) using a specific method. The LOD includes two considerations: an *instrument detection limit*, accounting for variation in the instrument when it is presented with repeated samples at the same concentration, and additional variation caused by the need to sample, handle the sample, etc. (which can cause variations in the relationship between the concentration in the environmental medium and the concentration presented to the instrument). The LOD is the horizontal line in the bar marked A. Note that the range of variation of results from a concentration at the LOD (shown as the bar marked A), and the lower end of this range just barely avoids moving into the range of background variability.

Detection Limits and Limits of Quantitation (continued)

The LOQ assumes best practice in performing the measurements. It also is of interest to ask what the LOQ would be using more common, routine practice. The *Practical Quantitation Limit* (PQL) is the minimum concentration that has a 99 percent probability of producing a result above the LOD under routine lab conditions (shown as the bar marked C). Under these conditions, the variation will be larger than under ideal conditions, and so the PQL is higher than the LOD. Each lab must establish these parameters for each method on each analytical instrument. When actual environmental samples are evaluated on an instrument, the actual PQL reported for any given sample may vary (for example, if a sample is highly concentrated and needs dilution before analysis, the resulting PQL for that sample will be elevated by an amount proportional to the dilution). It is for this reason that PQLs reported for actual samples are referred to as a **sample quantitation limits** or **SQLs**. When using analytical monitoring data for air toxics risk assessment purposes, ***the MDL is irrelevant***. The SQL is the key factor in developing exposure concentrations (see Chapter 7).

Having established these terms, some system then is needed to "flag" results as being either usable or unusable for the purposes of decision-making. For example, in the Superfund program,[a] results are flagged "*R*" if the data are unusable for some reason and *"J"* if the data fall between the SQL and the MDL. A more thorough description of data qualifiers if presented in Appendix I.

[a]U.S. Environmental Protection Agency. 1992. *Guidance for Data Usability in Risk Assessment (Part A)*. Office of Emergency and Remedial Response, Washington, D.C. EPA Publication 9285.7-09A; available at http://www.epa.gov/superfund/programs/risk/datause/parta.htm.

6. **Develop systems to ensure that data meet decision requirements**. Setting the objectives and selecting sampling and methods capable of meeting the DQOs are the prelude to determining whether and to what degree the data may support risk management decisions. Having collected and analyzed the data, it will be necessary to determine whether decisions can now be made with the desired confidence. For example, the actual data collected must be assessed for quality and compared against any decision criteria such as toxicity dose-response values. Where the quality is insufficient to support the decision (e.g., insufficient to determine whether the benchmark is or is not exceeded), the previous steps may need to be re-assessed.

   It is also important to evaluate the contribution to uncertainty that is related to sample collection and sample program design as well as analytical method uncertainty. Sampling uncertainty is decreased when sampling density increases, however resource limits often constrain sample density. Typically, errors in the collection of field samples are much greater than errors introduced by preparation, handling, and data analysis; yet, most sampling studies have devoted resources to assessing and mitigating laboratory errors. Ultimately, the proper use of a QAPP that considers the entire process (sample collection through lab data reporting) allows for evaluation of and reduction in uncertainty across all the activities of the monitoring program, focusing resources on those aspects contributing most significantly to uncertainty affecting decision-making.

7. **Develop documentation**. The QAPP and other planning documents must record the results of the environmental data collection design process. Information to be documented includes the assumptions, findings, outliers, biases, data confidences, and other factors that are critical to implementation, as well as evaluation and eventual interpretation of the data collected. Data collected and analyzed is often reviewed thoroughly to ensure they are adequate to support decisions; sufficient documentation allows such a review.

10.4.2 Specific Planning Issues

The design of the monitoring program also raises some specific issues:

- **Select appropriate monitoring or sampling methods for the chemical(s) to be measured**. In general, it is important that the methods selected have the sensitivity needed to monitor at concentrations likely to be of health and/or regulatory concern. At a minimum, the PQL or SQL should be below any relevant health benchmarks (e.g., the human health dose-response values discussed in Chapter 12). For some chemicals, the limit of the current technology may not allow for a PQL or SQL that is below a health benchmark (or, that level may be reached, but at a higher cost). In such instances, the planning and scoping team must decide how best to balance resources to support data quality needs.

- **Select appropriate monitoring sites, sample collection frequency, and length of sampling time for the spatial and temporal variation of the scale being assessed and for the objective of the air toxics monitoring being conducted**. The way monitoring captures this variation depends on the particular measure(s) needed to support the risk management decision. For example, the monitoring goal might be to estimate the average long-term exposure to people spread over a large geographic region (e.g., the average urban exposure for a typical resident in a town). In this case, measurements spaced on a grid throughout that region, or selected with a spatial density proportional to population density, may be appropriate. On the other hand, if the goal is to identify or verify the maximum modeled exposure or to perform a screening-level assessment in a population living down-wind from an industrial source, sampling should be performed at the location likely to represent the highest exposure, or in several different regions to identify the site representing the highest exposure. Again, issues such as atmospheric photochemistry and differential settling of metals are important considerations.

  Assessors often make similar decisions when considering temporal variation. For example, samples may vary over time due to fluctuations (e.g., emission rates from a facility may fluctuate over time) or a systematic temporal trend (e.g., a facility might change its production methods or products over time). In the former case, it is necessary to obtain enough samples spread over a large interval of time to estimate the mean over the measurement interval. In the latter case, the samples must be spaced in time so as to capture the trend (i.e., a **time-trend study** must be performed). In addition, the objective of a study may be to capture high short-term spikes in chemical concentrations. In this case, samples collected over a 24-hour period may "dilute out" these spikes, and frequent shorter term samples (e.g., collected over 15 minutes) may be required.

A recent evaluation of many of the issues regarding variability was recently published using data from a wide range of monitoring sites throughout the United States (see also Exhibit 10-4).[5] These results support the conclusions that: (1) environmental variability is a more important source of uncertainty than analytical uncertainty, emphasizing the need to carefully select the location and timing of monitoring; (2) temporal variability dominates data variability, emphasizing the need to not only carefully select the timing of monitoring, but to ensure that results are properly averaged over relevant exposure periods; and, (3) analytical uncertainty becomes a more significant contributor to overall uncertainty as ambient concentrations approach background levels.

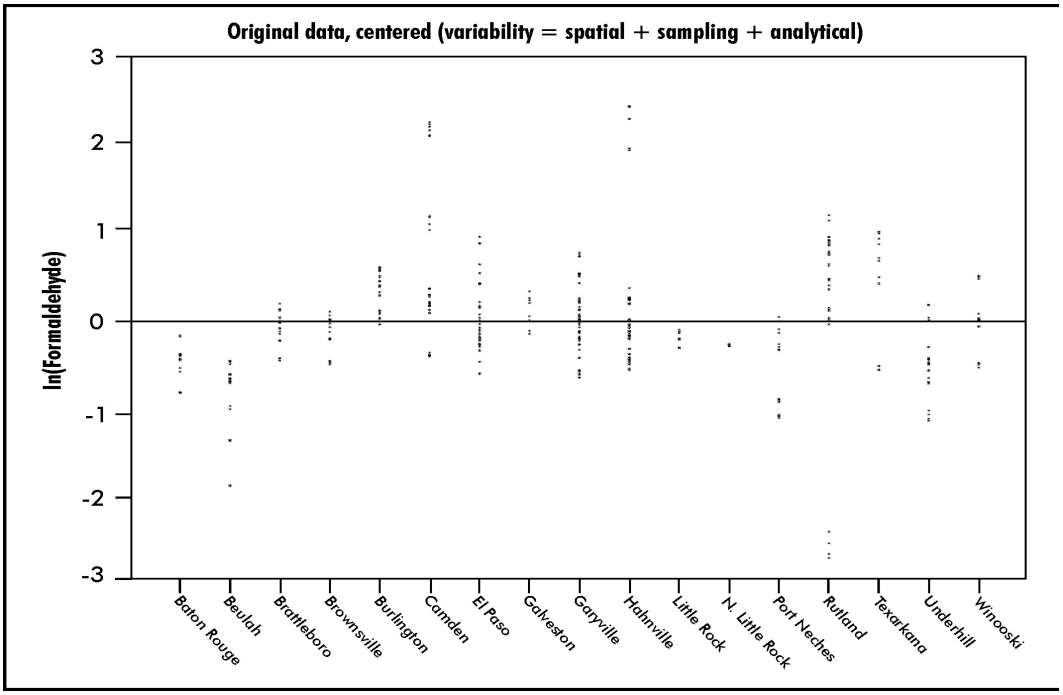
- **Most often, the monitoring efforts address the four main sources of variability in measurements**. These four sources are:

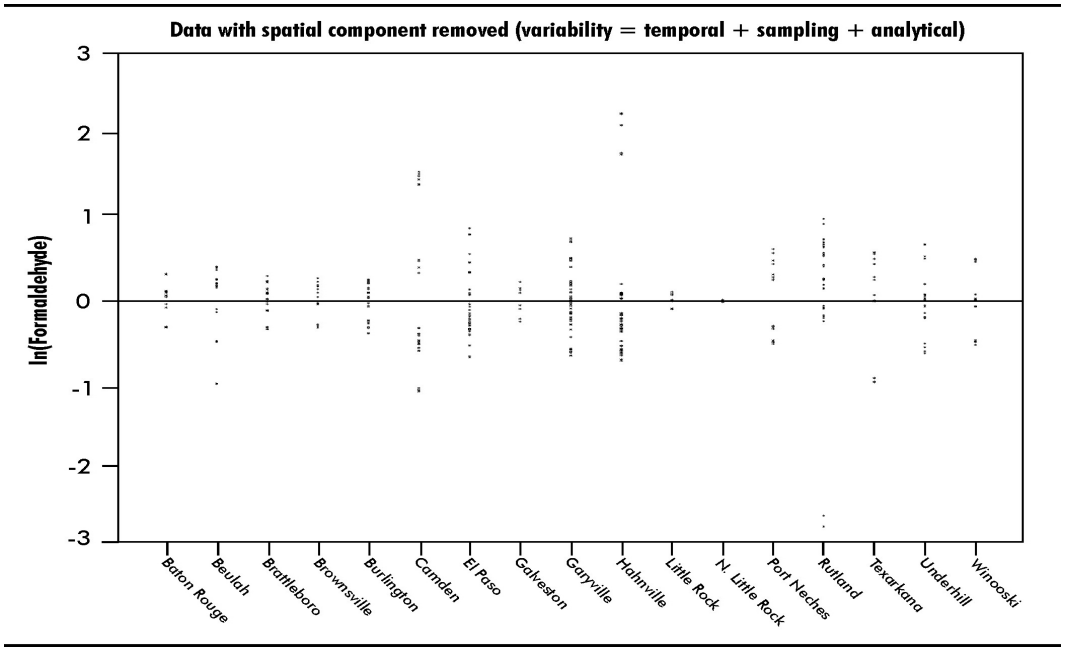
  - **Analytical**. The same sample analyzed repeatedly yields different concentrations.
  - **Sampling**. Duplicate samples collected using two identical monitoring devices from the same location and time yield different concentrations. This type of duplicate sampling is often performed to determine the precision of the method. In general, a minimum of 10 percent of the measurements in a monitoring program should be co-located to collect duplicate samples.
  - **Temporal**. Repeated samples at different times at the same location yield different concentrations.
  - **Spatial**. Samples from different locations at the same time yield different concentrations.

  Ideally, assessors allocate monitoring resources in a manner that is consistent with the relative contribution of these four sources to uncertainty. However, uncertainty may not be evident prior to establishing the sampling program. Some insights on the relative contributions can be obtained from the recent study of monitoring variability,[5] but it generally will be necessary to perform an analysis of the analytical uncertainty, the precision, and the degree of spatial and temporal variability before a firm judgment of the relative contributions can be made.

  As noted previously, ambient air monitoring data may not provide a completely accurate picture of exposure. There are several reasons for this limitation. First, air toxics monitors usually are physically located to provide an estimate of air concentration at a specific location. The assessor must then determine how representative the results are to populations in the geographic area around the monitor. For some chemicals, monitoring results can be reasonably representative, especially if the concentration does not show high levels of spatial variability. For other chemicals, results may not be very representative at all, especially at some distance from the monitor. In addition, because people move around outside, their exposures are an average of the ambient air concentrations over the geographic regions in which they move; this exposure may not correspond to the average at any particular monitoring location. People also receive protection from the ambient environment, either in vehicles or by moving indoors or through filters. Thus, ambient air concentrations measured through monitoring and analysis can be taken as an indication of the potential for exposure at a given location.

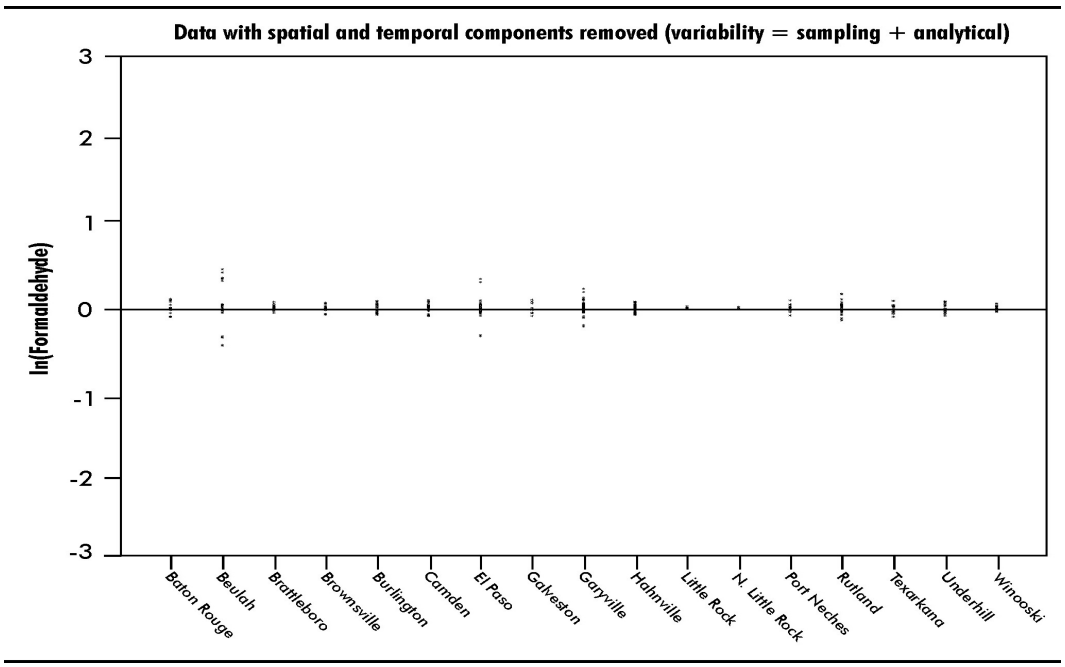
Exhibit 10-4. Temporal and Spatial Sources of Variability in Formaldehyde Sampling

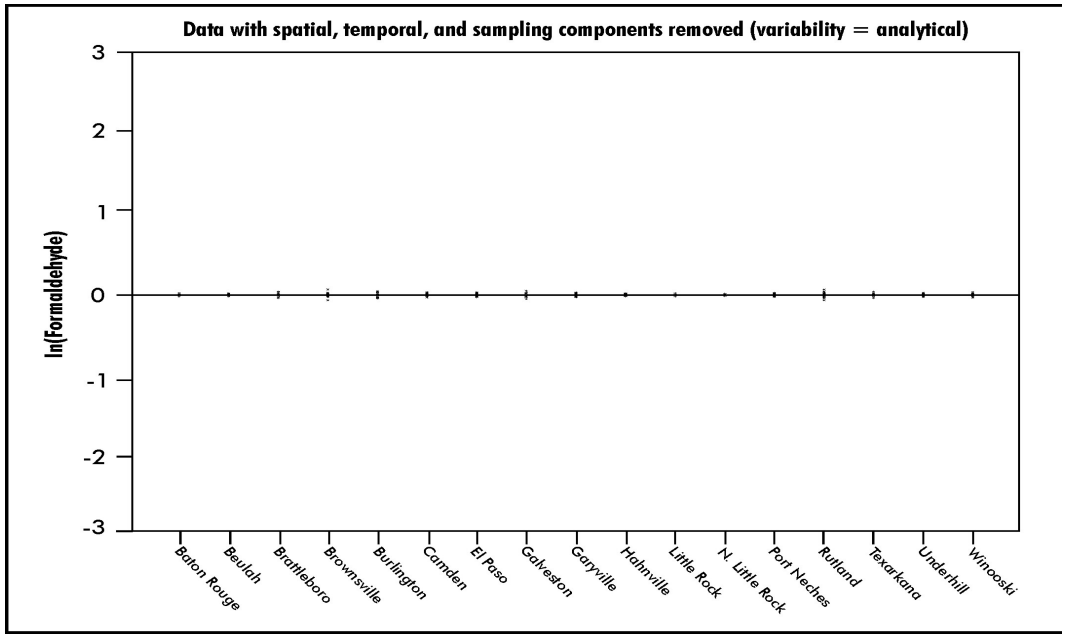




The four graphs in this exhibit summarize the results of Bortnick and Stetzer,[4] obtained by sequentially removing sources of variability. Note that the analytical variability is the smallest source of variability in this case, followed by sampling variability and temporal/spatial variability. Clearly in

Exhibit 10-4 (continued)





this case, a choice of sampling focused on temporal and spatial contributions to variability is needed; since temporal variability dominated, primary attention would focus first on that component in each sampled geographic region.

- **Follow and define standard operating procedures**. Risk assessors follow and define standard operating procedures both in the field (during sample collection and transport to the laboratory) and in the laboratory (during sample analysis). Procedures include those related to sample collection, sample transport, sample storage (including prevention of sample degradation), and chain of custody procedures, as well as sample analysis, validation, and data reporting. Procedures to identify potential problems are put in place. Periodic audits (both field and lab) are commonly performed to ensure procedures are being followed and that measurement and analytical devices are working properly.

- **Determine quantitation and compare limits**. A common approach is to determine quantitation limits and compare them against relevant decision needs, including health benchmarks and likely environmental levels. These quantitation limits should be below the health benchmarks and environmental levels to provide data of use in risk-based decisions.

- **Properly calibrate measurement processes**. One way to ensure the accuracy of the method is to properly calibrate measurement processes. To accomplish this, assessors perform calibration on a time schedule shorter than the time needed for the equipment to "drift"[(b)] further than is permitted under the criteria of accuracy and precision. It is for this reason that it is essential that systems be re-calibrated periodically, on a schedule that is related to the data quality objectives. In addition, it is desirable to cross-calibrate measurement methods by comparing results from several individuals and labs. In an inter-laboratory comparison, split and duplicate samples are submitted to several labs simultaneously, the results are collected, and variation between labs are assessed. Ideally, sample analysis in a monitoring study would be conducted at a laboratory that has participated in such an inter-laboratory comparison and has been certified to produce results within acceptable data quality limits.

- **Adequately record and archive results**. The best monitoring program can fail due to improper record-keeping. A periodic, random check of the archived records (e.g., computer files) is commonly made against "hard copies" to ensure the integrity of the process of recording the data. The recording of all results, including a description of the QA/QC and Data Quality Indicators, is essential because risk managers will use the results in their decisions.

- **Match measurement intervals to the relevant modeling assumptions or health endpoints**. Different health effects require varying averaging time-periods. Cancer and other chronic effects generally require averages over relatively long periods such as a year or more (up to a lifetime). In this case, samples may be taken randomly or systematically throughout the year, with the criterion of obtaining an accurate estimate of the mean. Acute effects, however, require an understanding of the temporal variability over short periods of time. For example, monitors need to measure benzene concentrations within shorter time intervals (e.g., 15 minute, one-hour, 24-hour) for comparison with a health benchmark reflective of the same time period.

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[b] "Drift" refers to the fact that monitoring systems that are calibrated generally change their electronic and other characteristics in time, so the calibration factor also changes in time.

- **Ensure that temporal sampling reflects diurnal (time-of-day) and seasonal variability**. It is important to recognize that source terms and meteorological conditions can vary systematically both over a day and throughout the seasons. Monitoring programs commonly reflect this pattern, providing proper averages throughout a day (by sampling at selected time points in a day) and between the seasons (by sampling in the different seasons).

In general, most monitoring schemes that are designed to attenuate and validate a model will collect samples and analyze a relatively short list of "indicator compounds." If attenuation and validation are the primary motivation for sample collection, it may not be necessary to measure every compound being modeled, as long as it can be assumed that unmodeled compounds would be expected to behave similarly. However, the amount and type of data collected in the monitoring program designed to validate predicted model results should match the assumptions of the modeling program. For example, if the goal of the modeling program is to estimate long term (usually annual average) concentrations, then monitoring data must also be collected in sufficient quantity to develop an annual average value to compare to the model results. (In general, monitoring samples collected every six days for a year are required to develop a stable estimate of annual average.)[2]

10.5 Implementing Air Toxics Monitoring

Implementing a monitoring program raises two issues in addition to the items above that relate to planning for a monitoring study. These include selecting the actual location of monitors and selecting methods for data analysis and reporting. Each is discussed in a separate subsection below.

10.5.1 Locating Monitors and Selecting Sample Size

Determining the location of an air toxics monitor depends on a number of factors, including the specific purpose of the monitoring (e.g., confirm modeled concentrations at a specific location, estimate background concentrations), meteorological and terrain constraints, and the relative magnitude and location of the source(s) of concern versus other emissions sources that might contribute to measured air concentrations. For example, locations too close to a source may underestimate exposure concentrations if the plume has not yet reached ground level where people can come into contact with the contaminants. Locations too far from the source may also underestimate exposure concentrations for large groups of people due to the dispersion that takes place between the point of touch-down of the plume and the point of monitoring.

10.5.1.1 Locating Monitors

EPA's *Quality Assurance Handbook for Air Pollution Measurement Systems*[6] provides a set of consistent QA practices that will improve the quality of the nation's ambient air quality monitoring data and ensure comparability among sites across the nation. Although these practices were developed specifically for criteria air pollutants, they provide useful guidance for air toxics risk assessments. Exhibit 10-5 summarizes some of the *Handbook's* guidance on the relationship between topography, air flow, and the location of monitoring locations. The following factors are usually considered when siting monitors:

- **Perform measurements at locations that are representative of exposure**. Determining the location will depend on whether the goal is to quantify exposures in general, or exposures to the maximally exposed individual. In the latter case, locations too close to a source may underestimate exposure if the plume has not yet reached ground level where people can come into contact with the contaminant. Locations too far from the source may also underestimate exposure to large groups of people due to the dispersion that takes place between the point of touch-down of the plume and the point of monitoring. Exhibit 10-3 above presented an example of this issue. In that hypothetical example, the area of maximum concentrations predicted by the air quality model falls somewhere within the area bounded by grid points 2, 4, S1, and S3. If the goal of monitoring is to verify these maximum concentrations, then the ideal location for the monitor would be on the plume centerline at the exact point of touch-down of the plume. However, if the goal of monitoring is to verify maximum concentrations at the point of actual exposures, location at the site indicated in Exhibit 10-3 may be more appropriate (measurements at the point of plume touch-down may overestimate maximum actual exposure if there are no individuals within that area). It is essential to determine whether monitoring will estimate exposures to existing individuals or to hypothetical individuals who might move into currently unoccupied areas.

Exhibit 10-5. Relationships of Topography, Air Flow, and Monitoring Site Selection

Station Category	Characterization
A (ground level)	Heavy pollutant concentrations, high potential for pollutant buildup. A site 3-5 m (10-16 ft) from a major traffic artery that has local terrain features restricting ventilation. A sampler probe that is 3-6 m (10-20 ft) above ground.
B (ground level)	Heavy pollutant concentrations, minimal potential for a pollutant buildup. A site 3-14 m (15-50 ft) from a major traffic artery, with good natural ventilation. A sampler probe that is 3-6 m (10-20 ft) above ground.
C (ground level)	Moderate pollutant concentrations. A site 15-60m (5-200 ft) from a major traffic artery. A sampler probe that is 3-6 m (10-20 ft) above ground.
D (ground level)	Low pollutant concentrations. A site ≥ 60 m (≥ 200 ft) from a traffic artery. A sampler probe that is 3-6 m (10-20 ft) above ground.
E (air mass)	A sampler probe that is 6-45 m (20-150 ft) above ground. Two subclasses: (1) good exposure from all sides (e.g., on top of a building), or (2) directionally biased exposure (probe extended from a window).
F (source-oriented)	A sampler that is adjacent to a point source. Monitoring that yields data directly relatable to the emissions source.

Source: Table 6.5 of EPA's *Quality Assurance Handbook for Air Pollution Measurement Systems*[6]

When source location is the goal of monitoring, the siting of a monitor depends on the meteorological conditions and the spatial locations of suspected sources. Again, the hypothetical example in Exhibit 10-3 provides some insights. If the source is suspected to be at the center of the geographic area, and if the wind direction is predominantly towards the east (as it is in that example), the monitor or sampler would be located to the east of the source and operated both at times when the wind blows towards the east and when the wind blows in the opposite (or another) direction. Support for the claim that the source is located

at the origin, and dominates exposures in the area around the monitor, would then be strongest if the ambient concentration increases significantly when the wind blows towards the east and drops significantly when it blows in other directions. If the data did not indicate this effect, then the source is not at the center, or there is an additional, and perhaps more significant, source in the area.

- **Take into account shielding and concentrating effects.** Buildings, hills, and trees can have shielding and concentrating effects. These effects may cause assessors to underestimate exposure if either measurement sites are shielded from normal air flow or if these same structures produce high concentrations downwind due to lee effects. Unless there is a pattern of movement of people that make sites near buildings and other structures of particular interest, assessors should perform measurements away from the influence of these structures. It is particularly important to locate monitors away from such structures if the goal is to locate sources, as the flow patterns for air are highly complex near these structures, greatly complicating the ability to identify the source location from monitoring data.

- **Be aware that sources of air toxics from mobile sources (cars, trucks, etc.) can complicate measurements of ambient air concentrations produced by stationary sources**. For the estimates of exposures from stationary sources, it may be preferable to make measurements at locations away from roads. Monitoring should occur at distances ranging from 3 to 61 meters from a major traffic artery (see Exhibit 10-5). These roads provide, in a sense, a "background" level, or noise, above which the source must rise to create a discernible signal. Of course, if total ambient exposure from all sources is to be estimated, and the exposed population spends a significant fraction of time near roads, this factor may be captured by selecting a sample of sites near those roads.

- **Make sure that the heights of monitoring and sampling devices are consistent with the breathing zones of people when public exposures are being evaluated**. This is generally between 1 and 2 meters (the lower end being for children and the upper end for adults). While less important for highly dispersed gases (i.e., gases with high diffusion coefficients), this consideration can be important for heavy gases and particulates, which produce significant vertical gradients of concentration.

- **Keep in mind that background concentrations can be difficult to determine**. Although background concentrations can be difficult to determine, it is important to estimate this factor as accurately as possible at the location of measurement (see below for a discussion of background concentrations). Unfortunately, even background levels can vary dramatically over time and over a geographic area, and so assessors should exercise caution in using past studies and studies from other geographic areas in establishing background for a measurement location. Meteorological and pollutant source information must also be carefully considered in selecting an appropriate background monitoring location. The location must not be near major sources of the contaminant, or in the predominant down-wind direction of those sources. The number of background samples should be determined during planning/scoping/problem formulation stage, and be based on statistical testing criteria specified in the DQOs.

The choice of monitoring or sampling locations depends on the spatial scale of the assessment being supported by the measurement program (i.e., micro, middle, neighborhood, urban, regional, or national). Note that samples collected (generally) at the micro-scale, middle-scale, or neighborhood-scale for the specific purpose of determining the impact of a source or co-located groups of sources on a specific population are called **source-oriented monitoring samples**.

In each case, selection of sites for the monitoring program should consider whether:

- A **mean value** is needed for a region (in which case, the sampling must be sufficient to allow interpolation of a surface concentration across that region, from which a mean may be estimated, or a mobile monitor/sampler must be used while moving throughout the region).

- A **mean value** is needed for an area. In this case, the monitor would be placed so as to capture the average of all the sources in the area (i.e., it is usually not oriented towards one source).

- A **maximum value** is needed (for example, for a screening assessment or an estimate of the maximum exposure to an individual from a particular source or co-located groups of sources; in this case, the task is to identify a location as close as possible to this point of maximal exposure).

- A **distribution of exposures** across the population in the region is needed, in which case sampling might be performed across a region. Information on the number of monitoring stations needed to perform this analysis with an acceptable level of accuracy/precision was recently evaluated and discussed by the Lake Michigan Air Directors Consortium (http://www.ladco.org/toxics.html).

- A **test of a model** is being conducted (in which case the location is selected to provide the most meaningful and unambiguous test of the model predictions under established source term and meteorological conditions).

In all five cases above, it is important to determine compounds that might interfere with the measurement of target compounds and, to the extent feasible, locate sampling devices in areas where such interference is small (without compromising the need to cover a geographic region). It also is important to establish one or more "background" and/or "control" locations so the elevation of concentrations or exposures at sampling locations due to sources not located in the assessment area can be determined.

In each case, site selection can improve through use of release data (source terms) and dispersion models. An accurate estimate both of average exposures and distributions of exposure (i.e., concentration measured across different monitors) generally will require adequate sampling in geographic regions characterized by the highest concentrations in addition to sampling in less impacted areas. Since such regions may represent a small fraction of the area in the overall study region, it may be necessary to "over-sample" in the highest exposed areas to ensure the points of maximal exposure are not missed. This process might be accomplished, for example, by sampling on a grid, with the grid density higher in the area surrounding the suspected point of maximal exposure; this will be particularly important if initial monitoring/sampling indicates high spatial variability in the area around the point of maximal exposure. For example, regions

near known, large emissions sources, and downwind of the predominant wind direction, should probably receive increased attention in sampling if a distribution of concentration is being developed across a larger assessment area. If samples were taken only in relatively non-impacted areas, the resulting distribution might not reflect the actual exposure of many area residents. (Ultimately, this is one of the prime reasons for using modeling to evaluate exposure; namely, that models can estimate exposure concentration at as many geographic points in a assessment area as the analyst wishes and for which sufficient emissions inventory data and computing power are available. Thus, modeling obviates these monitoring concerns.)

Background and Control Samples

Background monitors are monitors that are place in the predominant upwind direction (relative to sources) in the assessment area to measure the concentrations of the COPC in air that is moving into the assessment area. The results of such monitoring is helpful in understanding the monitoring results obtained in the assessment area; however, background monitoring results should not be subtracted from assessment area monitoring results because of the uncertainties in the background monitor as a truly representative measure of long term ambient background concentrations. Instead, EPA recommends bar charts that compare contemporaneous concentrations of a chemical in a background monitor to the same chemical at assessment area monitors; these charts provide a sense of the potential influence of background concentrations on the assessment area.

Unlike a background monitor, which is located upwind of the assessment area, a **control monitor** is located within the assessment area and is sited in such a way as to determine the average concentration of all pollutant sources, once mixing has occurred (including chemicals blowing into the assessment area from outside sources, mobile source emissions, and stationary source emissions within the assessment area). Control monitors should be located away from direct influence of any one or group of sources in the assessment area. Similar to background monitoring results, control monitor results should not be subtracted from other assessment area monitoring results (or modeling results). Instead, a simple bar chart comparison is usually adequate to compare the general "urban soup" to more focused monitors.

For the case of model testing, random sampling is not required or even desired. Instead, sampling is performed specifically in one or more locations where the conditions of emissions and dispersion are well established, and where there are no interfering sources or compounds. An ideal situation is a single, known source and a stable wind pattern during the period of sampling. Even in such cases, however, it will be necessary to provide a sampling grid covering the plume dimensions, since small errors in assigning wind direction can result in significant differences between model results and measurements. By sampling at a variety of locations in the plume, it is possible to adjust the model to determine whether a better fit might be obtained by more accurate information on the wind field, effective stack height, and other parameters.

As part of the national-scale assessment component of the 1996 National-Scale Air Toxics Assessment (NATA) activities, EPA compared monitoring to modeling results by using selected locations and compounds (seven HAPs) throughout the U.S. (see www.epa.gov/ttn/atw/nata/mtom_pre.html). The comparison goal was to assess the closeness of modeling and monitoring results, which would expose the overall uncertainty in estimating exposures. They found, for example, that modeled results generally underestimated results at monitors when the modeling was performed to predict air concentrations at the precise location

of the monitor; however, results were more comparable when the maximum concentration that the model predicted was compared against the maximum monitor concentration, without the requirement that modeling and monitoring be at the same location. These results indicate that uncertainties in the modeling produced errors that shifted the location of the point of maximal exposure, but not necessarily the magnitude of maximal exposure. A significantly more detailed uncertainty analysis currently is underway, with results expected in 2004 (these will be available at the NATA website).

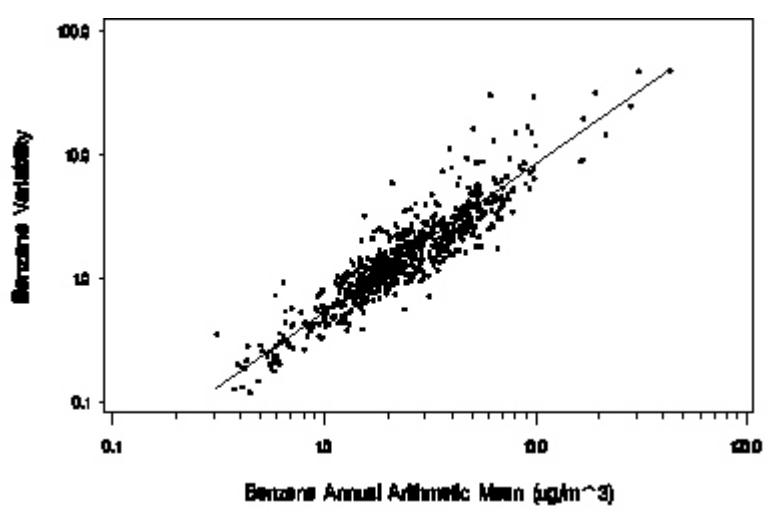
10.5.1.2 Selecting Sample Size

With respect to determining the quality of any estimates of mean concentration or exposure at a location, the coefficient of variation (CV) should be calculated to determine the number of samples needed to meet DQOs established by the decision problem. If σ is the standard deviation of a set of N measurements performed randomly throughout a geographic region and randomly in time, and μ is the mean for that sample set, the value of CV is:

$$CV = \frac{\frac{\sigma}{\sqrt{N}}}{\mu} \qquad \text{(Equation 10-1)}$$

The target value of CV depends on the decision criteria establishing the needed accuracy of an estimate of concentration or exposure, but a general target of less than 0.5 (50 percent) is suggested and a value of 0.2 or less should be possible. (This discussion assumes that the samples are representative of the geographic area and time period for which the average is being calculated.)

The above calculation of CV requires knowledge of σ and μ, which can only be obtained after the sampling program has been underway. It is possible, however, to estimate σ from an initial guess of the mean concentration or exposure, μ, through regression functions such as those established by Bortnick and Stetzer.[5] An example of such a regression is shown below based on a scatter plot of data from benzene monitoring.



Note that σ increases as μ increases. The authors use a lognormal relationship between σ and μ:

$$\ln \sigma = \ln a + \ln \mu \quad or \quad \sigma = a\mu^2 \qquad \text{(Equation 10-2)}$$

They perform a weighted least-squares regression (solid line in the figure above) and obtain for the case of benzene:

$$CV = \frac{\frac{0.54}{\sqrt{N}}}{0.2\mu} \qquad \text{(Equation 10-3)}$$

The approximate size of N needed to produce the desired value of CV may then be estimated from the above equation if an estimate of μ is available from either past monitoring data, similar geographic regions, or models.

10.5.1.3 Setting Up a Monitoring/Sampling Program

While the design of a monitoring program will depend in many ways on the kind of monitoring to be conducted, there are some general aspects of all monitoring programs that assessors should consider. EPA guidance describes many of these issues in detail.[7]

The general aspects related to designing a monitoring program that supports risk assessment are developed and written down in the planning, scoping, problem formulation phase (particularly, much of the following information is included in the study-specific conceptual model and the analysis plan and QAPP for monitoring activities). This activity involves three steps: (1) identify the sources, including the contaminants, the concentrations, the timing and locations of releases, as well as the hypotheses you want to test (e.g., whether a source exists, its relative contribution to overall exposures, etc.); (2) determine the exposure pathways (which in the case of air monitoring is inhalation and perhaps dermal absorption through immersion in air); and (3) determine the receptors of interest, including any sensitive subpopulations, their locations, how they are exposed, and relevant health benchmarks (e.g., IURs or RfCs). The conceptual model can be used to identify where significant exposures are likely to occur to receptors of interest, which in turn helps to guide the selection of monitoring sites. The following steps are then often used to develop, conduct, and evaluate the results of monitoring:

1. Collect and review existing air monitoring information for the site. This information should include data on concentrations, sources, locations of receptors, and other environmental data (e.g., meteorological data) needed to guide decisions. The sources of these data will depend on the location of the site, but a good start is to consider results from some of the national monitoring networks.

2. Determine the level of sophistication needed by the monitoring program. This level is established in the QAPP and the DQOs. The sophistication might range from simple screening procedures (e.g., to determine whether there are any exposures of concern) to more sophisticated methods intended to develop accurate maps of exposure across the region.

3. Develop a clear air monitoring plan, including determining the following: types of air monitors (these depend on the compounds identified as being of interest); the number and

location of monitors; the frequency and duration of monitoring, sampling and analysis of samples; and any QA/QC procedures that must be in place to meet DQOs.

4. Develop a detailed, written plan for day-to-day activities related to how equipment will be maintained and calibrated, and how to document results and QA/QC procedures. The data maintenance plan should include development of a system of logbooks for entering data, along with procedures to ensure the data are entered correctly and the logbooks are archived. There should be a clear procedure for maintaining chain-of-custody for both the samples and the logged results.

5. Evaluate the air monitoring results for their validity and reliability, including summary indicators of data quality (e.g., the data qualifiers discussed elsewhere in this chapter), and summarize these results so decision-makers can understand this quality and ensure the quality meets decision needs. This evaluation should include a summary of the statistical procedures used and the air concentration results, and an estimate of uncertainty in results deemed usable by the analyst (including uncertainty due to monitoring equipment, handling of samples, and sample analysis).

There are a number of specific issues that arise in Step 3 above that relate to the development of the monitoring program. These issues are summarized here in roughly the order in which they would be approached in developing a real program:

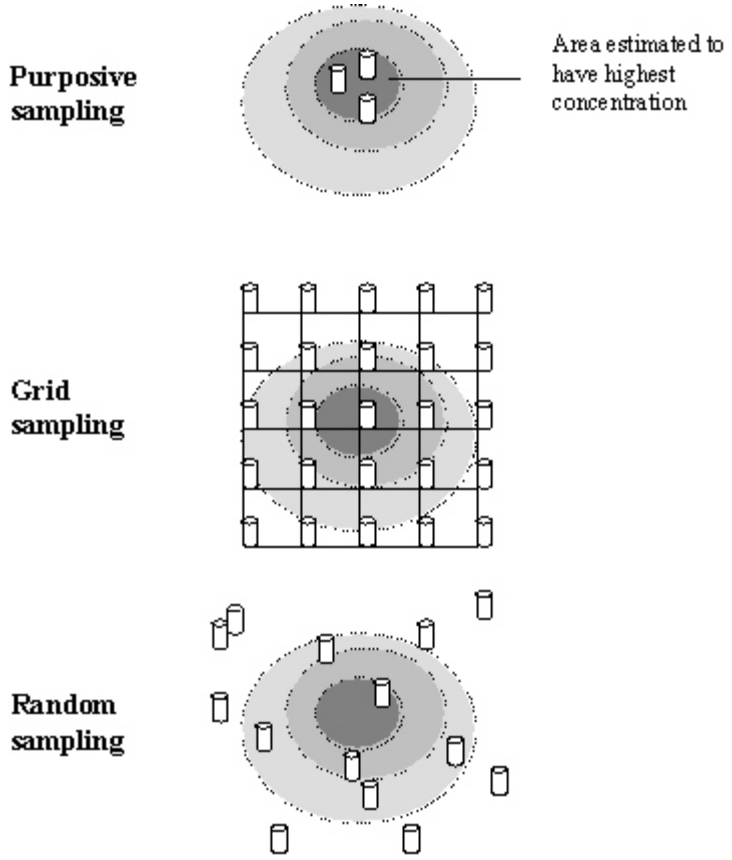
- **Establishing sampling locations**. Sampling may be purposive, random, or systematic. Purposive sampling refers to locating the monitor at a particular location because that location is of special interest. While such sampling can be useful to address specialized questions (such as the impacts of a specific source, or the reliability of model results), they generally are less useful for risk assessment purposes, and care should be taken when averaging the results along with results from the other forms of sampling. Random sampling involves selecting monitoring locations in a random and unbiased manner, with no correlation between locations (other than, perhaps, the fact that they are all in a defined region). Assessors could establish locations by creating a grid, and then randomly selecting the two coordinates (x and y) in that grid. Random sampling has the advantage of well established and relatively easy to apply statistical methods for evaluating results, but runs the risk of missing some "hot spots" of exposure. Systematic sampling involves establishing a grid and placing monitors systematically on the grid nodes. This ensures that sampling is uniform across an area, although statistical analysis is more complex because the samples are not truly random. Exhibit 10-6 illustrates common types of sampling programs.

A typical monitoring station, located at a site with easy access, power, and protection for the equipment

There also are practical considerations in selecting locations, regardless of which of the three procedures above is used. Monitors and samplers will require access to land, both in terms of

permission to locate the equipment and the ability to reach the site. It must also be possible to provide electrical power, and some protection of the equipment against theft, vandalism, and other disturbance; therefore, a fence may be needed.

Exhibit 10-6. Common Types of Sampling



Purposive sampling focuses the sampling effort in specific locations (in this example, the area estimated to have the highest concentration). Most air quality sampling is purposeful (i.e., monitoring stations are located in areas where monitoring is feasible (e.g., locations that are accessible), areas of direct (e.g., maximum) impact, or where concerns about potential exposures have been raised). Grid sampling consists of regularly-spaced samples in a predetermined grid. Random sampling consists of samples in locations selected by chance.

- **Determining the types of equipment and samples**. The sampling/monitoring method will depend on the compound being sampled, as well as the need for grab samples or composite (continuous) monitoring. See Section 10.6.1 for more detail on this issue.

- **Conducting field screening**. Before establishing the monitoring site, it is useful to conduct some limited screening of the region using relatively simply methods. This will help identify locations likely to be of interest (e.g., likely locations of maximal exposure). If this isn't possible, modeling results might be used. Guidance on this issue can be found in EPA's *Field Screening Methods Catalog*.[8] These results generally should not, however, be used in

the risk assessment of chronic exposures because a small number of samples taken over a short period of time will not provide an accurate estimate of long term exposure.

- **Accounting for temporal and meteorological factors**. Sampling must account for the fact that concentrations will fluctuate in time, in part because of meteorology (e.g., the wind blows in different directions during the day, carrying the contaminant to different locations). Where variability is high, a larger number of samples will be needed to achieve a desired level of accuracy. The sampling program should include a full annual cycle covering the seasons for a chronic exposure assessment. Where this is not possible due to limits on resources, the sampling should at least include two temporal extremes (e.g., under windy conditions blowing from major sources to the monitor, and under calm conditions). It is essential to include the variability of the samples in any estimates of accuracy for the monitoring location.

- **Implementing QA/QC measures**. It is essential that well-established, clear and documented methods for assuring the quality and reliability of data be developed. Many of these issues are described in the text box on the QAPP discussed in Section 10.3. A **sampling protocol** must be developed detailing (1) conditions under which samples are collected; (2) how training of individuals will be conducted; (3) how the precision and accuracy will be ensured so results are obtained reproducibly; and (4) the analytical strategies that will be used to ensure quantitation limits are met. Measures are also put into place to ensure that samples are handled appropriately from collection through analysis (e.g., chain-of-custody requirements, allowable sample holding times).

  Sampling devices used to collect, store, preserve, and transport samples must not alter the sample in any way that complicates analysis. Samples should be stored in a way that keeps the concentration as close as possible to that in the field. QC samples must be collected, stored, transported, and analyzed in a way that is identical to the treatment of site samples. For example, both field and trip blanks, which are sampling devices that have not been used for sampling in the field but otherwise are brought through all of the other procedures to which field samples will be subjected, must be treated identically to the actual field samples. These field and trip blanks provide information on the extent to which samples might become contaminated by non-site-related materials during handling in the field (field blanks) and subsequent transport back to the lab for analysis (trip blanks).

Field Blanks

A field blank is a clean sample, carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample. Field blanks are used to demonstrate that:

- Equipment cleaning has adequately removed contamination introduced by sampling at previous sites;
- Sampling and sample processing have not resulted in contamination; and
- Sample handling and transport, lab transport, and lab measurement have not introduced contamination.

10.5.2 Data Analysis and Reporting

As Section 10.4.1 mentions, adequate data analysis, recording, and archiving is essential to the design and conduct of a monitoring program. It is important that assessors enter each data point

into a file with relevant qualifiers, including location of sample; date and time of sample; method of sampling and relevant operating characteristics (e.g., flow rate); transfer process; storage time; analysis method; and identity of people performing all stages of the measurement. The integrity of this database should then be assessed periodically by comparing a random sample of file information against hard copies (e.g., laboratory books) to ensure reliability of transcription. For results using a common methodology, there should be a record of several key aspects of the method that assure reliability:

- A description of the calibration process, including certification of any standards used in that calibration.

- Results of any inter-laboratory comparison of uses of the method, and certification that the laboratory performing the analysis for the sampling program falls within a reasonable range of these inter-laboratory results.

- A record of background levels and levels in blanks, allowing a comparison of these against sample results.

- A summary of the frequency of "detects," or fraction of samples with values above the MDL or SQL (see Exhibit 10-7). If this fraction is small and the chemical is thought to be present, it may indicate that improvements in the method are needed. Of course, if the SQLs are well below any health benchmark, a small fraction of detects or quantifiable results need not trigger a call for improvements.

- A policy on significant digits and how these are related to the accuracy of the method. All results should be reported only with a number of digits consistent with this accuracy. In addition, rounding rules should also be established and followed.

- A description of how summary quantities such as means are calculated. This description includes such factors as how outliers are identified and dealt with, the possible influence of this process on sample mean and variance, and how results below the SQL are handled. For example, some laboratories will report a chemical that they detect below the SQL as "not detected" simply because it is below the SQL and they cannot accurately quantify it. Other labs will report such a chemical as detected, but with an estimated concentration and qualify the value as "J." In general, labs should report detected chemicals, regardless of whether they can accurately quantify their concentration. The use of J-qualified data for risk assessment purposes is described below.

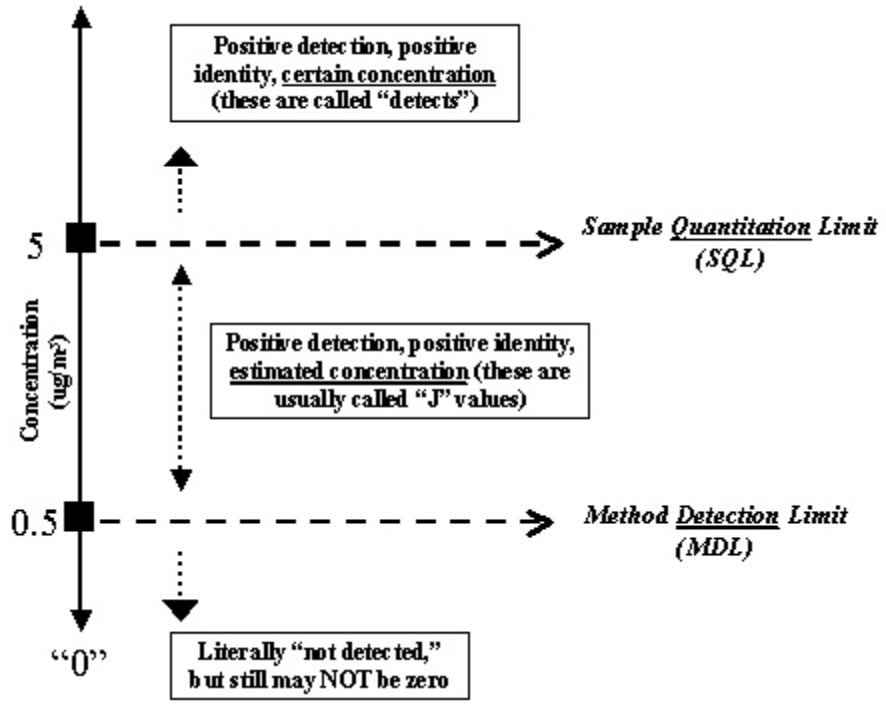
- A detailed description of the QA/QC flags that are used by the lab to report data and a clear description of how the lab deals with samples that are associated with blanks that are contaminated.

10.5.3 The Use of Monitoring Data to Calculate Exposure Concentrations

As the above noted, monitoring data can, under limited circumstances, be used to estimate exposure concentrations in the vicinity of the monitor. Some general rules that apply to this activity are as follows:

- Data from different monitors should not be combined to estimate exposure concentrations (with the exception of co-located duplicate monitors – see below).

Exhibit 10-7. Illustration of SQL and MDL



People often refer to the SQL as the "detection limit." When a lab reports a result as "undetected" (U) or "not detected" (ND), this is the level to which they are usually referring. The SQL is really a limit of quantitationthat can vary between samples (the MDL, on the other hand, is a true "detection limit"). For example, a result of "5U µg/m3" usually means "not detected at a sample-specific quantitation limit of 5 µg/m3." When a chemical is detected, but below the SQL (i.e., a "J" value), risk assessors often use the J value as is (i.e., the J value is used with no modification). When a chemical is not detected in a sample, but there is reason to believe it may be present, even at very small amounts (e.g., the chemical is found in some samples, but not in others), risk assessors often use ½ the SQL as a surrogate concentration for risk assessment purposes (in the example above, half of "5U" is 5/2 = 2.5). It is usually not appropriate to use ½ the MDL as a surrogate for concentration for exposure assessment purposes. The process of assessing and combining monitoring data for exposure assessment purposes is discussed in more detail in Appendices H and I.

- Monitoring data at a location are not generally used to describe variation of exposure concentrations experienced by individuals in a population of people, although temporal differences for the population as a whole (e.g., exposure to the population during the winter versus exposure to the population during the spring) may be appropriate. Variation in exposure concentration within a population is preferably described by looking at exposure concentrations across a set of monitors in the assessment area.

- The representativeness of the exposure concentrations, as represented by any one monitor's data, depends on the amount and quality of the data collected, and the individual chemicals involved. For example, some pollutants may be "regional" in nature, meaning that their concentration tends to be relatively homogeneous over a large area. In that case, a given monitor may be broadly representative of ambient concentrations throughout the region. Some compounds, on the other hand, show sharp

concentration gradients over space and the monitor may only be reflective of exposure concentrations for people living very near to the monitoring station.

- To assess acute exposures with monitoring samples, the results from the individual samples (not their average) should be compared to acute health benchmarks, and the sampling time should match the averaging time of the acute health benchmark (see Chapter 13).

- For chronic exposure assessment, all the valid samples collected and analyzed for a monitor (taken routinely throughout the course of at least one year) are averaged (see below) to provide an estimate of the long term exposure concentration.

Appendix I provides a general overview of how monitoring data should be evaluated, processed, and displayed to develop estimates of exposure concentration.

10.6 Monitoring Methods, Technologies, and Costs

EPA has developed a number of methods to measure the concentration of air toxics in ambient air. The majority of this information is found on EPA's Ambient Monitoring Technology Information Center (AMTIC) website (Exhibit 10-8), and assessors involved in monitoring should become familiar with this website and its contents. Given the breadth and scope of this website's contents, it is not possible here to fully review all of the information here. This section only provides an introduction to the methods. Appendix E summarizes relevant information from two key EPA compendia of methods, primarily for ambient air monitoring. In addition, this chapter does not examine indoor air measurements, as EPA has provided monitoring recommendations only for radon.

EPA has developed a *Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air* to assist federal, state, and local regulatory personnel in developing and maintaining necessary expertise and up-to-date monitoring technology for characterizing organic pollutants in the ambient air (Exhibit 10-9).[9] The Compendium contains a set of 17 peer-reviewed, standardized methods for the determination of volatile, semi-volatile, and selected toxic organic pollutants in the air. The Compendium, along with updates and addenda, is available at EPA's AMTIC Website at http://www.epa.gov/ttn/amtic/airtox.html.

Exhibit 10-8. EPA's Ambient Monitoring Technology Information Center (AMTIC)
Information on ambient concentrations for a wide variety of compounds can be found through AMTIC (http://www.epa.gov/ttn/amtic/welcome.html). This Center facilitates the exchange of ambient monitoring-related information collected throughout the U.S., and can provide valuable insights into the selection of monitoring methods. Established in 1991 as an electronic bulletin board system (BBS), AMTIC has evolved with changing technology into a page on the World Wide Web. It is operated by EPA's OAQPS through the Monitoring and Quality Assurance Group (MQAG). The database contains information on all the Reference and Equivalent Methods for the criteria pollutants, the toxic organic (TO) Methods for air toxics and other noncriteria pollutant methodologies, Federal Regulations pertaining to ambient monitoring, ambient monitoring QA/QC related information, information on ambient monitoring related publications, ambient monitoring news, field and laboratory studies of interest, and updates on any new or developing EPA Ambient Air standards.

Exhibit 10-9. EPA's Toxic Organic (TO) Monitoring Methods	
Method	**Description**
TO-1	Method for the Determination of Volatile Organic Compounds (VOCs) in Ambient Air using Tenax® Adsorption and Gas Chromatography/Mass Spectrometry (GC/MS)
TO-2	Method for the Determination of VOCs in Ambient Air by Carbon Molecular Sieve Adsorption and Gas Chromatography/Mass Spectrometry (GC/MS)
TO-3	Method for the Determination of VOCs in Ambient Air using Cryogenic Preconcentration Techniques and Gas Chromatography with Flame Ionization and Electron Capture Detection
TO-4A	Determination of Pesticides and Polychlorinated Biphenyls in Ambient Air Using High Volume Polyurethane Foam (PUF) Sampling Followed by Gas Chromatographic/Multi-Detector Detection (GC/MD)
TO-5	Determination of Aldehydes and Ketones in Ambient Air Using High Performance Liquid Chromatography (HPLC)
TO-6	Determination of Phosgene in Ambient Air Using High Performance Liquid Chromatography (HPLC)
TO-7	Method for the Determination of nitrosodimethylamine (NDMA) in Ambient Air Using Gas Chromatography
TO-8	Method for the Determination of Phenol and Methylphenols (Cresols) in Ambient Air Using High Performance Liquid Chromatography
TO-9A	Determination of Polychlorinated, Polybrominated, and Brominated/Chlorinated Dibenzo-p-Dioxins and Dibenzofurans in Ambient Air
TO-10A	Determination of Pesticides and Polychlorinated Biphenyls in Ambient Air Using Low Volume Polyurethane Foam (PUF) Sampling Followed by Gas Chromatographic/Multi-Detector Detection (GC/MD)
TO-11A	Determination of Formaldehyde in Ambient Air using Adsorbant Cartridge Followed by High Performance Liquid Chromatography (HPLC)
TO-12	Method for the Determination of Non-methane Organic Compounds (NMOC) in Ambient Air Using Cryogenic Preconcentration and Direct Flame Ionization Detection (PDFID)
TO-13A	Determination of Polycyclic Aromatic Hydrocarbons (PAHs) in Ambient Air Using Gas Chromatography/Mass Spectrometry (GC/MS)
TO-14A	Determination of VOCs in Air Using Specially Prepared Canisters with Subsequent Analysis by Gas Chromatography
TO-15	Determination of VOCs in Air Collected in Specially-Prepared Canisters and Analyzed by Gas Chromatography/Mass Spectrometry (GC/MS)
TO-16	Long-Path Open-Path Fourier Transform Infrared Monitoring of Atmospheric Gases
TO-17	Determination of VOCs in Air Using Active Sampling Onto Sorbent Tubes

10.6.1 Ambient Air Monitoring Methods and Technologies

The term "monitoring method" is a comprehensive term that includes everything from the sample collection devices to analytical laboratory methods. These methods fall into three broad categories related to the **time scale over which concentration will be averaged**:

- **Grab samples** provide a quasi-instantaneous measurement of a concentration. They generally are obtained in the field usually over a period of 24 hours or less and then returned to the laboratory for analysis. The sampling may be automated, allowing a time-series of samples to be drawn, but all samples still are generally returned to the laboratory for analysis. In rare instances, a mobile laboratory may be co-located with the sampling location, in which more "real-time" data is possible.

- **Continuous monitors** provide a time series of measurements in the field, with a stream of data at selected intervals (e.g., once each 24 hours). These monitors may be fully automated versions of grab sampling, taking samples at a set interval but then analyzing the samples internally rather than returning to the lab. An alternative is a continuous flow monitors, which draw ambient air through a chamber and analyzes it in real time (e.g., the semi-continuous formaldehyde monitor developed by the EPA, which runs through one complete cycle of sampling and analysis in 10 minutes).

- **Time-integrated samples** are collected over an extended period of time. Only the total pollutant collected is measured, and so only the average concentration during the sampling period can be determined. As with grab samples, these measurements generally are obtained in the field and returned to a laboratory for analysis.

Monitoring methods/systems can also be divided into a different set of categories based on the **method of collection**:

- **Integrated air sampling devices** use a pump to draw air continuously into the sample chamber, over a reactive medium, or through a filter during a prescribed period of time; the sample is returned to the laboratory for analysis.

- **Direct-read monitors** draw air through a measurement system and provide a direct reading of the concentration without returning samples to the lab.

- **Automated monitoring systems** collect samples, perform the analysis, and report results at regular intervals in the field.

- **Air deposition monitors** rely on deposition properties of compounds (e.g., particulates), and may consist of active and/or passive, wet and/or dry sampling methods.

- **Passive monitors** allow the compound to diffuse into contact with an active material; these generally are analyzed in the lab, although some indicate the presence of a compound by a color change.

- **Grab sampling devices** use an essentially instantaneous sampling method, such as an evacuated chamber into which ambient air is allowed to enter at a fixed rate; the sample collected is returned to the laboratory for analysis.

In some circumstances, grab samples may be collected by volunteers (for example, when residents near an industrial complex organize to capture samples when a strong odor is present). This process is commonly referred to as a "bucket brigade." Bucket brigades may provide useful information that a problem may exist that warrants more in-depth evaluation. They are also helpful, in some circumstances, to help the affected community become more involved in the air toxics evaluation process. Nevertheless, care should be taken to ensure that all of the necessary sampling and analysis protocols and QA/QC are established, understood, and followed by the bucket brigade team members to ensure that the grab samples are of sufficient quality to be used for decision making purpose at hand.

Mobile air monitoring platforms are sometimes used to evaluate air quality parameters. A "mobile platform" can be anything from a VOC sampling apparatus on a movable trailer to a sophisticated multi-pollutant sampling and analytical mobile trailer. The utility of mobile platforms is that they can be moved from place to place relatively easily (e.g., for hotspots analysis) and may only require a place to park the platform and an electrical hookup (as opposed to the more difficult process of establishing fixed monitoring locations, which requires access to land, often by establishing a leasing agreement, and permanent security measures, such as fencing).

Most existing air toxics monitoring programs have focused on the 188 HAPs, and especially on the 33 urban HAPs identified by OAQPS on a nationwide basis (Exhibit 10-10) as generally presenting the greatest contribution to risk to public health from air toxics in urban areas. Note that the highest-risk HAPs in a specific region or community may differ from this list. A significant database exists on national exposures to these compounds, especially those monitored by the National-Scale Air Toxics Assessment (see Chapter 2 and the website at www.epa.gov/ttn/atw/nata). A general starting point for most monitoring efforts should be an initial screening analysis to identify the COPCs. A description of the general process for screening analyses of this type is provided in Chapter 1.

Exhibit 10-10. 33 Urban HAPs (Nationwide Basis)

acetaldehyde	*formaldehyde*
acrolein	hexachlorbenzene
acrylonitrile	hydrazine
arsenic and compounds	*lead and compounds*
benzene	*manganese and compounds*
beryllium and compounds	mercury and compounds
1,3-butadiene	*methylene chloride*
cadmium and compounds	*nickel and compounds*
carbon tetrachloride	polychlorinated biphenyls
chloroform	polycylic organic matter
chromium and compounds	propylene dichloride
coke over emissions	quinolene
1,2-dichloropropane	1,1,2,2-tetrachloroethane
dioxin	*tetrachloroethylene*
ethylene dibromide	*trichloroethylene*
ethylene dichloride	*vinyl chloride*
ethylene oxide	

Compounds monitored in the NATA National Scale Assessment pilot sites are indicated by *italics*.

EPA has not developed methods for many compounds, including some of the 33 urban HAPs. Potential deficiencies in particular monitoring methods include:

- Quantitation limits are not low enough relative to environmental levels and/or health benchmarks;
- Lack of available standards for monitoring protocols (e.g., standards developed by the National Institute of Science and Technology);
- Methods are not practical or easy to implement;
- Compound stability is so poor that the compound degrades significantly between the time it is collected and the time it is analyzed, resulting in poor to no recovery at the time of analysis;
- Recover efficiencies are too low, resulting in poor precision and/or quantitation limits that are not low enough for use relative to health benchmarks;
- Methods have not been sufficiently tested in the laboratory and field;
- Methods are not producing results that are comparable to established methods; and
- Poor reliability.

The deficiencies noted in Exhibit 10-11 are particularly important and have been identified by EPA as needing methodology development.[10] Because they present a similar challenge, EPA has targeted several VOCs for programs to improve monitoring capabilities (Exhibit 10-12). In addition, both diesel exhaust (a complex mixture), acrolein, and arsenic require additional method development to yield accurate, reliable, and field-tested monitoring methods.

10.6.2 Sampling Costs

There is no general guideline for the costs associated with monitoring programs, as they depend on quite an array of factors. Several of the more critical include:

- Whether samples are analyzed "in house" or contracted out.
- Whether monitoring equipment is available or must be purchased or leased.
- The number of monitoring results or samples required (there is some economy of scale, but increased numbers of results also increases cost).
- Whether personnel must be hired and/or trained.
- The potential cost of leases and insurance for monitoring sites.
- Laboratory analytical costs for special analytes. For example, dioxin samples can run as high as $1,000 per sample, making an extensive dioxin sampling scheme generally out of reach for most studies.

10.7 Archiving Air Toxics Monitoring Data

When appropriate, results of a monitoring program should be submitted to the relevant air toxics database, such as EPA's Air Quality System (AQS).[11] The AQS website (www.epa.gov/ttn/airs/airsaqs/sysoverview.htm) provides detailed information on submitting and retrieving such data, including instructions on the file format for the data. Archived data may be accessed at the AQS site.[12]

Exhibit 10-11. Identified Deficiencies in Available Monitoring Methods		
Compound	**Candidate Method**	**Deficiency**
1,3-butadiene 1,2-dibromoethane 1,2-dichloroethane	TO14A/15	sensitivity issue; false highs
acrylonitrile	TO14A/15	NIST standard needed; recovery problems
ethylene oxide	None/NIOSH 1614	poor storage stability
1,1,2,2-tetrachloroethane	TO-15	NIST standard needed
arsenic and compounds	IO-3	sensitivity issues; filter contamination; resource intensive
beryllium and compounds	None	resource intensive; XRF sensitivity issue
mercury and compounds	IO-5	requires special equipment
acrolein	None	TO-11A results in unstable derivative poor recovery
2,3,7,8-tetrachlorodibenzo-p-dioxin	TO-9A	resource intensive

Exhibit 10-12. VOC Compounds Needing Improved Monitoring Methods	
vinyl chloride 1,2-dichloroethene dichloromethane chloroform 1,2-dichloroethane benzene carbon tetrachloride 1,2-dichloropropane trichloroethene	cis- and trans-1,3-dichloropropene 1,1,2-dichoroethane 1,2-dibromoethane tetrachloroethylene 1,1,2,2-tetrachloroethane hexachlorobutadiene acrylonitrile 1,3-butadiene ethylene oxide

10.8 Using Air Monitoring Data to Evaluate Source Contribution

Caution should be used in interpreting the results of a measurement as being uniquely associated with a given source. Most measurements from monitoring data are, depending on the chemical, a combination of background concentrations and the same chemical released from possibly multiple sources. Benzene, for example, is present in background air, is released from mobile sources, and is used and released from multiple types of stationary sources. This is not to say that monitoring data cannot be used to identify releases from a source. Under certain circumstances, analysis of multiple measurements at different locations may indicate a spatial pattern consistent with the known air dispersion pattern accompanying that source (and inconsistent with the patterns from other sources).

Use of Historical Monitoring Data

Historical monitoring data for an assessment area may be of use in developing the analysis plan. They can help with a range of uses, including:

- Identifying the types of chemicals that may be present in the air;
- Selecting locations for monitors;
- Performing preliminary screening level risk estimates; and
- Establishing acceptable monitoring protocols.

The utility of historical data will, of course, be based on an assessment of the quality of the data. For example, data that were not collected with sufficient QA/QC, may not be useful for any of the above purposes.

EPA also has developed "receptor models" which make use of monitoring data, together with emissions inventories, to perform source apportionment analyses, which provide a quantitative estimate of what percent of each pollutant comes from each identified source. EPA's Chemical Mass Balance Model is one such example (available on EPA's SCRAM website at http://www.epa.gov/scram001/tt23.htm). This model uses chemical concentrations measured in samples from sources (emissions) and receptor locations to estimate the contributions of source types to ambient air pollutant concentrations. The model is used primarily in the development of State Implementation Plans for PM_{10}. The model allows the user to select samples, chemical species, and source types for modeling, calculate source contributions and their standard errors, evaluate goodness-of-fit and validate the model results, prepare output documentation, and graph results.

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Chapter 11 Estimating Inhalation Exposure

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11.1 Introduction

The previous three chapters discussed how to quantify exposure and release rates and estimate chemical fate and transport. This chapter discusses the final step of estimating exposure. This chapter will discuss inhalation exposure only. Unless persistent bioaccumulative hazardous air pollutants (PB-HAPs) are present in source emissions, most air toxics risk assessments will only estimate inhalation **exposure concentrations**. Limiting the exposure assessment this way is possible because the dose-response values that characterize inhalation risk (e.g., reference concentrations, inhalation cancer unit risk estimates – see Chapter 12) take into consideration the complex physical and pharmacokinetic processes that influence how the chemical reaches the target organ, which may be a region of the respiratory tract or a remote site (see Chapter 12 for a more detailed discussion). Specifically, other than exposure modeling to account for things like time in different microenvironments and microenvironment concentrations, no adjustment for other exposure parameters (e.g., body weight and inhalation rate) are warranted. For multipathway risk assessments, however, where ingestion intake rate is the exposure parameter, it will be necessary to consider parameters such as body weight and contact rate (e.g., amount of soil ingested, fish eaten) for the indirect exposure pathway metrics of exposure (see Chapter 19).

Assessors determine human exposure to an environmental pollutant via inhalation by estimating the concentration of that pollutant in the ambient air and the contact of an individual with that air (along with the characteristics of the contact). Because concentrations in the air vary over space and time, it is important to know where and how long people spend their time in relation to the contaminated air under study. Through air quality modeling and monitoring, the ambient concentrations of pollutants in air can be estimated geographically and temporally. Through the use of exposure modeling, estimates of exposure via the inhalation route can be adjusted from modeling data to take into account the demographics of people in the study area and the time they may spend in various microenvironments.

The remainder of this chapter discusses how to estimate inhalation exposure concentrations for the risk assessment (Section 11.2); exposure modeling (Section 11.3); personal monitoring (Section 11.4); common descriptors (Section 11.5); evaluating uncertainty (Section 11.6); and presenting the results of an exposure assessment (Section 11.7).

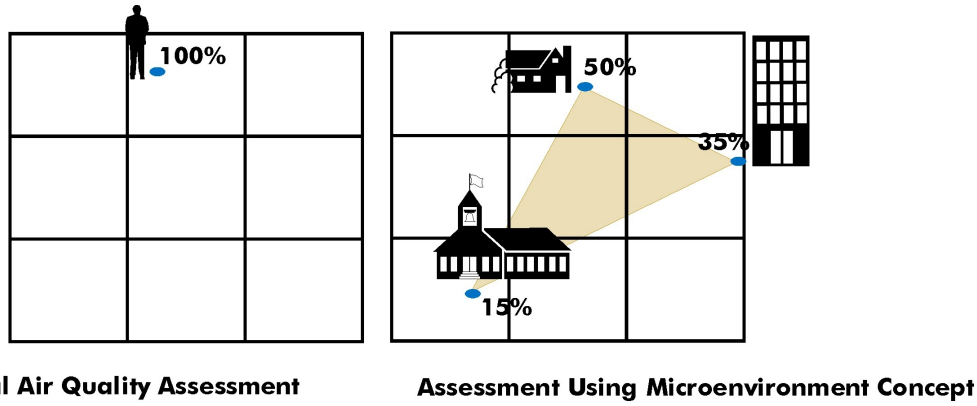
11.2 Estimating Inhalation Exposure Concentrations

The ambient air exposure concentrations (ECs) can be estimated using either (or both of) two general methods: air quality modeling and air quality monitoring. As discussed in Chapter 9, air quality modeling involves defining the pollutant sources and release characteristics and modeling pollutant fate and transport (how the air toxic is transported, dispersed, and transformed over the area of interest). As Chapter 10 discussed, monitoring involves measuring ambient concentrations of chemicals. Because of the time/expense and other limitations associated with monitoring (most notably, questions about representativeness), modeling is the most common approach for estimating ambient air concentrations to be used in the air toxics risk assessment. Monitoring is often used, instead, as a secondary tool to provide input data to the models and validate the model results and to look for important gaps in the emissions inventory used to run the model.

11.2.1 General Approaches for Deriving Exposure Concentrations

There are two general ways to derive the EC for a given risk assessment (see Exhibit 11-1). Both may incorporate the results of air quality modeling and/or monitoring efforts.

Exhibit 11-1. Two General Ways to Estimate Inhalation Exposure Concentration



The left-hand side illustrates the use of ambient air concentrations as a surrogate for the EC. In this example, the analysis assumes that individuals spend 100 percent of their time at a given location, so the estimate of ambient concentration thus represents the EC. The right-hand side illustrates the use of exposure modeling. In this example, the analysis assumes that an individual spends 50 percent of his/her time at home; 15 percent at a school; and 35 percent at an office. The EC is the weighted sum of the product of the ambient concentrations at each location and the amount of time spent there. Both indoor and outdoor concentrations usually are considered at each location.

- **Ambient Air Concentrations as a Surrogate**. For screening-level evaluations, assessors use the concentrations of air toxics generated at each modeling node (or interpolated nodes) or the concentrations determined by a monitor (if modeling is not performed) as surrogates of the inhalation exposure concentrations for the populations in the study locations. The default assumption in such a screening assessment is that the population of interest is breathing outdoor air continuously at the modeled or monitor location. This is believed to be a conservative assumption since indoor air concentrations of air toxics are expected to be the same or lower than the outdoor concentrations (when the indoor concentrations are produced solely by inflow from outside air).

- **Exposure modeling**. More comprehensive inhalation exposure assessments combine estimates of ambient pollutant concentrations (e.g., from air quality models) with information about the population of interest, including the types of people present (e.g., ethnicity, age, sex), time spent in different microenvironments, and microenvironment concentrations. The assessment objective is to identify a representative estimate of the pollutant concentration in the inhaled air in each microenvironment and combine it with an estimate of the time spent in different microenvironments (and the activities within these microenvironments) throughout the daily routine of different groups of people with similar attributes (called **cohorts**).

11.2.2 Common Ways to Estimate Exposure Concentrations

Risk assessors commonly use several different ways to estimate exposure concentrations. Some ways are used primarily for screening-level (Tier 1) assessments; others are used primarily for more refined assessments. Exhibit 11-2 illustrates several different ways to estimate exposure concentrations when ambient air concentrations are used as surrogates.

- **Monitoring locations**. Sites where air monitors are located provide a direct measure of ambient air concentrations at those locations. However, these locations may or may not be representative of ambient air concentrations in other parts of the study area. If monitors are not located where people live, the monitoring results may not be of much value for the risk assessment other than to check the accuracy of modeling. Monitoring results may be used as inputs to exposure modeling.

- **Point of maximum modeled concentration**. This is the modeling node where the maximum modeled ambient air concentration occurs, regardless of whether there is a person there or not. This generally provides a conservative estimate of exposure and could be used as the EC in a screening-level evaluation (for example, using the SCREEN3 model). This point can be used to provide an estimate of "high-end" exposure to the risk manager because, although no one may actually be living there at the present, someone might move their in the future. This point may be referred to as the point of the **"maximum exposed individual (MEI)."**

- **Point of maximum modeled concentration at an actual receptor location**. This is the modeling node where the maximum ambient air concentration occurs to an actual person in the area of impact, usually at an actual residence (or, if the residence falls between modeling nodes, an interpolated value). To identify this point precisely, it is necessary to know detailed information about the location of actual people in the study area. As with the point of maximum modeled concentration above, this point can be used to provide an estimate of "high-end" exposure to the risk manager (in this case, based on current actual exposures). This point may be referred to as the point of the **"maximum individual risk (MIR)."**

- **Census tract/block internal point**. The U.S. Census Bureau provides information about populations in geographic units called census tracts, which are subdivided into block groups/enumeration districts and blocks. In cases where there is only limited information about the census tract (e.g., nothing is known other than the number of people living within the tract), the Census Bureau's "internal point" (sometimes referred to as a centroid) for the tract typically is used as the point of exposure for all the population in the tract. The internal point is a set of geographic coordinates that generally represents the approximate geographic center of a geographic subdivison (see box on next page). The Census Bureau provides an internal point for each of its geographic subdivisions (i.e., tracts, blocks, and block groups). Note that the internal point **<u>is not population weighted</u>** (i.e., it is not located "in the direction of where the people are").

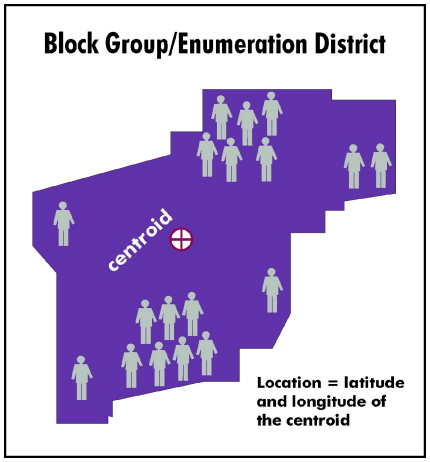
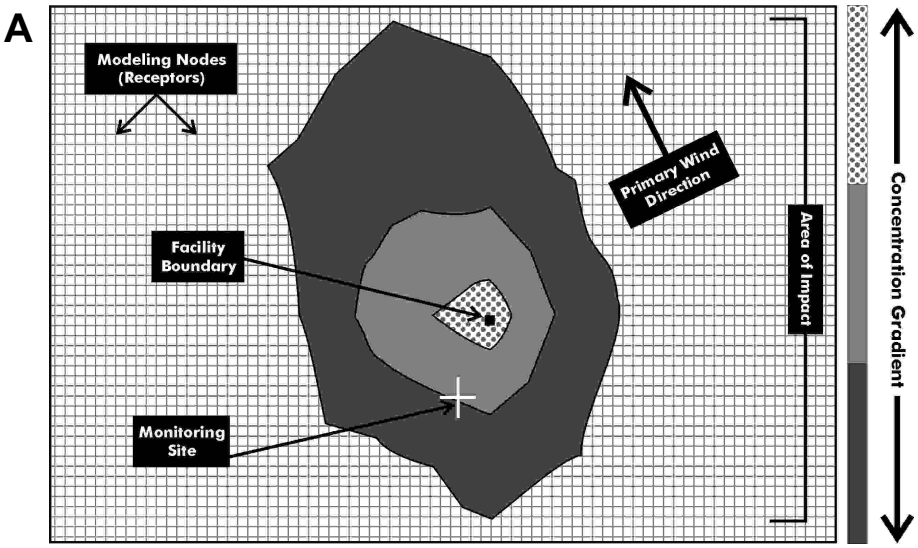


Exhibit 11-2. Illustration of Common Ways to Estimate Exposure Using Ambient Air Concentrations as Surrogates for Exposure Concentration



100 meter modeling grid

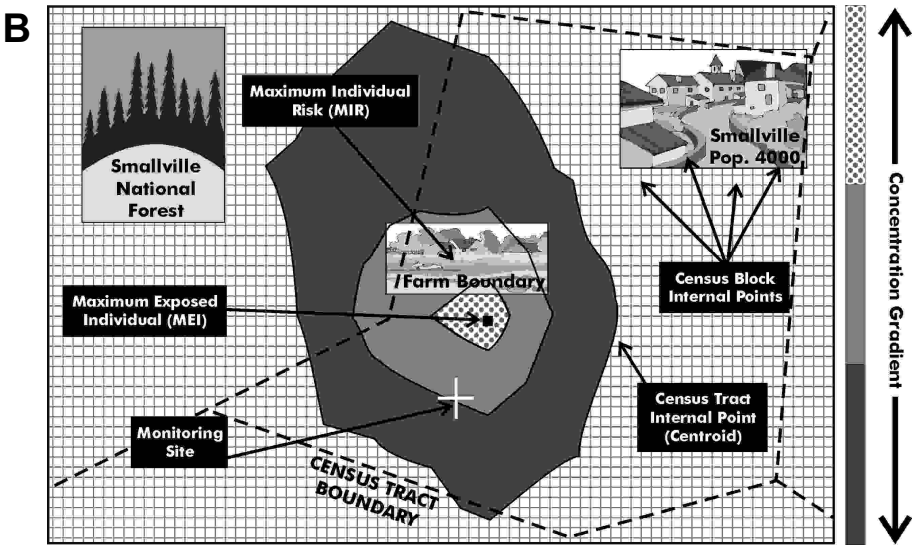
In this hypothetical example, the risk assessors have modeled a release of a volatile organic HAP from a facility using a computerized air quality model, and the ambient air concentration is used as a surrogate for the exposure concentration (EC). The area of impact surrounds the facility and is generally greater in the direction of the primary wind flow (and decreases in concentration with distance from the source). The model was set to make estimates of annual concentration at 100-meter distances from the source in a rectangular grid pattern. The points where the model makes estimates are called "modeling nodes" or "receptors." Note, however, that modeling receptors do not necessarily coincide with actual people (who are also sometimes referred to as receptors) – that is, there may or may not be a person at any given modeling node. There also is one monitoring site.

Knowing only the information displayed in the first version of the map (A), it is difficult to say much about exposure since we do not know where the people are in relation to the facility or the area of impact. To remedy this, our next step is to obtain demographic data (usually from the Census Bureau) and overlay it on the above map. We may also have first-hand knowledge of exactly where people live in the vicinity of the of the facility which we can also include on the map. Performing this analysis and redrawing the map gives picture B (next page).

In the second version of the map (B), we have included the census tract boundaries (dotted lines) and we also know from study area reconnaissance that there is an uninhabited national forest to the west of the facility, a farmer (Mr. MacDonald) directly to the north, and a small town in the northeast. (Note that the town, Smallville, actually can be further subdivided into smaller census blocks; however, they are not shown here to keep the picture simple.) Now that we have a better idea of where people are in relation to the facility (and the area of impact caused by the VOC release), we are in a better position to start making some statements about how people are exposed. Some of the more common ways to characterize the exposures that may be occurring include:

1. **Monitoring Site**. The monitoring site is located in one of the higher parts of the area of impact, but it is southwest of the facility and far from most of the area's populations. This monitoring site would not be appropriate for describing exposure for the people of Smallville, but it could be used for people in the immediate vicinity of the facility and to check the accuracy of the modeling.

Exhibit 11-2 (continued)



2. **Point of Maximum Modeled Concentration**. In this example, this point is located on the facility boundary, where no one currently lives. This point is called the Maximum Exposed Individual or MEI which is defined as the highest estimated risk to a hypothetical exposed individual, regardless of whether people are expected to occupy that area.

3. **Point of Maximum Concentration at a Location Occupied by People**. In this example, this point occurs at Mr. MacDonald's farm. This point is called the Maximum Individual Risk, or MIR, which is defined as the highest estimated risk to an exposed individual in areas that people are believed to occupy. Actually, the concentration used to represent Mr. MacDonald could be described using either an estimate of exposure at a point (e.g., his house) or some other estimate of exposure for the larger farm if there were a good justification for doing so (e.g., an average of all the farm's modeled points, since Mr. MacDonald spends much of his time working around the farm).

4. **Census Tract Internal Point**. In this example, we could simply use the census tract internal point to represent exposure for all people living in the census tract. This is sometimes used, especially when you do not have any first-hand knowledge of the area (i.e., you only have general demographic data from the Census Bureau). However, in this example the census track internal point would not be a very good estimate of exposure concentration because it is higher in concentration than that experienced by most of the population (i.e., the people of Smallville) and it is lower in concentration than that of the highest exposed person (i.e., Mr. MacDonald).

5. **Census Block Internal Points**. So far, this example has focused on characterizing an individual person's exposure living at defined points within the study area (either a real person like Mr. MacDonald, or a hypothetical person like the MIR). What if we wanted to know something more about *how many* people in the study area are living at different levels of exposure? One way to do this is to develop a frequency diagram that displays the exposure concentration at each of the census block internal points and identifies the number of people living in that block (see below). This kind of representation is very helpful to the risk managers because it gives them a sense of the range of exposures and the numbers of people living at different levels of exposure. (In addition, the assessor may also choose to represent the exposure with isopleths of risk (as in the above graphic) and by listing the approximate number people living within each isopleth.)

The internal point with the highest impact in the study area may also be referred to as the point of maximum concentration at a receptor location, although it may not be as precise as the example above where more local knowledge is applied to locate this point.

- **Population-based approaches**. Exposures may be evaluated by tracking individual members of a population and their inhalation through time and space. Such analyses may incorporate a user-specified number of **simulated individuals** or population groups (**cohorts**) to represent the population in the study area. A cohort is defined here as a group of people within a population with the same demographic variables who are assumed to have similar exposures. In this approach, the exposure analysis process consists of relating chemical concentrations in air (outdoor and/or indoor) and tracking the movement of a population cohort through locations where chemical exposure can occur according to a specific activity pattern. Population-based analysis is generally accomplished using exposure models (as described in Section 11.3 below).

- **Personal monitoring**. Exposures may be estimated directly by placing monitors on individuals, which allows collection of more detailed information specific to the exposure pattern for that individual. Such monitors are referred to as **personal monitors** because they provide information on exposure to that individual, rather than to the general area in which an individual might be moving. Personal monitoring is discussed in Section 11.4 below.

Note that the units for the EC estimates are typically expressed in terms of micrograms (or milligrams) of pollutant per cubic meter of air. For pollutants adsorbed to particles, inhalation exposure estimates should be provided as the concentration of these pollutants *on the particles*, not the concentration of the particles themselves.

11.3 Exposure Modeling

This section discusses exposure modeling, which uses the ambient air concentration estimates along with information about the population of interest and information on how the pollutant concentration can vary in different microenvironments to derive estimates of exposure concentration over the period of exposure. Information on human exposure modeling for air toxics can be found on EPA's Fate, Exposure, and Risk Assessment (FERA) website at http://www.epa.gov/ttn/fera/.

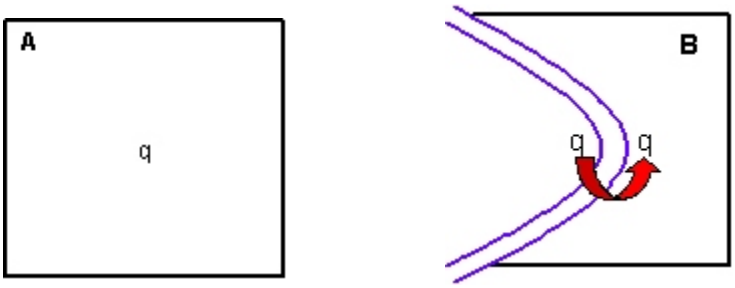
For example, suppose an analyst uses the air quality model, ISCLT3, to estimate the annual average concentration of benzene from a petroleum refinery at each census tract internal point for every census tract within 50 km of the source (for illustration, assume this is 25 census tracts). In a screening level analysis, the analyst may simply use the predicted ambient air concentration as a surrogate for the population chronic exposure concentration of benzene at each of the 25 internal points.

Internal Point or Centroid: Which is Correct?

When evaluating exposure to people in a given place, the modeled air quality at the "internal point" of a geographic entity (such as a census tract or census block) is often used as a starting point to represent exposure for the people in that geographic entity. According to the U.S. Census Bureau:

> *An internal point is a set of geographic coordinates (latitude and longitude) that is located within a specified geographic entity. A single point is identified for each entity; for many entities, this point represents the approximate geographic center of that entity. If the shape of the entity causes this point to be located outside the boundary of the entity or in a water body, it is relocated to land area within the entity. In computer-readable products, internal points are shown to six decimal places; the decimal point is implied. The first character of the latitude or longitude is a plus (+) or a minus (–) sign. A plus sign in the latitude identifies the point as being in the Northern Hemisphere, while a minus sign identifies a location in the Southern Hemisphere. For longitude, a plus sign identifies the point as being in the Eastern Hemisphere, while a minus sign identifies a location in the Western Hemisphere.*

To illustrate how internal points are established, consider the following two examples. In census tract A, the internal point (q) is simply the geographic center of the square. In census tract B, a river flows along the western edge of the tract and makes a sharp bend towards the tract's eastern edge. In this case, the "geographic center" of census tract B is actually outside the tract itself. Since the Census Bureau requires that the internal point be within the physical boundaries of the geographic entity, the Bureau physically moves the point into the tract, as shown (to a point that is no longer the geographic center).



Note that the internal point is generally set to reflect the geographic center of the entity in question, regardless of where people actually live in that entity. In other words, the point is not "population weighted" (the Census Bureau does not provide population weighted internal points for census tracts or block groups). Without population weighting, an exposure concentration estimated at the internal point might not be representative of the concentrations to which persons living in the census entity might be exposed. Analysts routinely modify the Census Bureau internal points for census tracts and census block groups (using census block data) to locate them to a spot more representative of where people are actually located within the geographic entity (e.g., a "population weighted" internal point).

Source: U.S. Department of Commerce, U.S. Census Bureau. 2000. *Geographic Glossary (Census 2000)*. Available at: http://www.census.gov/geo/www/tiger/glossry2.pdf.

However, a limitation of this is that each person in a census tract is not breathing air at the ambient concentration continuously. There are a variety of reasons why this is so. For example:

- People come and go from the census tract for work, play, or travel. They may go to another census tract in the vicinity with either a higher or lower concentration of benzene.

- People do not spend all their time outdoors (which is what our analyst has presumed in our hypothetical example). In fact, most people spend most of their time (with some estimates of about 90 percent) indoors. The chemical concentration of benzene may be higher or lower indoors than outdoors.

- The benzene concentration throughout the census tract, in our example, is probably not always the same as that at the internal point we selected (we have just assumed it was for computational ease).

Exposure modeling was developed to try and help move an analysis into considering these details. Thus, air quality modeling estimates how contaminated the air is in the different locations within a study area. Exposure modeling simulates how different types of people interact differently with that contaminated air to derive integrated (e.g., time weighted) estimates of their exposure for the duration of interest.

This section focuses on exposure models to evaluate inhalation exposures. Exposure models are also available for other routes of exposure as well (e.g., a model may be employed to track patterns of food and drinking water consumption across a population). These indirect pathway exposure models are discussed in Chapter 18.

The estimation of population exposure is a very difficult task because it requires information on the activity patterns of the population as well as information on the air toxics concentrations (indoor and outdoor) to which that population is exposed. Although several databases have been developed to characterize activity patterns (see Section 11.3.3), various sources of variability (e.g., among individuals and geographical regions) introduce uncertainty. Three main factors affect the overall accuracy of exposure modeling:

- Uncertainties associated with indoor air toxics concentrations (note that most people spend the majority of their time indoors);

- How well the subgroups (or cohorts) selected for analysis provide a realistic description of the population composition in a given area; and

- Uncertainty and variability associated with the inputs and parameters of exposure models.

Exposure models can be formulated in a **deterministic** framework, where the value for each input and output variable is characterized by a point estimate (i.e., a single value assumed to apply uniformly). Alternatively, the framework may be **stochastic** or **probabilistic**, with one or more input variables characterized by a frequency or probability distribution[(a)] (see Exhibit 11-3).

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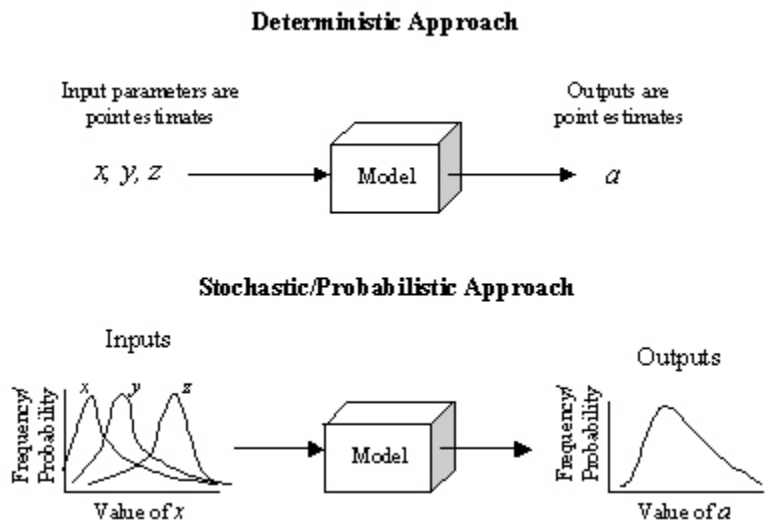
[a]These terms are introduced and defined in Part VI of this Reference Library.

If the input distributions represent variability[(a)] across the population, the resulting output distribution correspondingly represents the variability of exposures across the population. On the other hand, if the input distributions represent uncertainty[(a)] about input parameters, the output distributions will represent uncertainty about exposure levels. Some of the newer exposure models address both variability and uncertainty separately (see Section 11.3.4).

Exhibit 11-3. Deterministic versus Stochastic/Probabilistic Approaches to Exposure Modeling



In the Deterministic Approach, the assessment assumes that each input to the model is a specific number (and the answer is a number).

In the Stochastic/Probabilistic Approach, the assessment assumes that the inputs to the model may be specified as a distribution (and the answer is a distribution).

11.3.1 Inhalation Exposure Modeling

Inhalation exposure is characterized by the pollutant concentration in the air (i.e., the exposure concentration) reaching an individual's nostrils and/or mouth (in units of $\mu g/m^3$). Estimates of air concentrations from modeling or monitoring can be used in inhalation exposure modeling. When derived from monitoring measurements, exposure concentrations are an **aggregate** of the contributions from all emissions sources impacting the monitor. When derived from modeling studies, the estimated exposure concentrations reflect only the sources that were included in the modeling exercise. Models have an added benefit of allowing the analyst to determine the contribution of a source to the estimated exposure concentration for any of the exposed population groups. (Trying to determine "what source" contributed "how much" to a monitoring result can be a challenging and perhaps impossible task, depending on the chemical and number of sources in the study area).

Lead Exposure Modeling

Lead (Pb) poisoning presents potentially significant risks to the health and welfare of children all over the world today. The Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) attempts to predict blood-lead concentrations (PbBs) for children exposed to lead in their environment. The model allows the user to input relevant absorption parameters (e.g., the fraction of lead absorbed from water) as well as intake and exposure rates. Using these inputs, the IEUBK model rapidly calculates and recalculates a complex set of equations to estimate the potential concentration of lead in the blood for a hypothetical child or population of children (6 months to 7 years of age). Measured or estimated blood-lead concentration is not only an indication of exposure, but also a widely-used index for discerning future health problems. For additional information see http://www.epa.gov/superfund/programs/lead/ieubk.htm.

Because air pollutant concentrations vary over time and space, inhalation exposure models combine information on human activity patterns and microenvironmental concentrations to estimate exposure concentrations. **Activity patterns** are defined by an individual's or cohort's allocation of time spent in different activities in various microenvironments and various geographic locations. A **microenvironment** is a defined space that can be treated as a well-characterized, relatively homogeneous location with respect to pollutant concentration for a specified time period (e.g., rooms in homes, restaurants, schools, offices; inside vehicles; outdoors).

A common exposure model for inhalation that combines information on microenvironment concentrations and activity patterns calculates a **time-weighted average of all exposures** from the different microenvironments in which a person spends time during the period of interest:

$$EC_A = \frac{1}{T}\left(\sum_j C_j \times t_j\right) \qquad \text{(Equation 11-1)}$$

where:

EC_A = the adjusted average inhalation exposure concentration (µg/m^3),
T = total averaging time ($T = \sum t_j$; years),
C_j = the average concentration for microenvironment j (µg/m^3), and
t_j = time spent in the microenvironment j (years).

Note that the two critical parameters that need to be evaluated in this equation are the concentration of a chemical in a microenvironment and the amount of time spent in that microenvironment. Exhibit 11-4 presents a simple example. General information on how assessors go about obtaining such data is provided below. As a practical matter, most air toxics risk assessments will not actually gather such activity pattern data for study-specific exposure assessments. Rather, available exposure models have already incorporated much of this information for use by the general risk assessment community. However, every model is different and the data input requirements vary from model to model. Usually, assessors carefully review each model's documentation before deciding to use it to determine if it will answer the

question that needs to be answered and what resources would be needed to develop the required inputs.

Exhibit 11-4. Simple Example of How to Estimate Exposure Concentration (EC) for Exposure Modeling

EC. The following exposure profile has been developed for one year (which represents, for example, the 30 years of "work") for a representative individual within the population of interest:

Duration Spent in Each Microenvironment (% year)	Average Concentration of Pollutant A in Each Microenvironment (µg/m^3)
10 = outside	80
50 = at work	20
40 = inside house	10

The EC for that individual is calculated as:

$$EC = (0.1 \times 80) + (0.5 \times 20) + (0.4 \times 10) = 22\ \mu g/m^3$$

Lifetime EC. To derive a lifetime exposure concentration for that individual, annual estimates are combined as follows:

Duration Exposed to Each Annual Concentration (no. years)	Annual Average Concentration of Pollutant A (µg/m^3)
1 = newborn	10
4 = pre-school	40
12 = school	30
4 = college	30
30 = work	22
19 = retirement	40

The Lifetime EC is calculated as:

$$\text{Lifetime EC} = \frac{(1 \times 10) + (4 \times 40) + (12 \times 30) + (4 \times 30) + (30 \times 22) + (19 \times 40)}{70} = 30\ \mu g/m^3$$

Screening exposure estimate. One way to perform a screening level assessment using these data is to set the EC equal to the highest air concentration modeled (e.g., 80 µg/m^3 for annual adjusted or 40 µg/m^3 for lifetime adjusted – see examples above) for all microenvironments. If the hazard and risk, respectively, prove to be below acceptable risk values, the risk manager may conclude that no further evaluation is necessary.

11.3.2 Microenvironment Concentration: How is it Developed?

Microenvironments can be indoors (e.g., school, office, car, bus) or outdoors (e.g., filling station, roadway). Indoor microenvironment concentrations are comprised of contributions from a chemical in outdoor air penetrating the indoor environment and from indoor emission sources of that same chemical (if indoor sources are within the scope of the analysis). They may be derived from direct measurements or estimated from modeling.

There are two common approaches to modeling indoor microenvironment concentrations. One is the **microenvironment factors method**, where the outdoor contribution is estimated from the outdoor concentration and a microenvironment factor that represents the ratio of the microenvironment concentration to the outdoor concentration. Microenvironment factors are typically derived from concurrent measurements of concentrations in the microenvironment (containing no indoor emission sources) and outdoors. The indoor contribution is then added to estimate the overall microenvironment concentration (when indoor sources are included in the scope of the assessment). A general equation for the microenvironment factors method is:

$$C_j = M_j C_o + C_s \qquad \text{(Equation 11-2)}$$

where:

C_j = concentration in microenvironment *j*
M_j = microenvironment factor for microenvironment *j*
C_o = concurrent outdoor concentration
C_s = concentration contribution to the microenvironment *j* concentration from an indoor emission source

The second approach is the **mass-balance method**. The mass balance method typically assumes that an enclosed microenvironment is a single well-mixed "box," although multi-chamber configurations are possible. The time-varying concentration of an air pollutant in such a microenvironment is estimated from several variables (see Exhibit 11-5). A general formulation for the change in concentration in an enclosed microenvironment over time is:

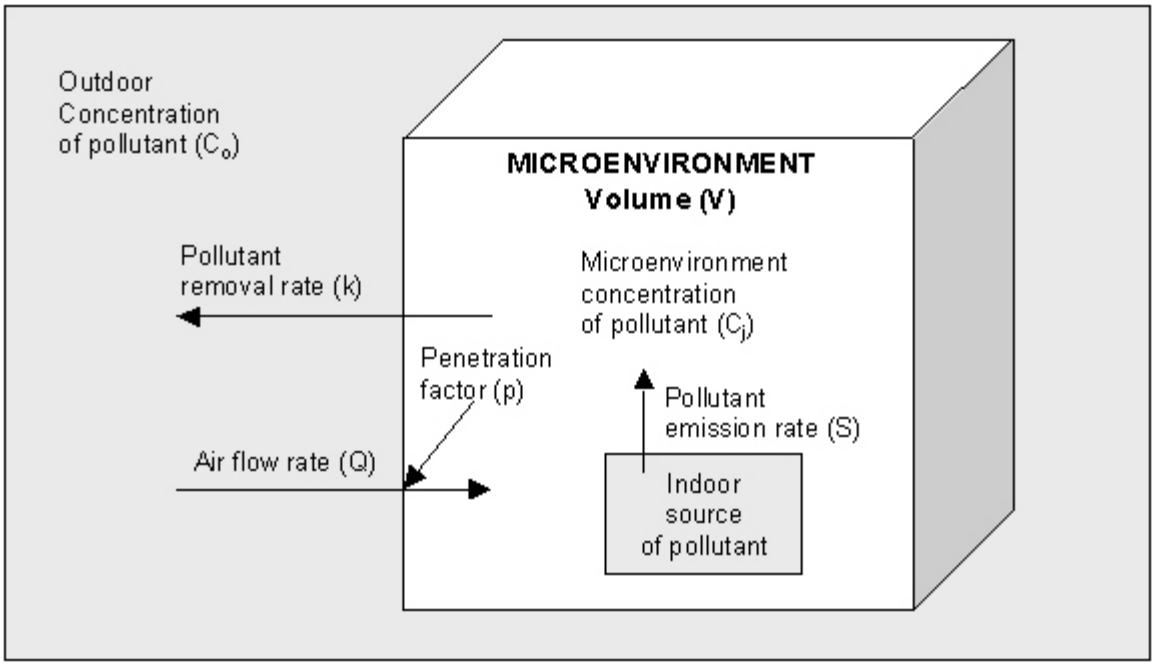
$$V \frac{d}{dt} C_j = pQC_o + S - kC_j - QC_j \qquad \text{(Equation 11-3)}$$

where:

V = volume of microenvironment enclosure
C_j = concentration in microenvironment *j*
p = penetration factor (only applies to incoming air)
Q = air flow rate
k = pollutant removal rate (includes all types of removal, including atmospheric decay, surface reactivity, surface adsorption, wall deposition, etc.)
C_o = concurrent outdoor concentration
S = indoor source emission rate

The solution to this differential equation can be used to predict a time sequence of microenvironment *j* concentrations.

Exhibit 11-5. Illustration of Mass Balance Method for Modeling Indoor Microenvironments



11.3.3 Sources of Data for Human Activity for Inhalation (and other) Exposure Assessments

Numerous EPA and related databases provide information useful for conducting exposure assessments, including information on activity pattern and demographic information useful for inhalation exposure modeling. Types of information included are human activity surveys, standard values for physiological processes and consumption of food and water, measured exposure data, health status surveys and measurements, nutrition surveys, and data on the spatial distribution of populations. This section provides several of the more notable information sources, some of which are important for inhalation exposure modeling, and some of which are important for modeling exposures through pathways other than inhalation (e.g., ingestion of contaminated fish, soil, and groundwater). Because they are so important for an understanding of exposure, we introduce them here (even though the focus of this Chapter is on inhalation). We will revisit many of these sources in Part III (Multipathway Exposure Assessment).

Indoor vs. Outdoor Concentrations

Indoor air concentrations may be an important consideration in an air toxics risk assessment. Depending on the pollutant and the sources being assessed, concentration levels may be substantially higher outdoors, in one or more indoor microenvironments, or inside vehicles. In general, pollutants that have important indoor emission sources will have higher concentrations indoors than outdoors. Important indoor emission sources include combustion sources, building materials, consumer products, and occupant activities like cigarette smoking. Similarly, pollutants that are primarily emitted by motor vehicles would be expected to have higher in-vehicle concentrations than at outdoor locations distant from roadways.

Information that may be useful to the various methods used to estimate microenvironment concentrations is available from studies involving measurements of indoor and personal exposure concentrations. These include the following EPA studies:

- The Building Assessment, Survey and Evaluation (BASE) study, which was a cross-sectional study of 100 buildings. Information relating to BASE is currently being updated to include basic summary results from the 100 buildings studied. The raw data collected for the 100 buildings is scheduled for release soon.[1]

- The Longitudinal Temporal Indoor Monitoring and Evaluation (TIME) Study in federal buildings.[1]

- The Los Angeles Total Exposure Assessment Methodology (TEAM) study,[2] which collected concurrent indoor and outdoor samples of 18 VOCs for two consecutive 12-hour periods in 1987, around 45 homes in February and 40 homes in July.

- **EPA Consolidated Human Activity Database (CHAD)**. CHAD contains data obtained from human activity studies that were performed at city, state, and national levels. CHAD is intended to provide input data for exposure/intake dose modeling and/or statistical analysis.[3] CHAD is a master database providing access to other human activity databases using a consistent format. This facilitates access and retrieval of activity and questionnaire information from those databases.

  The studies contained in CHAD cover a range of geographic areas. In addition to the National Human Activity Pattern Study (NHAPS) with information about residents from 48 states, there are studies targeting residents of Baltimore, Cincinnati, Denver, Los Angeles, Valdez, Washington DC, and the states of California and Michigan. Because the individual studies differed based on what information was collected, not all fields in the CHAD database are populated for all the records.

  Each CHAD diary record consists of a 24-hour sequence of activities. Specified for each activity is a start time, end time, duration, one of 113 location codes, and one of 145 activity codes. Each diary record is tagged with a CHAD ID, which relates it to a record in the demographic database identifying information about the subject of the diary. Demographic fields include personal characteristics (age, gender, ethnicity, weight), social characteristics (education, occupation, income), residential location (state, county, zipcode) and housing characteristics (heating fuel, cooking fuel). In addition, CHAD has the capability to estimate

the relative metabolic rate for each activity in a record using random sampling from distributions derived from clinical studies.

- **EPA Exposure Factors Handbook**. The Exposure Factors Handbook provides a statistical summary of the available data on various parameters and variables used in assessing human exposure. This Handbook is used by risk assessors who need to obtain data on standard factors to calculate human exposure to toxic chemicals. These factors include human activity factors and residential characteristics. Recommended values are for the general population and also for various segments of the population who may have characteristics different from the general population. Included are full discussions of the issues that assessors may want to consider in deciding how to use these data and exposure parameter recommendations. (The Exposure Factors Handbook is in final form, but as new data become available updates will be posted).[4]

- **EPA Human Exposure Database System (HEDS)**. HEDS is a web-enabled data repository for human exposure studies.[5] Its mission is to provide data sets, documents, and metadata for human exposure studies that can be easily accessed and understood by a diverse set of users. HEDS provides only data and accompanying documentation from research studies; it does not provide interpretations. It allows a user to download documents for review or data sets for analysis on their own computer system. Currently contained in HEDS are various components of the National Human Exposure Assessment Survey (NHEXAS).

- **National Human Exposure Assessment Survey (NHEXAS)**. The National Human Exposure Assessment Survey was developed by US EPA's Office of Research and Development (ORD) in the 1990's to provide information about multimedia and multipathway population exposure to chemicals of various types. Phase I consists of demonstration/scoping studies using probability-based sampling designs. Volunteer participants were randomly selected from several areas of the U.S. These studies included personal exposure, residential concentrations, and biomarker measurements. The Arizona study measured metals, pesticides, and VOCs. The Maryland study measured metals, pesticides, and polycyclic aromatic hydrocarbons (PAHs). The Region 5 study, conducted in Ohio, Michigan, Illinois, Indiana, Wisconsin, and Minnesota, measured metals and VOCs. Researchers worked with the participants to measure the level of chemicals in the air they breathed, in the foods and beverages they consumed (including drinking water), in the soil and dust around their homes, and in their blood and urine. Participants completed questionnaires to help identify possible sources of chemical exposure. Sample collection occurred between 1995 and 1997. The confidentiality of participants is strictly protected. Information about the studies can be found in the related study entries in EIMS and in the *Journal of Exposure Analysis and Environmental Epidemiology*.[6]

- **CDC National Health and Nutrition Examination Survey (NHANES)**. NHANES is a survey conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention.[7] This survey has been designed to collect information about the health and diet of people in the United States. NHANES is unique in that it combines a home interview with health tests that are done in a Mobile Examination Center. The current NHANES is eighth in a series of national examination studies conducted since 1960. The results of these surveys are compiled in databases and summarized in a variety of tables and reports. Data from direct examination, testing, and measurement of national samples of the

civilian noninstitutionalized population provide the basis for (1) estimates of medically-defined prevalence in the US and the distribution of the population with respect to physical, physiological, and psychological characteristics, and (2) analysis of relationships among various measurements without reference to an explicit finite universe of persons. Reports also present information about dietary patterns in various segments of the US population.

- **U.S. Census Data**. The U.S. Census provides data on the spatial distribution of population and population subgroups at several geographic levels: national, state, county, tract, block group and block. (For detailed analysis, Summary File 3 is most useful.) Examples of useful spatially-resolved data for exposure assessment include: population by age, gender, and ethnic group; house heating fuel use; estimated travel time to work by various modes of transportation; and levels of employment in various industries. Associated geographic data specifying boundaries of the various geographic entities for mapping are also available in Topologically Integrated Geographic Encoding and Referencing (TIGER) files.[8]

- **LandScan USA**. LandScan is a high resolution population distribution database for the continental U.S. currently under development, following the methodology used to create a similar global database called LandScan1998 (updated in 2000).[9] LandScan uses satellite imagery in population distribution modeling to produce population distribution data at a much finer resolution than previously available. LandScan 1998 and 2000 have a grid cell size of 30 seconds (<1 kilometer) and use census data in combination with many other geospatial data, such as land use/cover, topography, slope, roads, and nighttime lights, in order to improve the estimation and prediction of the spatial distribution of residential populations. Future LandScan updates will use a much smaller grid cell size of 3 seconds (<100 meters). Currently, a pilot study in a 29 county area in southeast Texas (around Houston and Port Neches) is being conducted. LandScan will be very useful for exposure modeling, environmental justice studies, and other types of risk assessments.

11.3.4 Examples of Inhalation Exposure Models

Several exposure models have been or are being developed by EPA and others for a variety of purposes. Some of the important characteristics that vary among the models include:

- Ambient concentrations
  - Modeling or monitoring estimates
  - Time scales (e.g., averaging time)

- Exposure concentration time scale
  - Time increment for calculations (e.g., by minute, hourly, seasonally, annually)
  - Averaging time for reporting (e.g., hourly, annually)

- Spatial scale
  - Geographic resolution of predictions (e.g., Census tracts, Census blocks, grids)
  - Potential size of modeling domain (e.g., neighborhood, county, nation)

- Population activity data
  - Type (e.g., time in microenvironments, commuting locations, food and water ingestion rates)

- Temporal resolution (e.g., by minute, hourly, seasonally, annually)
- Area specific resolution (e.g., national or regional)
- Demographic resolution (e.g., by age, gender, or ethnic group)

- Framework
  - Deterministic: inputs and outputs are characterized as point estimates
  - Stochastic or probabilistic: inputs and outputs are characterized as distributions representing variability and/or uncertainty; Monte Carlo techniques are used to randomly select input values from the distributions for repeated simulations

The remainder of this section provides brief descriptions of some of the most recently developed inhalation exposure models. The features of each model described are summarized in Exhibit 11-6.

Exhibit 11-6. Comparison of Inhalation Exposure Model Features

Model	Population Activity Data	Source of Ambient Concentrations	Spatial Resolution	Framework
HEM-3	none (screening model)	ISCST3	census blocks (additional points can be specified)	deterministic
HAPEM	micro-environment time/sequence, commuting	external model or monitoring data	census tract	stochastic
TRIM.Expo (a.k.a. APEX)	micro-environment time/sequence, commuting	external model or monitoring data	depends on resolution of air quality and demographic inputs	stochastic
CPIEM	micro-environment time/sequence, commuting	external model or monitoring data	user-specified for the selection of activity patterns (e.g., state, region)	stochastic

Human Exposure Model (HEM)

The Human Exposure Model (http://www.epa.gov/ttn/fera/human_hem.html) was designed to screen major stationary sources of air pollutant emissions efficiently, ranking the sources according to the potential cancer risks and noncancer hazard associated with long-term (annual) average exposure concentrations.[10] The current version, Version 3 (HEM-3), is implemented on a Windows platform for ease of use. HEM-3 contains a version of the Gaussian atmospheric dispersion model ISCLT2 (with included meteorological data), and U.S. Census Bureau population data (2000) at the Census block level. A limited amount of source data are required as model inputs (e.g., pollutant emission rates, facility location, height of the emission release, stack gas exit velocity, stack diameter, temperature of the off-gases, pollutant properties, and source location). HEM-3 estimates the magnitude and distribution of ambient air concentrations of pollutant in the vicinity of each source. The model usually estimates these concentrations

within a radial distance of 50 kilometers (30.8 miles) from the source. Exposure concentrations for the residents of each Census block are assumed to be the outdoor concentration at the Census block "internal point." This actually represents a surrogate for exposure, as important exposure variables (e.g., indoor-outdoor concentration differences, human mobility patterns, residential occupancy period, breathing rates) are not explicitly addressed. Multiple facilities (including clusters of facilities, each having multiple emission points) can be addressed by HEM-3. Variability and uncertainty in input data and parameters are not considered.

The Hazardous Air Pollutant Exposure Model (HAPEM5)

The latest version of EPA's Hazardous Air Pollutant Exposure Model (HAPEM5) is a stochastic screening-level inhalation exposure model appropriate for assessing average long-term (annual) exposures of the general population, or a specific sub-population, over spatial scales ranging from urban to national (http://www.epa.gov/ttn/fera/human_hapem.html). This application requires a moderate level of computer modeling skills.

HAPEM5 uses the general approach of tracking representatives of specified demographic groups as they move among 37 indoor, in-vehicle, and outdoor microenvironments and among geographic locations. The estimated pollutant concentrations in each microenvironment visited are combined into a time-weighted average concentration, which is assigned to members of the demographic group (the cohorts). Microenvironment concentrations are estimated from outdoor concentrations with the factors method. HAPEM5 uses five primary sources of information: population data from the U.S. Census; population activity data from CHAD commuting data developed by the Bureau of the Census; user supplied air quality data either from measurements or an air dispersion model; and microenvironmental factors data.

The previous version of HAPEM5, namely HAPEM4, was used in the NATA national scale assessment of the 1996 NEI to develop estimates of risk, by census tract, for each of the 33 HAPs (http://www.epa.gov/ttn/amtic/netamap.html). Specifically, HAPEM4 was used to predict population exposure for each of 10 demographic groups in each tract.

Total Risk Integrated Methodology Exposure Event Model (TRIM.Expo$_{Inhalation}$), also known as Air Pollutants Exposure Model (APEX)

The Air Pollutants Exposure Model (APEX) comprises the inhalation portion of the TRIM exposure module, TRIM.Expo (http://www.epa.gov/ttn/fera/human_apex.html).[b]

TRIM.Expo (a.k.a. APEX) uses a personal profile approach rather than a cohort simulation approach. That is, individuals are selected for simulation by selecting combinations of demographic characteristics and finding an activity pattern to match it, rather than directly selecting an activity pattern. If the selection probabilities for the demographic characteristics are the same as within the population to be simulated, this approach will provide a representative sample of that population's activity patterns without the need for post-simulation weighting of results.

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[b]EPA has developed the Total Risk Integrated Methodology (TRIM) for use in the assessment of air pollutants (both hazardous and criteria). APEX comprises the inhalation exposure component of TRIM.

The current version (APEX3, available on the web) includes a number of useful features including automatic site selection from large (e.g., national) databases, a series of new output tables providing summary statistics, and a thoroughly reorganized method of describing microenvironments and their parameters. The model has the capability to estimate microenvironment concentration from the mass-balance method, but also provides the option of using the factors method. Most of the spatial and temporal constraints were removed or relaxed in APEX3. The model's spatial resolution is flexible enough to allow for the use of finely resolved modeled air quality values, as well as sparser measured values. Averaging times for exposure concentrations are equally flexible. Like HAPEM5, the user must supply the air quality data (from modeling or monitoring) to the model.

California Population Indoor Exposure Model (CPIEM)

The CPIEM[11] is a stochastic inhalation exposure model developed for the California Air Resources Board's (ARB's) Indoor Program to evaluate indoor exposures for the general California population as well as certain sub-populations. CPIEM combines indoor air concentration distributions with Californians' location and activity information to produce exposure and dose distributions for different types of indoor environments.

The temporal resolution and averaging time are user-selected from the options of 1-hour, 8-hour, 12-hour, and 24-hour. The spatial resolution and modeling domain similarly are specified by the user according to county, state region, or the entire state. Although outdoor concentrations may be included in the application, the focus is on indoor exposures and indoor emission sources. The model is implemented on a Windows-based platform for ease of use.

The model uses location/activity profiles that were collected in ARB studies. Microenvironment concentrations are derived from measurement studies for up to nine microenvironments. Concentration distributions from measurement studies for many pollutants and microenvironments are included in the CPIEM database. However, for pollutants and microenvironments not included in the database, the CPIEM presents two alternatives. The first is to estimate indoor air concentration distributions based on distributional information for mass balance parameters with a mass-balance module. The second is for the user to directly specify concentration distributions.

11.3.5 Exposure Modeling Examples

The following applications of air quality modeling and exposure modeling at real-world sites provide useful insights into air toxics modeling. The TRIM.Expo (a.k.a. APEX) inhalation exposure model has also been used with the ISCST3 air quality model to predict human inhalation exposures. A report documenting this aspect of the case study will be available at: http://www.epa.gov/ttn/fera/human_apex.html.

National-scale Air Toxics Assessment (NATA). EPA's NATA is designed to provide a comprehensive evaluation of air toxics exposure and risk across the U.S. Activities include expansion of air toxics monitoring, improving and periodically updating emission inventories, improving national- and local-scale modeling, continued research on health effects and exposures to both ambient and indoor air, and improvement of assessment tools. As noted previously, one component of NATA is a National Scale Assessment conducted with the ASPEN and the

HAPEM4 to estimate annual average exposure concentrations of the 33 urban air toxic pollutants in every US Census tract. Specific examples of the results of the National Scale Assessment and additional information on NATA activities can be found on-line.[12]

Houston Case Study. This study was carried out by EPA's Office of Air Quality Planning & Standards (OAQPS) and the Office of Transportation and Air Quality (OTAQ) as a component of the Integrated Urban Strategy.[13] For the Houston metropolitan area, ISCST3 modeling was applied, using emissions data for point, non-point, and mobile sources from EPA's 1996 National Toxics Inventory. Ambient air concentrations for numerous air toxics were predicted at the census tract level with ISCST3 and HAPEM, which were then employed to obtain estimates of population exposures. Modeling results were compared to the results obtained through studies of this area carried out as part of the NATA National Scale Assessment. The study demonstrated that modeling using ISCST3 and an improved emissions inventory provides more realistic patterns and better agreement with monitoring data. In addition, elevated concentrations (hot spots) were found that were not detected in the national scale analysis.

11.4 Personal Monitoring

Thus far, we have focused on monitoring devices that generally are located in a secure compound (and sometimes on roof tops) that measure air quality that is representative of some specific geographic scale. An alternative to such an approach is to place monitors directly on individuals, which allows collection of more detailed information specific to the exposure pattern for that individual. Such monitors are referred to as **personal monitors** because they provide information on exposure to that individual, rather than to the general area in which an individual might be moving. An advantage is that personal monitors reflect the time-varying concentrations (unless they are integrating monitors) an individual experiences as he or she moves about through various activities. Personal monitors have seen increasing use in recent years due to two factors: they are more readily available, reliable, and cheaper than in the past, and there is growing evidence that personal exposures may at times be correlated poorly with average values derived for larger geographic areas (see Exhibit 11-7).

Two modes of personal monitoring have been developed. One relies on direct measurements of air concentration for toxics in the breathing zone or otherwise on/near the body of an individual (these are called direct measurement methods). The other relies on changes in biological properties such as blood level of an air toxic (or metabolite). The latter is not considered here because it does not strictly measure ambient air concentrations or estimate exposure. Personal monitors, as with area or fixed monitors described previously in this chapter, are available in two types:

- **Active monitors** use a small air pump to draw air through a filter, packed tube, or similar device. They can be both continuous and integrated. Such a personal exposure monitor is available to measure PM_{10} and $PM_{2.5}$ in air using a 37 mm Teflon filter and a 4 L/min flow rate. The pump and battery pack are worn in a bag, while the filter can be located essentially anywhere on the body. In addition, cyclone personal samplers are available for measuring particulates in air (the term "cyclone" refers to the fact that the sampler measures the particulates by "spinning" the particles in an air stream, which then collect on the sides of the device for collection and analysis). Combinations of impactor and denuder filter packs are

available to sample both aerosols and gases such as SO_2, NH_3, and HNO_3. Different coating materials on the diffuser tube can be used to collect different gases.

Exhibit 11-7. Examples of the Use of Personal Monitoring
• **Relationship of Indoor, Outdoor and Personal Air (RIOPA) study**.[14] Indoor and outdoor concentrations of 30 polycyclic aromatic hydrocarbons (PAHs) were measured in 55 homes in Los Angeles, CA, Houston, TX, and Elizabeth, NJ. The study focused on areas in each city characterized by worst-case conditions in the outdoor air, generally located close to major sources. Integrating MSP samplers, polyurethane foam cartridges, and quartz fiber filters were used for the field sampling, and the samples were analyzed subsequently in the lab. Among many results, the study showed that indoor air was dominated by outdoor sources for these compounds, with reasonably strong correlations between the indoor and outdoor air concentrations.
• **National Human Exposure Assessment Survey (NHEXAS)**.[15] The NHEXAS program was designed to "describe the distribution of human exposure to multiple chemicals from multiple routes on a community and regional scale, and its association with environmental concentrations and personal activities." It is being conducted in three stages: (1) design, field evaluation and demonstration projects; (2) exposure field studies; and (3) special studies to examine issues such as highly exposed populations and long-term exposures. Extensive statistical analyses of the data have been performed, including characterizations of background levels of exposure to selected chemicals, as well as correlations among environmental concentrations, individual exposures, biomarkers, and survey data on personal activities.
• **EPA's Total Exposure Assessment Methodology (TEAM)** studies[16] estimated exposures of about 800 persons to 25 VOCs; about 300 persons to 32 pesticides; and 1,200 persons to carbon monoxide. The general approach in all four of the main TEAM studies was the same: a probability-based selection of respondents, so that they would represent a much larger population (e.g., the 800 persons in the TEAM VOC studies actually represented about 800,000 persons in 8 cities); the use of personal monitors as well as outdoor monitors to estimate actual personal exposure; and the use of an Office of Management and Budget (OMB)-approved questionnaire and activity diary to try to pinpoint local sources. In two of the TEAM Studies for VOCs and carbon monoxide, an effort was made to measure body burden, by collecting a breath sample from each of the 2,000 persons involved. This was important in identifying active smoking as the main source of exposure to benzene and styrene, for example. Also, the breath measurements identified a "dirty dozen" pollutants that were prevalent in almost every person. The Centers for Disease Control later collected blood samples from 800 different persons and found essentially the same dozen pollutants prevalent in blood.

- **Passive monitors** rely on sorption, entrapment, etc., driven largely by diffusion. They are primarily integrated sampling devices, giving a estimate of average exposure over the sampling period. Examples include diffusion tubes, badges, and detector tubes. Diffusion badges currently are available for measurement of NO_2, O_3, SO_2, CO and formaldehyde. Organic vapors can be measured in passive devices using activated charcoal badges, although the range of compounds, aside from organics, that can be sampled in this way is small.

Reviews of such methods of personal sampling can be found in Bower et al. (1997).[17] However, many of the same limitations as ambient methods exist, and in some cases additional quantitation limit and precision problems are present.

In general, air toxics risk assessments that rely on monitoring to characterize exposure will generally not rely on personal monitoring because of the highly complex and resource intensive nature of this technique, and because personal monitoring and its findings are currently more geared toward basic research.

11.5 Exposure to a Population: Common Descriptors

There are a wide variety of ways to describe exposure to a population, some of which may be legally required, others which may be chosen based on the requirements of the risk manager. No matter what specific measure is chosen, the risk assessment needs a clear and scientifically supportable rationale for the approach taken; risk assessors generally describe that approach clearly and thoroughly in the exposure assessment portion of the risk assessment documentation. Risk assessors aim for there to be no ambiguity about what was done in the exposure assessment.

EPA policy and guidance recommend that exposure to a population be described using several different ways to give the risk manager a sense of the range and magnitude of the exposures. For example, a "high end" exposure estimate might describe the exposure experienced by actual people in the most highly concentrated part of the area of impact, while a "central tendency" exposure estimate might describe the exposure experienced by people in the study area who experience more modest concentrations.

A variety of statistical values are used to describe high-end and central tendency exposures, including 95th percentile exposures (for high-end) and 50th percentile values for central tendency. Risk assessors will want to obtain and become familiar with EPA's *Risk Characterization Handbook* to better understand various ways exposure and risk can be adequately characterized.[18] EPA's *Guidelines for Exposure Assessment*[19] is also invaluable in this regard. Some of the alternative approaches for characterizing air toxics exposures are illustrated in Exhibit 11-2 above.

11.6 Evaluating Uncertainty

Uncertainty includes the assumptions and unknown factors inherent in the exposure assessment. Discussing uncertainty places the risk estimates in proper perspective. Specific uncertainties associated with the chemical monitoring data, fate and transport models, and the input data (especially emissions inventory data) that assessors use to estimate exposure concentrations usually account for the bulk of uncertainty within the assessment. Exposure models also contribute to the overall uncertainty in exposure assessment. The assessor needs to understand the extent to which variability and uncertainty are considered in all the fate and transport and exposure models that are used. HAPEM and other exposure models can accept input data on the distributions of time spent in different micro-environments and produce time-average exposure estimates for defined populations.

The assessor should be familiar with the extent to which the various components of the exposure assessment can and do accommodate uncertainty and variability analyses. In addition, it is important to consider the compatibility of models in the various steps in the exposure assessment (emissions, transport, etc.) with regard to addressing important sources of uncertainty. Once the capabilities and data requirements of the various models are known, the assessor should consider

the appropriate level of detail for addressing uncertainty in specific variables, and approaches for integrating uncertainty analyses across the models.

11.7 Presenting the Results of an Exposure Assessment

The summary of exposure assessment for air toxics consists of presenting the ECs for each chemical of potential concern (COPC) with the duration of exposure for the populations of interest, as well as characterizing salient features of the study population(s), particularly those that may be influencing their exposure and resultant risk (e.g., size and proximity to sources and /or locations of highest ambient concentrations). The assumptions used to develop these estimates should also be presented and discussed. In addition to the summary tables, it is useful to show sample calculations for each pathway to aid in the review of the calculations. (If exposure modeling is used, a thorough discussion with sample calculations is usually also provided.)

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Chapter 12 Inhalation Toxicity Assessment

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12.1 Introduction

The purpose of the toxicity assessment is to weigh available evidence regarding the potential for toxicity in exposed individuals (**hazard identification**) and to quantify the toxicity by deriving an appropriate dose-response value (**dose-response assessment**). Toxicity assessment is the second part of the general risk equation. Although the toxicity assessment is an integral and important part of the overall air toxics risk assessment, it is usually accomplished prior to the risk assessment. EPA has completed this toxicity assessment for many HAPs and has made available the resulting toxicity information and dose-response values, which have undergone extensive peer review (see Appendix C).[1]

Risk = *f* (metric of exposure, metric of toxicity)

Toxicity Assessment is a 2-Step Process:

1. **Hazard Identification** – What types of effects does the chemical cause? Under what circumstances?
2. **Dose-response Assessment** – How potent is the chemical as a carcinogen and/or for noncancer effects?

In most air toxics risk assessments, little new toxicological evaluation of primary data will be required. However, it is important to understand how the available data were analyzed to produce the dose-responses values used in a risk assessment. In the risk characterization step, the risk assessor will need to describe the nature of the available toxicological evidence and the uncertainties inherent in the development of the dose-response values used in the inhalation risk assessment (see Chapter 13).

Additionally, in the event that there are significant data analysis and interpretation issues, or if a dose-response value does not exist and needs to be developed for a particular air toxic of interest, this chapter provides information about how to locate toxicity assessments, accompanying dose-response values, and relevant guidance documents. However, development and interpretation of toxicity information and dose-response values requires toxicological expertise and should not be undertaken by those without appropriate training and experience.

12.1.1 Hazard Identification and Dose-Response Information

As part of the hazard identification step, evidence is gathered from a variety of sources regarding the potential for an air toxic to cause adverse health effects in humans. These sources may include human data, experimental animal studies, and supporting information such as *in vitro* laboratory tests. The source of data affects the overall uncertainties in the resulting human dose-response values, as discussed below.

- **Human data**. Human toxicity data associated with exposures to air toxics may be located in epidemiological studies, controlled exposure studies, or studies of accidental exposures. Well-conducted epidemiological studies that show a positive association between exposure to a chemical and adverse health effects often provide evidence about human health effects associated with chronic exposures. Such data, however, are available only for a limited number of air toxics. Epidemiological data also are very difficult to interpret, because the number of exposed individuals may be small, the incidence of effects may be low, doses are usually not well-characterized, and there may be complicating factors such as simultaneous exposure to multiple chemicals and heterogeneity among the exposed group in terms of age, sex, diet, and other factors. Controlled exposure studies provide stronger evidence, since both the exposure duration and exposure concentrations are more accurately known. However, such studies with humans are generally limited to acute exposure durations. Studies reporting health effects associated with accidental exposures may be helpful, although exposure concentrations to air toxics may be high, and effects may be acute rather than chronic. Also note that small sample size is often a significant limitation to interpreting controlled and accidental exposure studies.

> **Epidemiology** is the study of the distribution and determinants of disease or health status in a population.

- **Animal data**. The toxicity database for most air toxics is drawn from experiments conducted on non-human mammals such as rats, mice, rabbits, guinea pigs, hamsters, dogs, or monkeys. The underlying assumption is that the susceptibility of humans and these animals to the effects of the chemicals is broadly similar because we share many common biological attributes (e.g., similar organs, similar and, in some cases, identical metabolic processes). However, some observations in animals may be of uncertain relevance to humans (e.g., if tumors are observed in an animal experiment, but the organ in which the tumor is formed does not exist in humans). Also, it is necessary to adjust the results from animal studies to humans due to differences in body mass, anatomy, metabolic rate, and other species-specific factors (see, for example, Section 12.3.3). This is why derivation of dose-response values from animal studies requires considerable expertise.

- **Supporting data**. Metabolic, pharmacokinetic, and genotoxicity studies are sometimes used to infer the likelihood of adverse effects in humans. Metabolic studies on absorption, distribution, metabolism, and elimination can provide information about the mechanisms of toxicity associated with a particular chemical in humans. In physiologically based pharmacokinetic (PBPK) models,[a] the body is subdivided into a series of anatomical or physiological "compartments" that represent specific organs or lumped tissue and organ groups, and the behavior of the chemical is modeled in each compartment. Data on a chemical's pharmacokinetics, genotoxicity, and possible mode of action can be used to refine a toxicity assessment. In some cases, computer models using structure-activity relationships (i.e., predictions of toxicological activity based on analysis of chemical structure) also may be used as supporting evidence. EPA considers these types of data to be supportive, not definitive, evidence of a chemical's toxicity.

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[a] A PBPK model estimates the dose to a target tissue or organ by taking into account the rate of absorption into the body, distribution among target organs and tissues, metabolism, and excretion.

Information from these sources is considered in the hazard and dose-response assessment steps in characterizing a chemical with regard to the type(s) of effect a chemical produces (the hazard) and the circumstances in which this occurs, as well as the level of exposure required to produce that effect. The output of the dose-response assessment is the relationship between **dose** (the level of exposure) and the resulting **response** (the increased incidence and/or severity of adverse effects). A dose-response assessment is the process of quantitatively evaluating toxicity information, characterizing the relationship between the dose of the contaminant received (or the inhalation exposure concentration, for inhalation assessments) and the incidence of adverse health effects in the exposed subjects (which may be animal or human) and then, as appropriate, extrapolating these results to human populations. Depending on the type of effect and the chemical, there are two types of dose-response values that traditionally may be derived: predictive cancer risk estimates, such as the **inhalation unit risk estimate (IUR)**, and predictive non-cancer estimates, such as the **reference concentration (RfC)**.[b] Both types of dose-response values may be developed for the same chemical, as appropriate.

Inhalation Dose-Response Values[a]

Inhalation Unit Risk (IUR): The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent via inhalation per $\mu g/m^3$ over a lifetime. The interpretation of the IUR would be as follows: if IUR = 2×10^{-6} $\mu g/m^3$, not more than 2 excess tumors are expected to develop per 1,000,000 people if exposed continuously for a lifetime to 1 µg of the chemical per cubic meter of inhaled air. The number of expected tumors is likely to be less; it may even be none.

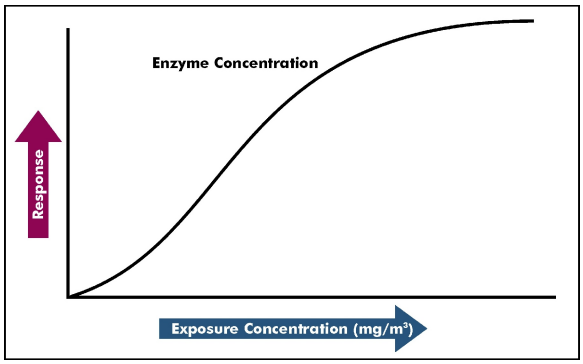
Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive sub-populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Generally used in EPA's noncancer health assessments.

[a]The phrase "dose-response" is used generally here and elsewhere in the document. EPA's values for inhalation, however, are derived for exposure concentration, although with consideration of dose. Consideration of the relationship between exposure concentration, dose, and dosimetry (how the body handles a chemical once it is inhaled) is inherent in the derivation of these exposure concentration-response values.

The relationship of dose to response can be illustrated as a graph called a **dose-response curve**. There are two general types of response data that may be considered and graphed. One is termed "continuous" and refers to responses such as the severity in changes to a physiological parameter in a given individual as dose increases (see Exhibit 12-1, A) . The second describes the incidence of a particular response in a population (see Exhibit 12-1, B). By convention, dose or exposure is represented on the x-axis; response on the y-axis (Exhibit 12-1).

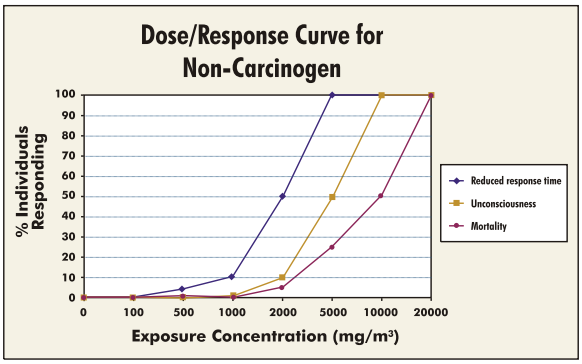
[b]While the majority of RfCs are derived for effects other than cancer, RfCs may be derived for all effects, including cancer, when a non-linear mode of action has been demonstrated for carcinogenicity.

Exhibit 12-1. Examples of Dose-Response Curves



A. Continuous Response Data

Simple example of a dose-response curve for graded responses of a specific physiological parameter to increasing exposure.



B. Different Responses in a Population

Simple example of the incidence of three different effects in an exposed population in response to different exposure concentrations (over the same duration).

While the primary focus of this chapter is on description of dose-response values relevant to chronic (long-term) exposures, the information reviewed for developing those values may include effects associated with acute (short-term) exposures. Additionally, information on acute exposures is essential to the development of acute exposure reference values (see Section 12.6).

- **Acute exposures** are usually relatively short in duration, but relatively high in concentration and may result in immediate respiratory and sensory irritation, chemical burns, narcosis, eye damage, and various other effects. Acute exposures also may result in longer-term health effects.

- **Chronic exposures** are usually relatively long in duration, but relatively low in concentration and may result in health effects that do not show up immediately and that persist over the long term, such as cardiovascular disease, respiratory disease, liver and kidney disease, reproductive effects, neurological damage, and cancer.

Generally, chronic reference values are derived for exposure periods between seven years and a lifetime. Acute reference values (see section 12.6) are generally developed for very short exposures (e.g., hours to days; Exhibit 12-2). For intermediate exposures, subchronic reference values are available from some sources (e.g., ATSDR). Most air toxics risk assessments will focus on chronic and acute evaluations; however, under more limited circumstances, subchronic evaluations may be performed.

Exhibit 12-2. Reference Values of Different Durations
In the Agency's *Review of the Reference Dose and Reference Concentration Processes*,[2] it was recommended that in addition to the traditional chronic reference value (i.e., RfC or RfD) included in the IRIS database, values of several shorter durations also be developed, where possible. As a first step in this direction, the *Review* proposed the following definitions. EPA currently is considering these and other recommendations made in the *Review*. These definitions are based on exposure durations for humans, and were not intended to be rigid specifications, but simply general descriptions of the relevant exposure time period. • **Acute**: Exposure by the oral, dermal, or inhalation route for 24 hours or less. • **Short-term**: Repeated exposure[(a)] by the oral, dermal, or inhalation route for more than 24 hours, up to 30 days. • **Longer-term**: Repeated exposure by the oral, dermal, or inhalation route for more than 30 days, up to approximately 10 percent of the life span in humans[(b)] (more than 30 days up to 90 days in typically used laboratory animal species[(c)]). • **Chronic**: Repeated exposure by the oral, dermal, or inhalation route for more than approximately 10 percent of the life span in humans (more than approximately 90 days to 2 years in typically used laboratory animal species).
[(a)]A repeated exposure may be either continuous, periodic, or intermittent. A continuous exposure is a daily exposure for the total duration of interest. A periodic exposure is one occurring at regular intervals (e.g., inhalation exposure 6 hours/day, 5 days/week; or oral exposure 5 days/week). An intermittent exposure is one in which there is no effect of one exposure on the effect of the next; this definition implies sufficient time for the chemical and its metabolites to clear the biological system before the subsequent (i.e., noncumulative pharmacokinetics). A periodic exposure may or may not be intermittent. [(b)]An average of 70 years is typical default used for chronic exposures. [(c)]Examples of typically used laboratory species include rats, mice, and rabbits.

12.1.2 Dose-Response Assessment Methods

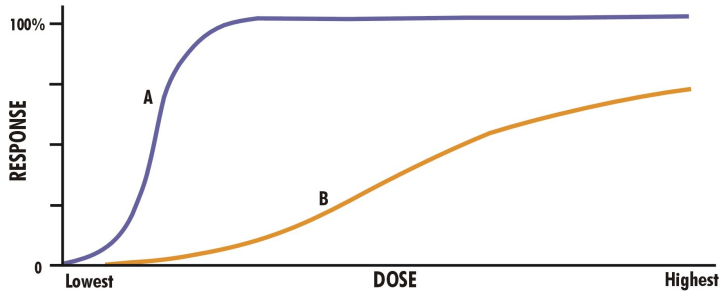
Depending on whether a substance causes cancer and whether its dose-response curve is thought to have a threshold, EPA may use either of two approaches in a dose-response assessment. One approach produces a predictive estimate (e.g., inhalation cancer risk estimate), and the other produces a reference value (e.g., RfC). Historically, the use of a predictive estimate has been limited to cancer assessment. That is, dose-response assessments for cancer have been expressed as predictive cancer risk estimates based on an assumption that any amount of exposure poses some risk. Assessments of effects other than cancer usually have been expressed as reference values at or below which no harm is expected. Many substances have been assessed both ways: the first for cancer and the second for adverse effects other than cancer. While this use of predictive estimates for cancer and reference values for other effects is still the practice for the vast majority of chemicals, EPA now recognizes that there are chemicals for which the data support an alternate approach.

An important aspect of dose-response relationships is whether the available evidence suggests the existence of a threshold. For many types of toxic responses, there is a **threshold dose** or dose rate below which there are thought to be no adverse effects from exposure to the chemical. The human body has defenses against many toxic agents. Cells in human organs, especially in the liver and kidneys, break down many chemicals into less toxic substances that can be eliminated from the body in urine and feces. In this way, the human body can withstand some chemical exposure (at doses below the threshold) and still remain healthy. For example, many air toxics are naturally occurring substances to which people routinely receive trace exposures at non-toxic levels.

Identification of a threshold dose depends on the type of response and the way in which the toxic chemical produces it. EPA has developed guidelines [3] for assessing the dose-response for various types of adverse effects, which provide more information about evaluating evidence to determine if a threshold exists.

> *All substances are poisons: there is none which is not a poison. The right dose differentiates a poison and a remedy.*
> – Paracelsus

Different Responses Exhibit Different Dose-Response Curves

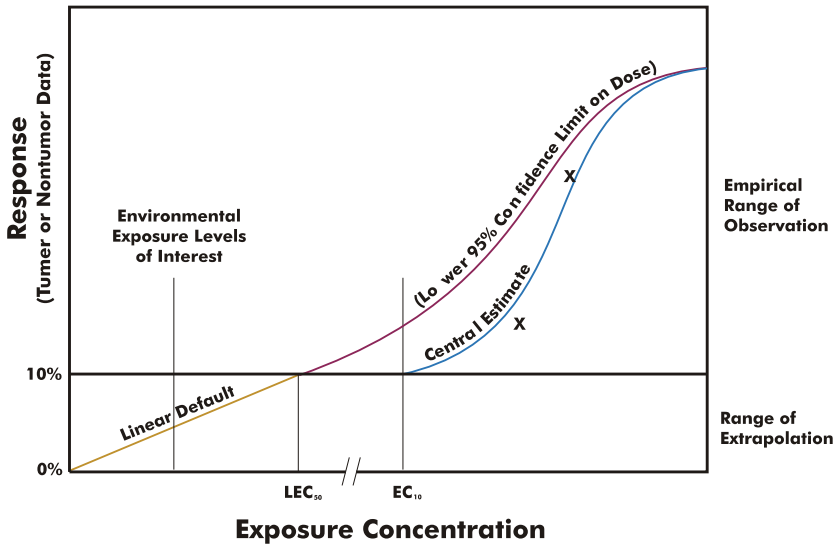


Line A – A sharp increase in response with increasing dose
Line B – A more gradual increase in response with increasing dose

Both the point at which the dose-response curve begins to ascend (its threshold, which may be zero) and the slope of the curve (its steepness) provide information about the toxicity of a chemical (Exhibit 12-3). The potency of a chemical is a measure of its strength as a toxicant compared with other chemicals. Therefore, the lower the threshold dose, the more potent (or toxic) the chemical. The slope of the curve is a measure of the range of doses from the threshold dose (at which the adverse effect is first measured) to the dose at which the effect is complete (i.e., higher doses produce no additional incidence of that effect, although other adverse effects may begin to appear). The steeper the dose-response curve, the smaller the range between the first appearance of an effect and a substantial response.

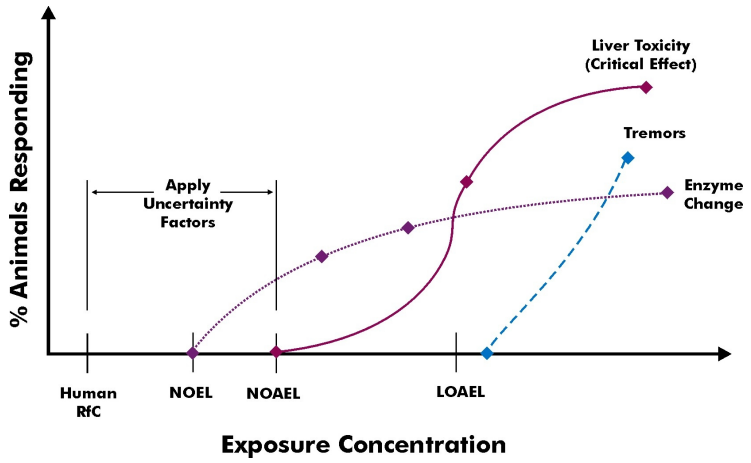
Exhibit 12-3. Dose-Response Relationships for Carcinogens and Noncarcinogens

A. Example Linear Carcinogen



In the absence of clear evidence to the contrary, EPA assumes as a matter of science policy that even a very low exposure to a cancer-causing pollutant can increase the risk of cancer (albeit a small amount). Experimental data are used to construct a dose-response relationship and identify the point of departure – the dose that can be considered to be near or in the range of observed responses and, thus, no significant extrapolation is needed. To estimate the dose-response relationship at doses below the point of departure, the dose-response relationship between the point of departure and zero is assumed to be linear. Thus, at doses below the point of departure, with each unit of increase in exposure (dose), there is an increase in cancer response. Where evidence supports the acceptance of a non-linear mode of action, a reference concentration approach may be employed, as shown in "B" below. LEC_{50}= lethal effective concentration for 50 percent of the population; EC_{10}= effective concentration that causes an observable adverse effect in 10 percent of the population.

B. Example Non-linear Approach



A dose may exist below the minimum health effect level for which no adverse effects occur. EPA typically assumes that at low doses the body's natural protective mechanisms prevent or repair any damage caused by the pollutant, so there is no ill effect at low doses. Even long-term (chronic) exposures below the threshold are not expected to have adverse effects. The dose-response relationship (the response occurring with increasing dose) varies with pollutant, individual sensitivity, and type of health effect. NOEL = no-observed-effect-level; NOAEL = no-observed-adverse-effect-level; LOAEL = lowest-observed-adverse-effect-level.

Epidemiologic and toxicologic data on air toxics typically result from exposure levels that are high relative to environmental levels. Therefore, **low-dose extrapolation** (prediction) is necessary to derive an appropriate dose-response value. For a few air toxics (e.g., the criteria air pollutants ozone and carbon monoxide), data are sufficient to characterize dose-response relationships at environmental levels. In such cases, there is no need for extrapolation of toxicity data to lower doses. Such is not the case for most air toxics. Low-dose extrapolation requires either information or assumptions about the type of dose-response curve likely under low dose situations. EPA risk assessment guidelines provide more detailed information on how EPA performs low-dose extrapolation for chemicals with various toxic effects, such as developmental effects or neurotoxic effects.[3]

12.2 Hazard Identification

The hazard identification, which is usually part of an existing dose-response assessment for each chemical, provides a summary of the available toxicity information for the air toxics being studied, and includes the weight of evidence determination and identification of critical effects. This step should answer the following questions:

Items to Include in the Hazard Identification of an Air Toxics Risk Assessment

- List of chemicals detected
- Summaries of toxic effects and quality of the toxicological evidence
- Discussion that focuses the risk assessment on chemicals most likely to cause adverse effects

- Can exposure to a chemical be linked causally to particular health effects?
- Could these effects occur at environmentally relevant concentrations?
- What is the nature and strength of the evidence of causation?

By definition, all HAPs and many other air toxics have the potential to cause adverse effects in the exposed population. Exhibit 12-4 provides examples of cancer and non-cancer effects, and Appendix C identifies which HAPs have been associated with carcinogenic (cancer) effects or non-cancer effects, along with the strength and ratings of the toxicity evidence that has been evaluated by EPA or other international environmental agencies.

Exhibit 12-4. Examples of Adverse Health Effects
• Birth defects • Tremors • Infertility • Skin rash • Melanoma

An air toxics risk assessment should include in its hazard identification a summary of the quality of the toxicological evidence (i.e., the nature and strength of the evidence of causation) for the chemicals of concern. Study factors such as the route of exposure used, the type and quality of health effects, the biological plausibility of findings, and the consistency of findings across studies all contribute to the strength of the hazard identification statement.

12.2.1 Weight of Evidence – Human Carcinogenicity

A major determination made during the hazard identification step concerns the potential of a chemical to cause cancer in humans. This determination, which involves considering (or weighing) all the available evidence, is called the weight of evidence determination. This determination is complicated by possible inadequacies of the published studies, as well as differences in body processes between people and laboratory animals. EPA's *Guidelines for Carcinogen Risk Assessment* guide scientists in interpreting available studies to assess the potential human carcinogenicity of environmental pollutants. (EPA's carcinogen risk assessment guidelines were first published in 1986. Revisions were proposed in 1996 and 2001 and the July 1999 draft of the revisions was adopted as interim guidance. A subsequent 2003 draft of the Guidelines has been released for public and scientific review prior to adoption as final. The guidelines are available on the web.)[4] When compared with EPA's original 1986 guidelines, the 1999 interim Guidelines recommend a more comprehensive evaluation of the evidence with regard to a chemical's potential mode of action, and a more complete description of the context of a chemical's carcinogenic potential (e.g., "likely carcinogenic by inhalation and not likely carcinogenic by oral exposure"). The weight of evidence determination now includes one of five descriptors, and is accompanied by additional text that more completely summarizes EPA's interpretation of the evidence. The narrative statements consider the quality and adequacy of data and the consistency of responses induced by the agent in question (see Exhibit 12-5).

Exhibit 12-5. Information Regularly Included in a Narrative Statement Describing the Characterization of Weight of Evidence for Carcinogenicity (1999 Interim Guidelines)

- Name of agent and Chemical Abstracts Services number, if available
- Conclusions (by route of exposure) about human carcinogenicity, using one of five standard descriptors: "Carcinogenic to Humans" "Likely to be Carcinogenic to Humans" "Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential" "Data are Inadequate for An Assessment of Human Carcinogenic Potential" "Non Likely to be Carcinogenic to Humans".
- Summary of human and animal tumor data on the agent or its structural analogues, their relevance, and biological plausibility
- Other key data (e.g., structure-activity data, toxicokinetics and metabolism, short-term studies, other relevant toxicity or clinical data)
- Discussion of possible mode(s) of action and appropriate dose-response approach(es)
- Conditions of expression of carcinogenicity, including route, duration, and magnitude of exposure

Source: EPA (1999) *Guidelines for Carcinogen Risk Assessment. Review Draft*[(4)]

Many existing carcinogen assessments were developed pursuant to EPA's 1986 *Guidelines for Carcinogen Risk Assessment*, which used a simpler but less informative weight of evidence system (see Exhibit 12-6).

Information bearing on the qualitative assessment of carcinogenic potential may be gained from human epidemiological data, animal studies, comparative pharmacokinetic and metabolism studies, genetic toxicity studies, structure-activity relationship (SAR) analysis, and other studies of an agent's properties. Information from these studies helps to elucidate potential modes of action and biological fate and disposition.

Exhibit 12-6. EPA's Weight of Evidence Classification for Carcinogens (1986 Guidelines)	
Group A:	Human Carcinogen (sufficient evidence of carcinogenicity in humans)
Group B:	Probable Human Carcinogen (B1 - limited evidence of carcinogenicity in humans; B2 - sufficient evidence of carcinogenicity in animals with inadequate or lack of evidence in humans)
Group C:	Possible Human Carcinogen (limited evidence of carcinogenicity in animals with inadequate or lack of human data)
Group D:	Not Classifiable as to Human Carcinogenicity (inadequate or no evidence)
Group E:	Evidence of Noncarcinogenicity for Humans (no evidence of carcinogenicity in adequate studies)
Source: EPA (1986). *Guidelines for Carcinogen Risk Assessment*[4]	

Upon such consideration, both EPA systems assign a consensus interpretation to the weight of evidence, evaluating the likelihood that the agent is a human carcinogen. Toxicological evidence is characterized separately for human studies and animal studies as: sufficient, limited, inadequate, no data, or evidence of no effect. The characterizations of these two types of data are combined, and based on the extent to which the agent has been shown to be a carcinogen in experimental animals or humans, or both, the chemical is given a weight of evidence classification.

Generally, no single factor is determinative. For example, strength of association is one of the criteria for causality. A strong association between exposure and cancer in animals is more likely to indicate causality than a weak association. However, finding of a large cancer incidence in a single study must be balanced against the lack of consistency as reflected by null results from other equally well-designed and well-conducted studies. In this situation, the positive association of a single study may either suggest the presence of chance, bias, confounding factors, or different exposure conditions. On the other hand, evidence of weak but consistent associations across several studies suggests either causality or that the same confounder may be operating in all of these studies.

If information is available to consider the mode of action for carcinogenicity, the carcinogenicity assessment will evaluate that information and draw conclusions that influence the dose-response method for the substance. If the evidence is sufficient to support a conclusion of nonlinear dose-response, then the information on carcinogenicity may be considered in combination with the information on other effects in deriving a reference value such as an RfC (see section 12.4). Otherwise, a linear dose-response approach leading to a predictive risk estimate, such as an IUR, will usually be pursued. If the information supports it, the guidelines also accommodate the development of a non-linear predictive risk estimate.

Biological Effects of Carcinogens

Carcinogens are chemicals that induce cancers. Examples include:

- *4-Aminobyphenol*, which targets the bladder;
- *Benzene*, which targets the tissue that make white blood cells;
- *Asbestos*, which targets the lung's tissue;
- *Benzidene*, which targets the bladder;
- *Beryllium*, which targets the lungs;
- *Chromium*, which targets the respiratory tract;
- *Radionucleotides*, which targets bone marrow and the lungs; and
- *Vinyl chloride*, which targets the liver.

There are various types of carcinogens, including:

- **Primary Carcinogens**: A primary carcinogen is a substance that is carcinogenic as it occurs in the environment.
- **Procarcinogen**: A procarcinogen is a substance that becomes carcinogenic only after conversion from some benign form. Most environmental carcinogens are of this type.
- **Cocarcinogen**: A cocarcinogen is a substance that is not carcinogenic by itself, but potentiates the carcinogenic effect of other chemicals.

Chemicals also can serve as **mutagens**, causing changes in genetic material that can disrupt cell function and lead to cancer or other health problems.

12.2.2 Identification of Critical Effect(s) – Non-Cancer Endpoints

As part of the characterization of the available information on non-cancer health effects (or including cancer, if a threshold mode of action has been established), the targets of chemical toxicity within the body are identified, along with what have been termed "critical effects" associated with the toxicity. A **critical effect** is described as "either the adverse effect that first appears in the dose scale as dose is increased, or as a known precursor to the first adverse effect." Underlying this designation is the assumption that if the critical effects are prevented, then all other adverse effects observed at higher exposure concentrations or doses are also prevented.[(c)] Note that not all observed effects in toxicity studies are considered adverse effects. The identification of the critical effect(s) depends on a comprehensive review of the available data with careful consideration of the exposure conditions associated with each observed effect, so that comparisons of effect levels or potential reference values are made on a common basis (see Section 12.4). A more comprehensive discussion of hazard identification and the evaluation of the underlying database for non-cancer effects is included in the EPA documents *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (1994) and *A Review of the Reference Dose and Reference Concentration Process* (2002).[5]

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[c]A similar, more recent term, "key event," is defined as "an empirically observed precursor" to an adverse effect (e.g., liver cancer or other liver toxicity) consistent with a particular mode of action. The phrase "mode of action" refers to the way a given chemical may act in the body to initiate one or more adverse effects.

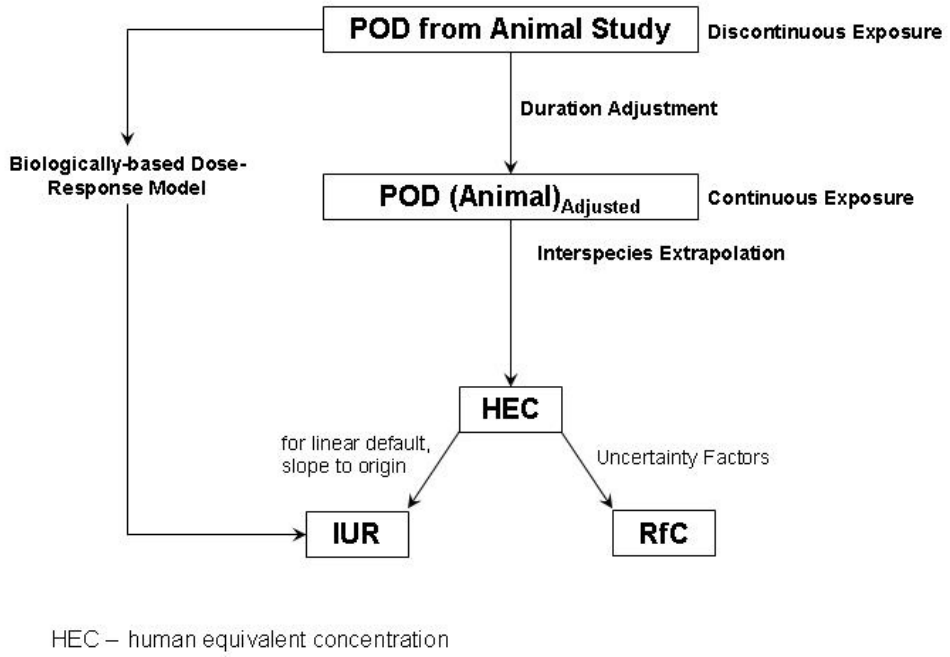
12.3 Dose-Response Assessment for Cancer Effects

The process for deriving a quantitative dose-response estimate for cancer (e.g., a cancer slope factor) involves the following three steps:

1. Determination of the concentration associated with the point of departure or POD (Section 12.3.1);
2. Derivation of the human equivalent concentration corresponding to the POD (Section 12.3.2); and
3. Extrapolation from the POD (expressed as human equivalent concentration) to derive carcinogenic potency estimates (Section 12.3.3).

The first two steps are also performed in the derivation of reference values such as the RfC (Exhibit 12-7); in that case, these steps are followed by the application of uncertainty factors (see Section 12.4).

Exhibit 12-7. Steps involved in deriving an RfC or IUR From an Animal Study



12.3.1 Determination of the Point of Departure (POD)

Dose-response assessment for cancer and other effects begins with identification of the point of departure (an exposure concentration or intake) from the experimental data. This point (in terms of its human equivalent), while within the range of observation, is the point from which extrapolation begins, either for the purposes of deriving a cancer risk estimate (the IUR) or a RfC for non-cancer health effects.

Example POD for Benzene

EPA's characterization of the carcinogenic effects of benzene was updated in 1998. The IUR for benzene is based on epidemiologic studies showing clear evidence of a causal association between exposure to benzene and leukemia. The specific mechanisms by which benzene and its metabolites lead to cancer remain uncertain.

EPA selected the Rinsky et al. 1981 epidemiologic study of 1,165 Pliofilm rubber male workers at three facilities in Ohio as the data set for the dose-response relationship for determining the IUR. The workers had been employed between 1940 and 1965 and were followed through 1981. Rinsky et. al. expanded the study to include additional workers and published it in 1987. The Rinsky data suffers - as many epidemiologic studies do - from uncertainties about exposure levels in the early years. There are no measurements of benzene in the facilities' air prior to 1946, so exposures for these years must be estimated.

Using one set of exposure estimates with the Rinsky et al. study, EPA concluded that exposure to benzene increases the risk of leukemia at a level of 40 ppm-years of occupational exposure (8 hours/day, 5 days/week, 50 weeks/year). Below this number, the shape of the dose-response curve cannot be determined. Converting the occupational exposure of 40 ppm-years to an equivalent lifetime of environmental exposure yields 120 ppb, as a POD, below which the shape of the dose-response curve is uncertain.

EPA decided there is not sufficient evidence to demonstrate that the dose-response relationship below the POD is non-linear. As a science policy default, EPA assumed low-dose linearity for extrapolation from the POD to zero. Given a range of plausible exposure estimates for the Rinsky et al. study, the Agency determined that the benzene inhalation unit risk at 1 $\mu g/m^3$ ranges from 7.1×10^{-3} to 2.5×10^{-2} depending on the exposure estimates and modeling approach used to derive the POD.

Source: U.S. EPA. 1998. *Carcinogenic Effects of Benzene: An Update.* Office of Research and Development, National Center for Environmental Assessment, Washington, D.C. EPA/600/P-97/001F.; Rinsky, R.A., Young, R.J., and Smith, A.B. 1981. Leukemia in benzene workers. *American Journal of Industrial Medicine.* 2(3) 217:245.

The POD may be the traditional no observed adverse effect level (NOAEL), lowest observed adverse effect level (LOAEL), or **benchmark concentration (BMC)**.[(d)] EPA has recommended the use of the BMC approach, where possible, because the traditional use of the LOAEL or NOAEL in determining the POD has long been recognized as having several limitations (and

[d]Note that the corresponding value for ingestion exposures is the benchmark dose (BMD). This often is used as the general term for the BMC/BMD process.

generally is not used in dose-response for cancer effects. In particular, the LOAEL-NOAEL approach:

- Is limited to one of the doses in the study and thus is dependent on study design;
- Does not account for variability and uncertainty in the estimate of the dose-response relationship;
- Does not account for the slope of the dose-response curve; and
- Cannot be applied, where there is no NOAEL, except through the application of an uncertainty factor.

If the dose-response data are of high quality, a mathematical dose-response model may be fitted to the data to determine a more precise POD than the NOAEL or LOAEL. When a model is used, the POD is calculated as the statistical lower confidence limit of the dose at which there is a low toxic response (usually 5 or 10 percent incidence in populations with an effect or a change in a physiological measurement indicating adversity).[(6)] The selection of the response percentage is intended to coincide with the sensitivity limit of the experimental design or professional judgment. This calculated POD is called the BMC.

The BMC approach is an alternate way of determining the point of departure for low-dose extrapolation. It can be used in cancer and noncancer risk assessment as the starting point for linear low-dose extrapolation, calculation of a margin of exposure, or application of uncertainty factors for calculating RfCs or other dose-response values. BMC methods involve fitting various mathematical models for dose-response to reported data and using the different results to select a BMC that is associated with a predetermined benchmark response, such as a 10 percent increase in the incidence of a particular lesion or a 10 percent decrease in body weight gain (Exhibit 12-8). EPA has developed the Benchmark Dose Software (BMDS) to facilitate these operations. BMDS currently offers 16 different mathematical models that can be fit to the laboratory data. EPA plans to continually improve and expand the BMDS system.[6]

It is likely that there will continue to be situations that are not amenable to BMC modeling and for which a NOAEL or LOAEL approach should be used. In some cases, there may be a combination of benchmark doses and NOAELs to be considered in the assessment of a particular agent.

12.3.2 Derivation of the Human Equivalent Concentration

Because inhalation toxicity studies typically involve discontinuous exposures (e.g., animal studies routinely involve inhalation exposures of 6 hours per day, 5 days per week), the POD will usually need to be extrapolated to a continuous exposure scenario (as appropriate for the RfC and IUR). This duration adjustment step is essential in interpreting inhalation studies, but is not routinely necessary for the interpretation of oral exposures. Operationally, this is accomplished

by applying a concentration-duration product, or **C × t product**[e] for both the number of hours ina daily exposure period and the number of days per week that the exposures are performed. For example, for a POD of 100 mg/m^3 derived from an animal study in which animals are exposed by inhalation for 6 hours per day, 5 days per week, the adjustment to a continuous

$$100\,mg/m^3 \times \frac{6}{24} \times \frac{5}{7} = 18\,mg/m^3 \qquad \text{(Equation 12-1)}$$

exposure concentration would consider both hours per day and days per week:

Thus, 18 mg/m^3 is the POD concentration adjusted for continuous exposure versus 100 mg/m^3 unadjusted. This approach assumes there is no dose-rate effect (i.e., that the same total inhaled material produces the same effect regardless of the time over which this material was inhaled).

Exhibit 12-8. Example Derivation of Benchmark Dose Level

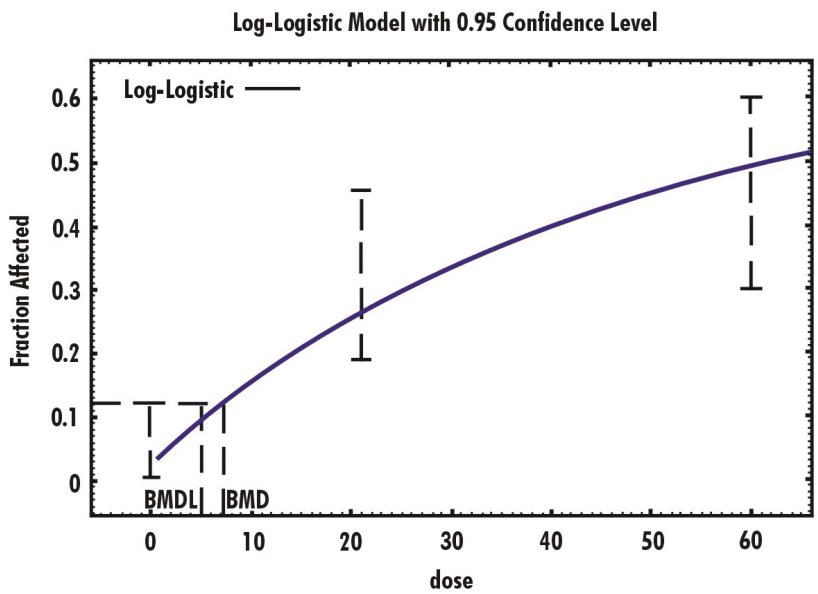


Illustration of the computation of a benchmark dose (BMD) and BMDL (a lower one-sided confidence limit on the BMD) for an extra risk of 0.10 (as suggested by the BMDS guidance document), using a one-sided 95 percent confidence interval. A number of models were fit to the data, and the log-logistic model illustrated provides the best fit to the example data. The predicted curve comes well within the confidence limits for each data point. Other data and models are illustrated in examples provided in the BMDS guidance document.[6]

[e] "C × t" is a component of Haber's Law that refers to the default assumption (in lieu of information to the contrary) that effects observed are related to the cumulative exposure or "area under the curve" (quantified by concentration, C, multiplied by duration, t). It is noted that when going from a discontinuous inhalation exposure regiment to a continuous exposure, the result will always be a lower value for concentration, thus providing an automatic margin of protectiveness for chemicals for which C alone (vs. C × t) may be appropriate, while providing the appropriate conversion for substances for which cumulative exposure is the appropriate measure.[4]

Exposures documented from human occupational epidemiological studies are most often reported as 8-hr time-weighted averages (TWAs) and therefore, also are discontinuous. Adjustment of these exposures is usually done as part of the dosimetric adjustment to derive a human equivalent concentration (HEC), rather than as a discrete step, and is explained below in Section 12.3.3. The duration adjustment step also is explicitly incorporated into physiologically based pharmacokinetic (PBPK) models used to extrapolate an animal or occupational study-derived POD into an HEC.

After duration adjustment, the POD is converted into a **human equivalent concentration (HEC)** from the experimental animal dose. This conversion may be done using default methods specific to the particular chemical class of concern or more refined methods such as PBPK modeling.

The Agency's inhalation dosimetry methodology[5] provides a recommended hierarchy, as well as default generalized procedures for deriving **dosimetric adjustment factors** (**DAFs**) for this extrapolation. Application of DAFs to an animal exposure value yields an estimate of the corresponding concentration relevant to humans (i.e., the HEC) given differences in physiology and in the form of the pollutant that influence how the chemical exerts its effect. The DAF depends on the chemical category (i.e., gas or particle) and whether the adverse effect occurs in the respiratory tract or outside of the respiratory tract. HECs are derived using DAFs for both RfC development (noncancer effects) and IUR development (cancer).

Choice of a Default DAF for Extrapolation from Animal Data Depends on the Physical and Chemical Properties of the Pollutant

Gases

- Category 1 (effect in respiratory system) – default DAF based on inhalation rate, and surface area of target portion of respiratory tract
- Category 2 (some characteristics intermediate or common to category 1&3) – default DAF is the more restrictive of the defaults for category 1 & 3
- Category 3 (systemic effect[s]) – default DAF based on blood:air partition coefficient

Particles

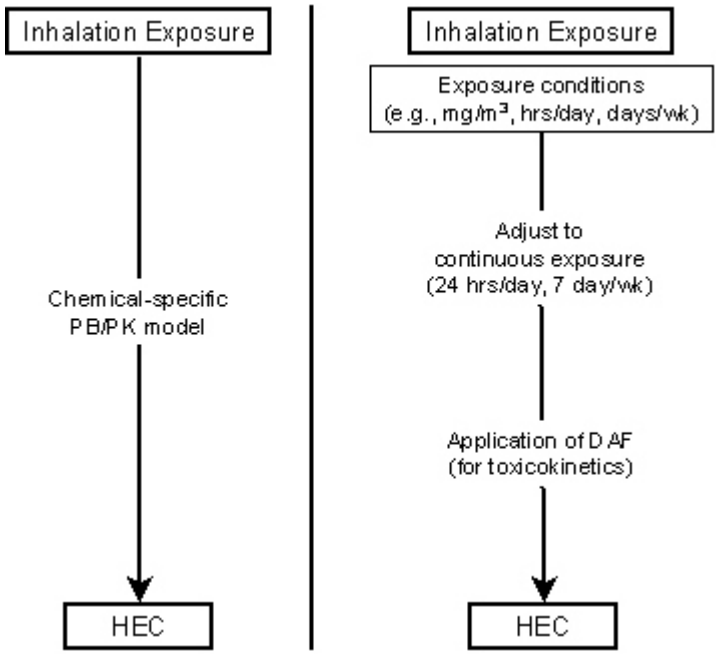
- Respiratory toxicant – default DAF based on fractional deposition, inhalation rate, and surface area of target portion of respiratory tract
- Systemic toxicant – default DAF based on inhalation rate, body weight, and fractional deposition

Source: U.S. EPA. 1994. *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*.[5]

When data are adequate to support it, the preferred EPA approach for calculating a HEC is to use a chemical-specific PBPK model parameterized for the animal species and regions (e.g., of the respiratory tract) involved in the toxicity (Exhibit 12-9).

In PBPK models, the body is subdivided into a series of anatomical or physiological "compartments" that represent specific organs or tissue and organ groups. The transfer of chemicals between compartments is described by a set of differential equations. The parameters of the model are of three types: physiological parameters (such as tissue perfusions or tissue volumes), physicochemical parameters (such as partition coefficients that describe the degree of partitioning of a given chemical to a given tissue), and biochemical parameters describing metabolic processes. The structure of a PBPK model is determined by the intended use of the model, the biochemical properties of the chemical studied, and the effect site of concern.

Exhibit 12-9. Extrapolation of Inhalation Exposure to Calculate the HEC



EPA employs a hierarchy of approaches for deriving the human equivalent concentration. Preference is given to the use of a physiologically-based pharmacokinetic model, followed by intrermediate, less detailed approaches, which are followed by the default approach, which utilizes a DAF specific to the type of chemical and how it exerts its effect.

With sufficient data, a PBPK model is capable of calculating internal doses to a target organ in an animal from any exposure scenario and then estimating what human exposure would result in this same internal dose (i.e., the HEC). A formal DAF is not calculated in this process; rather, the model itself serves as a DAF in estimating HECs. However, constructing a PBPK model is an information-intensive process, requiring much chemical-specific data. Consequently, these models are usually available for only a subset of chemicals. For example, EPA's IRIS toxicity assessment for vinyl chloride relies on a PBPK model.

12.3.3 Extrapolation from POD to Derive Carcinogenic Potency Estimates

Observable cancer rates in laboratory or human occupational epidemiologic studies tend to be several orders of magnitude higher than cancer risk levels that society is willing to tolerate from involuntary chemical exposures. To obtain observable results, laboratory studies need to be

conducted at exposures usually well above environmentally relevant concentrations. Thus, extrapolation from the POD-HEC to lower doses is usually necessary. This extrapolation is performed consistent with the mode of action, if adequately supported. Where the mode of action supports a biologically-based model and the data set is not rich enough to support a biologically based model, a non-linear reference concentration approach is employed (see Section 12.4.2). When the data are insufficient to support a mode of action decision, or where the data support a linear mode of action, a linear extrapolation is employed.

For linear extrapolation, a straight line is drawn from the point of departure expressed as a human equivalent dose to the origin (i.e., zero incremental dose, zero incremental response) to give an incremental probability dose unit. That is, the slope of the line expresses extra risk per dose unit (e.g., the IUR, expressed as extra risk per $\mu g/m^3$ of lifetime exposure). EPA's 1999 proposed guidelines[4] for carcinogen risk assessment recommend the use of the lowest effective dose using a 10 percent response level (LED_{10}) (as estimated by the lower one-sided confidence limit on the benchmark concentration [or $BMCL_{10}$]) as the POD for linear extrapolation. This approach is to draw a straight line between the estimated point of departure, generally, as a default, the LED_{10}. The LED_{10} is the lower 95 percent limit on a dose that is estimated to cause a 10 percent response. The linear extrapolation approach to assessing risk is considered generally conservative of public health, including sensitive subpopulations, in the absence of specific information about the extent of human variability in sensitivity to effects.

The inhalation cancer dose-response value derived by linear extrapolation is the IUR. It is presented as an upper-bound estimate of the excess cancer risk resulting from a lifetime (assumed 70-year) of continuous exposure to an agent at a concentration of 1 $\mu g/m^3$ in air. As illustrated previously in Exhibit 12-2(A), risk is the product of the slope and the estimated exposure. The IUR is a plausible upper-bound estimate of the risk (i.e., the risk is not likely to be higher but may be lower and may be zero). When adequate human epidemiology data are available, maximum likelihood estimates may be used instead of upper bounds to generate the IUR. When only animal data are available and linear extrapolation is used, the IUR is derived from the largest linear slope that is consistent with the data (within the upper 95 percent confidence limit). In other words, the true risk to humans, while not identifiable, is not likely to exceed the upper-bound estimate (the IUR), and is likely to be lower. This means that any estimate of risk for air toxics using an IUR is likely to be protective of all potentially exposed populations. In addition, this means that air toxics risk estimates are likely to be conservative, that is, protective of public health.

Risk = EC × IUR, where

EC	=	lifetime estimate of continuous inhalation exposure to an individual air toxic
IUR	=	the corresponding inhalation unit risk estimate for that air toxic

The evidence for the carcinogenic mode of action may lead to a conclusion that the dose-response relationship is nonlinear, with response falling much more quickly than linearly with dose, or may be most influenced by individual differences in sensitivity. In some cases this may be due to the mode of carcinogenic action being a secondary effect of toxicity or of an induced physiological change that is itself a threshold phenomenon. EPA does not generally try to distinguish between modes of action that might imply a "true threshold" from those with a nonlinear dose-response relationship. Except in unusual cases where extensive information is available, it is not possible to distinguish between

these empirically. Therefore, as a matter of science policy, nonlinear probability functions are only fitted to the response data to extrapolate quantitative low-dose risk estimates when the carcinogenic mechanism of the toxicant is very well-understood. When the evidence indicates a non-linear dose response function containing a significant change in slope, and alternate nonlinear approach may be considered. For example, when carcinogenesis can be shown to be a secondary effect of threshold toxicity, the EPA draft carcinogen guidelines recommend derivation of a reference concentration.

12.4 Dose-Response Assessment for Derivation of a Reference Concentration

The reference concentration is defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive sub-populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfC is expressed as a chronic exposure level to the chemical in ambient air (in units of milligrams of the substance per cubic meter of air, or mg/m^3). This value is usually derived for use with effects other than cancer. But when a chemical's carcinogenicity has been shown to be associated with a nonlinear mode of action (see Agency's Cancer Guidelines),[4] a reference concentration may be derived for use with all effects, including cancer.

Inherent in the derivation of a reference concentration is the recognition of an exposure level likely to be without an appreciable risk of adverse effects (e.g., a sub-threshold level for adverse effects). The objective of this type of dose-response assessment, then, is to estimate that exposure level for humans. The RfC is derived after a thorough review of the health effects database for an individual chemical and identification of the most sensitive and relevant endpoint (the "critical effect") along with the principal study(ies) demonstrating that endpoint. In addition to an analysis of the study data available for the chemical, risk assessors also use uncertainty factors to account for differences in sensitivity between humans and laboratory animals, the possibility of heightened sensitivity of some population groups (e.g., people with respiratory disease, very young children, the aged), and any limitations of the database. The methodology for derivation of an inhalation reference concentration is described in detail in EPA's *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*.[5]

The first part of this type of assessment, which involves a careful qualitative and quantitative analysis of the study data, parallels that performed for linear cancer dose-response assessment (i.e., derivation of the point of departure in terms of a human equivalent concentration [POD_{HEC}]). The qualitative analysis is described in Section 12.2.2, while the quantitative analysis is described in Sections 12.3.1 and 12.3.2. The latter part of this type of assessment involves the application of uncertainty factors to address limitations of the data used (e.g., the factors raised above).

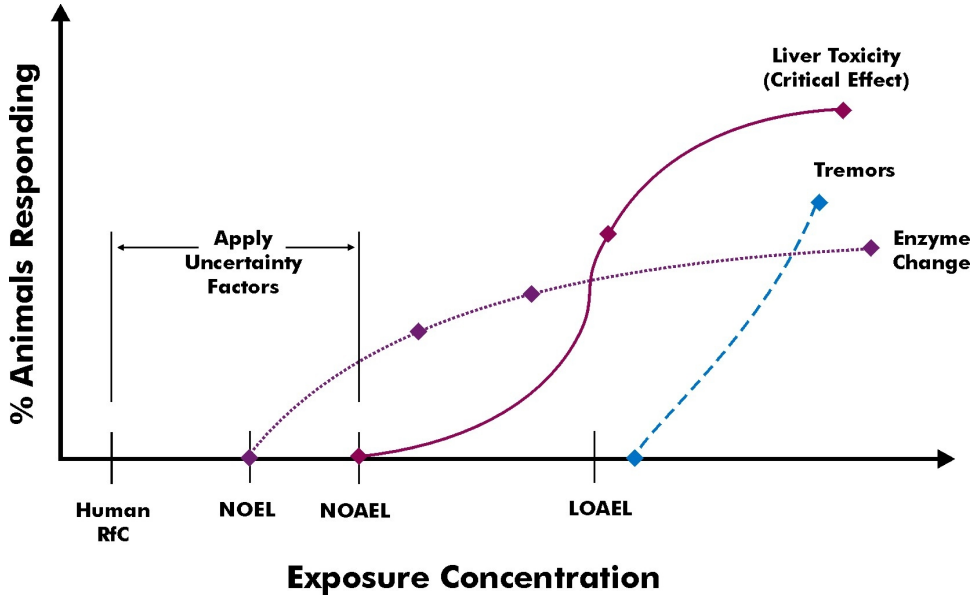
In IRIS, EPA includes with each RfC a statement of high, medium, or low confidence based on the completeness of the database for that substance. High confidence RfCs are considered less likely to change substantially with the collection of additional information, while low confidence RfCs may be especially vulnerable to change.[5]

12.4.1 Determination of the Point of Departure and Human Equivalent Concentration

In earlier sections (Section 12.2.2, 12.3.1 and 12.3.2) the analysis of the database and identification of the critical effect, as well as the derivation of the POD in terms of human equivalent concentrations are discussed.

In developing a dose-response assessment, toxicologists evaluate the available data for a substance. Studies of high quality are selected, and the assessment is focused on the most appropriate studies. As the RfC is a chronic value, preference is given to long-term studies over short-term ones, to studies using animals that exhibit effects similar to those experienced by humans, to studies using an appropriate exposure route (e.g., inhalation exposure for developing an RfC), and to studies showing a clear pattern of increasing frequency or severity of response with increasing dose. Toxicologists use the information to identify the **critical effect** (i.e., the adverse effect that appears at the lowest dose). Afterwards, appropriate human data are chosen as the basis for the RfC or, if human data are not adequate, data from the most appropriate species are identified. If this is not known, the data from the most sensitive species is usually chosen. This analysis is described in Section 12.2.2. The objective in identifying the critical effect or effects is to identify the effect(s) - among all those associated with exposure to the chemical of interest - that occur at the lowest exposure and would lead to derivation of the lowest RfC (Exhibit 12-10).

Exhibit 12-10. Overview to Develop a Reference Concentration



The LOAEL (HEC) and NOAEL (HEC) are illustrated with low-dose extrapolation with the application of uncertainty or modifying factors to derive the human health-protective RfC. Note that this figure represents data from appropriate animal species.

Using the dose-response relationship for the critical effect, toxicologists identify the POD from the experimental data. This exposure concentration (in terms of its human equivalent) which marks the boundary between the range of observation and that of extrapolation, is the point from

which extrapolation begins for derivation of a RfC. The POD may be derived from benchmark modeling (see Section 12.3.1 regarding the derivation of a BMCL). If the data do not meet requirements for benchmark modeling, the POD is derived by the use of a statistical analysis to identify the **no-observed-adverse-effect-level**, or **NOAEL**, defined as the highest dose level administered to laboratory animals that did not cause statistically or biologically significant observable adverse effects after chronic (usually lifetime) exposure in the studied population. In some cases, a LOAEL is used in the absence of a NOAEL. In either case, the POD is transformed into a continuous inhalation exposure (e.g., from an intermittent animal exposure, 6 hours/day, 5 days/week) and then into a human equivalent concentration (as described in Section 12.3.2). In order for the appropriate critical effect to be identified, a comparison of PODs across different endpoints is done in terms of human equivalent concentrations (or potential RfC values, which incorporate the application of UFs, need to be compared).[5]

Derivation of RfC Using BMC Methodology – 1,3-dichloropropene

A review of the available animal studies indicated changes to the surface cells of the nasal portion of the respiratory tract as the critical effect for 1,3-dichloropropene. Benchmark modeling was performed on the data demonstrating this effect. The seven statistical models for dichotomous data from the Agency's benchmark dose modeling software (BMDS Version.1b) were applied to the incidence data for the adjusted administered doses. The best model fit was determined by eliminating all models that did not have a statistically significant goodness-of-fit ($p<0.05$). The remaining models were then ranked by best visual fit of the data, especially for the lower doses, as observed in the graphical output of the Benchmark Dose Software. The model with statistically significant goodness-of-fit and best visual and statistical fit was used to estimate the BMC at 10 percent risk and the 95 percent lower confidence limit of the BMC (the BMCL). The gamma, logistic, multistage, Weibull, and quantal-quadratic models provided statistically significant fits. The gamma model was the best fit overall because it provided the best visual fit. This model yielded a BMC_{10} of 5.9 mg/m^3 and a $BMCL_{10}$ of 3.7 mg/m^3.

The $BMCL_{10}$ was identified as the POD and was adjusted from experimental conditions to a continuous inhalation exposure value (POD_{adj}). Because the critical target was the nasal mucosa, algorithms for extrathoracic effects for Category 1 gases were used to adjust continuous animal exposure concentration to HEC. The POD_{HEC} for a Category 1 gas was derived by multiplying the animal $BMCL_{10}$ by an interspecies dosimetric adjustment for gas:respiratory effects in the extrathoracic area of the respiratory tract. Using default values, the adjustment factor was equal to 0.2. For example, for 1,3-dichloropropene:

$$POD_{HEC} = BMCL_{10}(HEC) = BMCL_{10}\ (adj) \times 0.2 = 3.7 \times 0.2 = 0.7\ mg/m^3$$

The POD_{HEC} was divided by uncertainty factors for interspecies extrapolation (UF of 3) and intraspecies variation (UF of 10) and rounded to one significant figure to yield the RfC for 1,3-dichloropropene:

$$RfC = POD_{HEC} / 30 = 0.02\ mg/m^3$$

12.4.2 Application of Uncertainty Factors

The RfC is an estimate derived from the POD_{HEC} for the critical effect (based on either a $BMCL_{HEC}$, $NOAEL_{HEC}$ or $LOAEL_{HEC}$) by consistent application of UFs. The UFs are applied to account for recognized uncertainties in the use of the available data to estimate an exposure concentration appropriate to the assumed human scenario. The general formula for deriving an RfC from a POD_{HEC} is:

$$RfC\,(mg/m^3) = \frac{PODHEC(mg/m^3)}{UF} \qquad \text{(Equation 12-2)}$$

A UF of 10, 3, or 1 is applied for each of the following extrapolations used to derive the RfC (see Exhibit 12-11):

- Animal to human;
- Human to sensitive human populations;
- Subchronic to chronic;
- LOAEL to NOAEL; and
- Incomplete to complete database.

The UFs are generally an order of magnitude (10), although incorporation of dosimetry adjustments or other information may result in the use of reduced UFs for RfCs (3 or 1). The composite UF applied to an RfC will vary in magnitude depending on the number of uncertainties involved; however, an RfC will not be derived when use of the data involves more than four areas of extrapolation. The composite UF when four factors are used generally is reduced from 10,000 to 3,000 in recognition of the lack of independence and the conservatism of these factors.

The 2002 Agency review of the reference dose (RfD)/reference concentration process[(2)] encouraged the development of guidance in the area of chemical-specific adjustment factors (CSAFs). These factors utilize specific data to replace the default UFs for interspecies or inter-individual variation. The review panel noted, however, that the CSAF approach for any single substance is determined principally by the availability of relevant data. For many substances there are relatively few data available to serve as an adequate basis to replace defaults for interspecies differences and human variability with more informative CSAFs.

Because of this procedure to address the lack of information on the translation from experimental data to a human scenario, the resulting RfC for many HAPs is on the order of 100 to 300 times lower than the NOAEL actually observed in the animal testing (see Exhibit 12-12). This reflects the lowering of the RfC to address the uncertainties in the extrapolations mentioned above. For those HAPs that have had their effects well documented in human studies, the RfC may be much closer to the highest concentration at which an adverse effect was not observed (e.g., within a factor of 3 to 10).

Exhibit 12-11. Uncertainty Factors Used in the Derivation of an Inhalation RfC	
Standard Uncertainty Factors	**Processes Considered in UF Purview**
A = Animal to human Extrapolation from valid results of long-term studies on laboratory animals when results of studies of human exposure are not available or are inadequate. Intended to account for the uncertainty in extrapolating laboratory animal data to the case of average healthy humans.	• Pharmacokinetics/Pharmacodynamics • Relevance of laboratory animal model • Species sensitivity
H = Human to sensitive human Extrapolation of valid experimental results for studies using prolonged exposure to average healthy humans. Intended to account for the variation in sensitivity among the members of the human population.	• Pharmacokinetics/Pharmacodynamics • Sensitivity • Differences in mass (children, obese) • Concomitant exposures • Activity Pattern • Does not account for idiosyncrasies
S = Subchronic to chronic Extrapolation from less than chronic exposure results on laboratory animals or humans when there are no useful long-term human data. Intended to account for the uncertainty in extrapolating from less than chronic NOAELs to chronic NOAELs.	• Accumulation/Cumulative damage • Pharmacokinetics/Pharmacodynamics • Severity of effect • Recovery • Duration of study • Consistency of effect with duration
L = LOAEL to NOAEL Derivation from a LOAEL instead of a NOAEL. Intended to account for the uncertainty in extrapolating from LOAELs to NOAELs.	• Severity • Pharmacokinetics/Pharmacodynamics • Slope of dose-response curve • Trend, consistency of effect • Relationship of endpoints • Functional vs histopathological evidence • Exposure uncertainties
D = Incomplete to complete data Extrapolation from valid results in laboratory animals when the data are "incomplete". Intended to account for the inability of any single laboratory animal study to adequately address all possible adverse outcomes in humans.	• Quality of critical study • Data gaps • Power of critical study/supporting studies • Exposure uncertainties
Source: U.S. EPA. 1994. *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*.[5]	

Exhibit 12-12. Examples of the Use of Uncertainty Factors in Deriving RfCs	
RfC from NOAEL **Example: Diesel Engine Emissions**	**RfC from LOAEL** **Example: Toluene**
Toxicity data: 144 µg chemical/m^3 air ($NOAEL_{HEC}$ from chronic rodent study) *Uncertainty factors*: 3 x 10 = 30 3 = animal-to-human extrapolation 10 = human to sensitive human subpopulations RfC = 144/30 = 4.8 µg/m^3 = 0.005 mg/m^3	*Toxicity data:* 119 mg chemical/m^3 air ($LOAEL_{HEC}$ from chronic occupational study) *Uncertainty factors*: 10 x 10 x 3 = 300 10 = human to sensitive human subpopulations 10 = LOAEL-to-NOAEL extrapolation 3 = database deficiencies RfC = 119/300 mg/m^3 = 0.4 mg/m^3
$NOAEL_{HEC}$ = No-Observed-Adverse-Effect Level (Human Equivalent Concentration) $LOAEL_{HEC}$ = Lowest-Observed-Adverse-Effect Level (Human Equivalent Concentration) *Source*: EPA's IRIS database http://www.epa.gov/IRIS/.	

In some of the older IRIS assessments a "modifying factor" may have been applied in addition to the traditional uncertainty factors. It had been used with professional judgement when it was determined that another uncertainty factor was needed; its magnitude depended upon the professional assessment of scientific uncertainties of the study and database not explicitly treated via the other uncertainty factors.[5] The 2002 Agency review of the RfD/RfC process, however, recommended against continued use of the modifying factor. It was felt that the traditional factors could account for any remaining uncertainties.[2]

12.5 Sources of Chronic Dose-Response Values

Appendix C provides a current listing of appropriate chronic dose-response values (i.e., RfCs or comparable values and IURs) for HAPs.[f] References for acute exposure levels are provided below in Exhibit 12-13. Hazard identification and dose-response assessment information for chronic exposure, presented in Appendix C, was obtained from various sources and prioritized according to (1) conceptual consistency with EPA risk assessment guidelines, and (2) level of review received. The prioritization process was aimed at incorporating into our assessments the best available science with respect to dose-response information. The sources listed below were used, and provide this information for chemicals beyond the 188 Clean Air Act hazardous air pollutants listed in Appendix C.

- **U.S. Environmental Protection Agency (EPA)**. EPA has developed dose-response assessments for chronic exposure to many pollutants. These assessments typically specify an RfC (to protect against effects other than cancer) and/or IUR (to estimate the probability of

[f] As noted earlier, see http://www.epa.gov/ttn/atw/toxsource/summary.html for a current listing of this information.

contracting cancer). Background documents, particularly for the more recent files, also contain information on physical and chemical properties, toxicokinetics, and hazard characterization. EPA disseminates dose-response assessment information in several forms, based on the level of review. Dose-response assessments that have achieved full intra-agency consensus are incorporated in the **Integrated Risk Information System (IRIS)**, which is regularly updated and available on-line (www.epa.gov/iris). All IRIS assessments since 1996 also have undergone independent external peer review. In the past, dose-response assessments for some substances were prepared by the EPA Office of Research and Development, but were never submitted for EPA consensus. EPA has assembled the results of many such assessments in the **Health Effects Assessment Summary Tables (HEAST)**. Although the values in HEAST have undergone some review and have the concurrence of individual Agency program offices, they have not had enough review to be recognized as Agency-wide consensus information. In addition, since HEAST has not been updated since 1997, other sources described here are, for many chemicals, more reliable.

- **Agency for Toxic Substances and Disease Registry (ATSDR)**. ATSDR, which is part of the US Department of Health and Human Services, develops and publishes Minimum Risk Levels (MRLs) for many toxic substances. The MRL is defined as an estimate of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects (other than cancer) over a specified duration of exposure. MRLs are derived for acute (1-14 days), intermediate (>14-364 days), and chronic (365 days and longer) exposures by inhalation and oral routes. ATSDR describes MRLs as substance-specific estimates to be used by health assessors to select environmental contaminants for further evaluation. MRLs are presented with only one significant figure and are considered to be levels below which contaminants are unlikely to pose a health threat. Exposures above an MRL do not necessarily represent a threat, and MRLs are therefore not intended for use as predictors of adverse health effects or for setting cleanup levels. The MRL data undergo a rigorous review process, including internal ATSDR review, peer reviews, and public comment periods. Appendix C shows the ATSDR chronic MRL where no IRIS value is available, because the MRL's concept, definition, and derivation are philosophically consistent (though not identical) with EPA's guidelines for assessing noncancer effects. ATSDR publishes MRLs as part of pollutant-specific toxicological profile documents, and also in regularly-updated on-line tables.[7]

- **California Environmental Protection Agency (CalEPA)**. The CalEPA Office of Environmental Health Hazard Assessment (OEHHA) has developed dose-response assessments for many substances, based both on carcinogenicity and health effects other than cancer. The process for developing these assessments is similar to that used by EPA to develop IRIS values and includes significant external scientific peer review. The non-cancer information includes inhalation health risk guidance values expressed as chronic inhalation reference exposure levels (RELs). CalEPA defines the REL as a concentration level at (or below) which no health effects are anticipated, a concept that is substantially similar to EPA's approach to non-cancer dose-response assessment. Appendix C shows the chronic REL (including both final and proposed values) where no IRIS RfC/RfD or ATSDR MRL exists. CalEPA's quantitative dose-response information on carcinogenicity by inhalation exposure is expressed in terms of the IUR, defined similarly to EPA's IUR. Appendix C shows specific CalEPA UREs where no IRIS values exist. CalEPA's dose response assessments for carcinogens and noncarcinogens are available on-line.[8]

- **International Agency for Research on Cancer** (**IARC**). The IARC, a branch of the World Health Organization, coordinates and conducts research on the causes of human cancer and develops scientific strategies for cancer control. The IARC sponsors both epidemiological and laboratory research, and disseminates scientific information through meetings, publications, courses and fellowships. As part of its mission, the IARC assembles evidence that substances cause cancer in humans and issues judgments on the strength of evidence. IARC's categories are Group 1 (carcinogenic in humans), Group 2A (probably carcinogenic), Group 2B (possibly carcinogenic), Group 3 (not classifiable), and Group 4 (probably not carcinogenic). The categorization scheme may be applied to either single chemicals or mixtures; however, IARC does not develop quantitative dose-response metrics such as UREs,. IARC's categories for substances are included in Appendix C to support or augment EPA's weight-of evidence (WOE) determinations, which do not cover all substances and in some cases may be out-of-date. The list of IARC evaluations to date is available on-line (http://193.51.164.11/monoeval/grlist.html).

Additionally, the EPA has compiled fact sheets for the 188 CAA hazardous air pollutants and makes them available on the Air Toxics website (http://www.epa.gov/ttn/atw/hapindex.html). This collection is called the **Health Effects Notebook for Hazardous Air Pollutants**, and provides for each HAP a summary of available information in the following categories: hazard summary, physical properties, uses, sources and potential exposure, and health hazard information. These fact sheets are useful for describing hazards associated with the 188 HAPs.

12.6 Acute Exposure Reference Values

Many air pollutants can cause adverse health effects after acute or short-term exposures lasting from a few minutes to several days. For some pollutants, acute exposures may be of greater concern than chronic exposures. The severity of effects from acute exposures may vary widely. Agency-wide guidance on how to assess toxic effects from short-term exposures is currently being developed. This guidance for Acute Reference Exposure (ARE) levels is intended to assist acute risk assessment activities. A variety of other short-term, acute exposure limits are also described in Exhibit 12-12.[9] Appendix C provides a current listing of acute dose-response values for HAPs.

Methods for dose-response assessment of acute exposures are usually similar to the approach for chronic exposure, with their derivation involving the identification of a "critical effect," determination of a NOAEL or comparable value for that effect, and application of uncertainty factors (e.g., animal to human population). However, the process by which most acute inhalation dose-response assessment values are derived differs from the chronic RfC methodology in two important ways. First, "acute" may connote exposure times varying from a few minutes to two weeks. The time frame for the value is critical, because the safe dose (or the dose that produces some defined effect) may vary substantially with the length of exposure. Second, some acute dose-response assessments include more than one level of severity. A typical assessment may have values for level 1 (at which only mild, transient effects may occur), level 2 (above which irreversible or other serious effects may occur), and level 3 (above which life-threatening effects may occur). Therefore, many acute assessments present dose-response assessment values as a matrix, with one dimension being length of exposure and the other a severity-of-effect category.

Exhibit 12-13. Examples of Available Short-Term, Acute Exposure Levels				
Acronym	**Full Name**	**Group or Agency**	**Purpose/Definition**	**Source/Website**
AEGL	Acute Exposure Guideline Level	National Research Council (NRC) National Advisory Committee (NAC)	The AEGLs represent short-term threshold or ceiling exposure values intended for the protection of the general public, including susceptible or sensitive individuals, but not hypersusceptible or hypersensitive individuals. The AEGLs represent biological reference values for this defined human population and consist of three biological endpoints for four different single emergency (accidental) exposure periods (30 minutes, 1 hour, 4 hours, and 8 hours). In some instances, AEGLs also are developed for 5 or 10 minutes. The biological endpoints are defined as follows: • AEGL-1 is the airborne concentration (expressed as parts per millions [ppm] or milligrams [mg]/meters [m]^3) of a substance at or above which it is predicted that the general population, including "susceptible" but excluding "hypersusceptible" individuals, could experience notable discomfort. Airborne concentrations below AEGL-1 represent exposure levels that could produce mild odor, taste, or other sensory irritations. • AEGL-2 is the airborne concentration (expressed as ppm or mg/m^3) of a substance at or above which it is predicted that the general population, including "susceptible" but excluding "hypersusceptible" individuals, could experience irreversible or other serious, long-lasting effects or impaired ability to escape. Airborne concentrations below the AEGL-2 but at or above AEGL-1 represent exposure levels that may cause notable discomfort. • AEGL-3 is the airborne concentration (expressed as ppm or mg/m^3) of a substance at or above which it is predicted that the general population, including "susceptible" but excluding "hypersusceptible" individuals, could experience life-threatening effects or death. Airborne concentrations below AEGL-3 but at or above AEGL-2 represent exposure levels that may cause irreversible or other serious, long-lasting effects or impaired ability to escape.	http://search.nap.edu/books/0309072948/html/
ARE	Acute Reference Exposure	U.S. Environmental Protection Agency	The ARE is an informed estimate of the highest inhalation exposure (concentration and duration) that is not likely to cause adverse effects in a human population, including sensitive subgroups, exposed to that scenario, even on an intermittent basis.[10] For these purposes, acute exposures are single continuous exposures lasting 24 hours or less; AREs may be derived for any duration of interest within that period. "Intermittent" implies sufficient time between exposures such that one exposure has no effect on the health outcome produced by the next exposure. EPA is in the process of finalizing the methodology for development of AREs.	

Exhibit 12-13. Examples of Available Short-Term, Acute Exposure Levels				
Acronym	**Full Name**	**Group or Agency**	**Purpose/Definition**	**Source/Website**
BEI	Biological Exposure Indices	American Conference of Governmental Industrial Hygenists	BEIs® are health-based values for use by industrial hygienists in making decisions regarding safe levels of exposure to various chemical and physical agents found in the workplace.	http://www.acgih.org/TLV/
CEEL	Community Emergency Exposure Level	National Research Council (NRC) National Advisory Committee (NAC)	CEELs are ceiling exposure values for the public applicable to emergency exposures of foreseeable magnitude and duration, usually not exceeding 1 hour. Three CEELs were established: • CEEL-1: Concentration above which discomfort, for example eye and nose irritation or headaches, becomes increasingly common; • CEEL-2: Concentration above which disability, for example, severe eye or respiratory irritation, becomes increasingly common; • CEEL-3: Concentration above which death or life-threatening effects, for example, pulmonary edema, cardiac failure, or cancer, become increasingly common.	Guidelines for Developing Community Emergency Exposure Levels for Hazardous Substances (NRC, 1993)
EEGL	Emergency Exposure Guidance Level	NAS Committee on Toxicology	Exposure levels judged to be acceptable for military personnel performing tasks during emergency situations. Not considered safe exposure level for routine or normal operations.	
ERPG	Emergency Response Planning Guideline	American Industrial Hygiene Association's (AIHA) Emergency Response Planning Committee	These guidelines are intended for application by persons trained in emergency response planning. ERG-1: The maximum concentration in air below which it is believed nearly all individuals could be exposed for up to one hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined objectionable odor. ERG-2: The maximum concentration in air below which it is believed nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms that could impair their abilities to take protective action. ERG-3: The maximum concentration in air below which it is believed nearly all individuals could be exposed for up to one hour without experiencing or developing life-threatening health effects.	http://www.bnl.gov/scapa/erpgpref.htm http://www.bnl.gov/scapa/scapawl.htm
IDLH	Immediately Dangerous to Life or Health Concentration	National Institute for Occupational Safety and Health (NIOSH)	An immediately dangerous to life or health condition is one "that poses a threat of exposure to airborne contaminants when that exposure is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from such an environment. The purpose of establishing an IDLH is to ensure that the worker can escape from a given contaminated environment in the event of failure of the respiratory protection equipment.	NIOSH Respirator Decision Logic [NIOSH 1987], http://www.cdc.gov/niosh/idlh/intridl4.html

Exhibit 12-13. Examples of Available Short-Term, Acute Exposure Levels				
Acronym	**Full Name**	**Group or Agency**	**Purpose/Definition**	**Source/Website**
LOC	Level of Concern	U.S. Environmental Protection Agency, Federal Emergency Management Agency, U.S. Department of Transportation	Defined by the Technical Guidance for Hazards Analysis (a guide developed to assist in planning for accidental chemical releases). As the concentration of an extremely hazardous substances in air above which there may be serious irreversible health effects or death as a result of a single exposure for a relatively short period of time. In the 1987 Technical Guidance for Hazards Analysis document, an LOC was estimated by using one-tenth of the IDLH level published by the National Institute for Occupational Safety and Health. For the purposes of offsite consequence analysis performed as part of accidental release requirements under Section 112(r) of the CAA, this value is superceded by ERPG-2 values as available, and the Agency intends to supercede those values with AEGL-2 values as they are developed and adopted.	Technical Guidance for Hazards Analysis. Emergency Planning for Extremely Hazardous Substances. (USEPA, FEMA, USDOT, 1987). 61 FR 31672; June 20, 1996
MRL	Acute Minimum Risk Levels	U.S. Agency for Toxic Substances and Disease Registry (ATSDR)	The MRL is an estimate of human exposure to a substance that is likely to be without an appreciable risk of adverse effects (other than cancer) over a specified duration of exposure, and can be derived for acute exposures by the inhalation and oral routes. Unlike the one-hour focus of most of the other values listed here, acute MRLs are derived for exposures of 1 to 14 days duration.	http://www.atsdr.cdc.gov/mrls.html
REL	Reference Exposure Level	California EPA Office of Environmental Health Hazard Assessment (OEHHA)	The acute REL is an exposure that is not likely to cause adverse effects in a human population, including sensitive sub-populations, exposed to that concentration for one hour on an intermittent basis. RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact OEHHA has defined the lowest available acute severity level as the REL.	http://www.oehha.ca.gov/air/pdf/acuterel.pdf
SPEGL	Short-term Public Emergency Exposure Guidance Level	National Academy of Sciences (NAS) Committee on Toxicology	The NAS develops short-term public emergency exposure guidance levels (SPEGLs) to apply to the exposures of the general public to contaminants during airborne chemical releases; SPEGLs are generally set at a level of 0.1 to 0.5 times the EEGL and are measured as 60 minute or 8 hour exposure time frames.	*Criteria and Methods for Preparing Emergency Exposure Guidance Level (EEGL), Short-Term Public Emergency Guidance Level (SPEGL), and Continuous Exposure Guidance Level (CEGL) Documents.* 1986. National Academy Press, National Academy of Sciences ,Washington, D.C.

Exhibit 12-13. Examples of Available Short-Term, Acute Exposure Levels				
Acronym	**Full Name**	**Group or Agency**	**Purpose/Definition**	**Source/Website**
STEL	Short-Term Exposure Limit	American Conference of Governmental Industrial Hygenists (ACGIH)	STELs are time weighted average (TWA) guidelines for the control of short term exposure in the workplace. These are important supplements to the eight-hour TWA exposure standards which are more concerned with the total intake over long periods of time. Generally, STELs are established to minimize the risk of the occurrence in nearly all workers of: intolerable irritation; chronic or irreversible tissue change; and narcosis to an extent that could precipitate industrial accidents, provided the eight hour TWA exposure standards are not exceeded. STELs are recommended for those substances only when there is evidence either from human or animal studies that adverse health effects can be caused by high short term exposure. STELs are expressed as airborne concentrations of substances, averaged over a period of 15 minutes.	

12.7 Evaluating Chemicals Lacking Health Reference Values

12.7.1 Use of Available Data Sources

If EPA-derived IRIS assessments are available for the chemicals being examined, these values should generally be used in the risk assessment. Use of IRIS or other EPA-derived dose-response values prevents duplication of effort in toxicity assessment and ensures consistency in the dose-response values among risk assessments. If EPA-derived dose-response values are not available, the other sources described in Section 12.6 should be given next priority. Use of these sources in a hierarchical manner has been implemented in tables developed for the 188 hazardous air pollutants (see Appendix C and http://www.epa.gov/ttn/atw/toxsource/table1.pdf). The Toxicology Excellence for Risk Assessment (TERA) maintains a database of international dose-response values (see www.TERA.org/iter).

If those sources also lack inhalation dose-response values, then route-to-route extrapolation (discussed below) may be considered. This approach, however, may be quite detailed, and requires assistance from a professional toxicologist. If all sources and approaches have been researched, and no dose-response value is available, the assessor should describe the effects of the chemical qualitatively and discuss the implications of the absence of the chemical from the risk estimate in the uncertainty section of the risk assessment.

12.7.2 Route-to-Route Extrapolation

For cases in which appropriate dose-response values are not available for the route of exposure being considered, but are available for another route, it may be possible to use route-to-route extrapolation. Route-to-route extrapolation is recommended only from oral to inhaled exposure and only for carcinogens. The ability to perform quantitative route-to-route extrapolation is critically dependent on the amount and type of data available. Regardless of the toxic endpoint being considered, a minimum of information is required to construct plausible dosimetry for the routes of interest. This information includes both the nature of the toxic effect and a description of the relationship between exposure and the toxic effect.

Route to route extrapolations should only be done by qualified toxicologists.

Data from other routes of exposure may be useful to derive an RfC (for carcinogens only; discussed below) only when respiratory tract effects and/or "first pass" effects can be ruled out. First pass effects are cases where metabolism takes place in the portal-of-entry tissues, prior to entry into the systemic circulation. The respiratory tract can exhibit a first-pass effect after inhalation. Unless the first-pass effect and dosimetry are adequately understood, there can be substantial error introduced in route-to-route extrapolation that does not account for these considerations.

Oral toxicity data should *not* be used for route-to-route extrapolation in the following cases (unless these effects can be accounted for in a PBPK model):

- When groups of chemicals have different toxicity by the two different routes (e.g., metals, irritants, and sensitizers);
- When a first-pass effect by the respiratory tract is expected;

- When a first-pass effect by the liver is expected;

- When a respiratory tract effect is established, but dosimetry comparison cannot be clearly established between the two routes;

- When the respiratory tract is not adequately studied in the oral studies; and

- When short-term inhalation studies, dermal irritation, in vitro studies, or characteristics of the chemical indicate potential for portal-of-entry effects at the respiratory tract, but studies themselves are not adequate for an RfC development.

The actual impact of exposure by different routes can only be estimated by taking account of factors that influence absorption at the portal of entry, such as (1) physicochemical characteristics of the chemical; (2) exposure factors; and (3) physiologic parameters. The preferred method for performing route-to-route extrapolation involves the development of a PBPK model that describes the disposition of the chemical for the routes of interest. As previously discussed, PBPK models account for fundamental physiologic and biochemical parameters and processes such as blood flow, ventilatory parameters, metabolic capacities, and renal clearance, tailored by the physicochemical and biochemical properties.

If appropriate toxicity information is not available, a qualitative rather than quantitative evaluation of the chemical is recommended. The implications of the absence of the chemical from the risk estimate should be discussed in the uncertainty section.

12.8 Dose-Response Assessment for Mixtures

The recommended approach for assessing risks from exposure to a mixture of pollutants (e.g., coke oven emissions, diesel exhaust, etc.) is to utilize a dose-response assessment developed for that mixture or a mixture judged similar.[11 12] Where such an assessment is not available, a component-by-component approach may be employed. There are several commonly used approaches. Selection among the approaches involves consideration of the similarity of the mixture components with regard to their toxicological activity. There are a few groups of toxicologically similar chemicals for which the Agency recommends the use of relative potency factors (RPFs) or toxicity equivalence factors (TEFs). These factors have been developed by EPA and other organizations for two classes of compounds: PAHs and dioxins/furans. The World Health Organization (WHO) has developed TEFs for polychlorinated biphenyls (PCBs) as an extension of the factors for dioxins/furans (see Exhibit 12-14).

- **Polycyclic Aromatic Hydrocarbons (PAHs)**. EPA has not developed IURs or CSFs for carcinogenic PAHs other than benzo(a)pyrene. EPA recommends use of a RPF based on the potency of each compound relative to that of benzo(a)pyrene.[13] Although several references may be found in the literature with proposed RPFs for PAHs, EPA recommends the following RPF values for seven PAHs, which are classified as B2, probable human carcinogens:[(g)]

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[g]CalEPA has developed IURs based on RPFs for several additional PAHs that have been classified as probably or possibly human carcinogens (e.g., IARC).

PAH	RPF
Benzo(a)pyrene	1.0
Benzo(a)anthracene	0.1
Benzo(b)fluoranthene	0.1
Benzo(k)fluoranthene	0.01
Chrysene	0.001
Dibenz(a,h)anthracene	1.0
Indeno(1,2,3-c,d)pyrene	0.1

Thus, for these seven PAHs, the IUR for benzo(a)pyrene is multiplied by the applicable RPF to derive the IUR.

- **Dioxins, Furans, and PCBs**. For carcinogenic dioxins and furans, the TEF approach has an underlying assumption of additivity across mixture components. EPA currently recommends TEFs for specific congeners, rather than isomeric groups (see Exhibit 12-13). TEFs were determined by inspection of the available congener-specific data and an assignment of an "order of magnitude" estimate of relative toxicity when compared to 2,3,7,8-TCDD. The cancer potency of certain dioxin and furan congeners is estimated relative to 2,3,7,8-TCDD based on other toxicity information that is available for the congeners. Scientific judgment and expert opinion formed the basis for these TEF values. External review of the toxicity and pharmacokinetic data utilized in setting these TEF values supported the basic approach as a "reasonable estimate" of the relative toxicity of polychlorinated dibenzo-dioxins (PCDDs) and polychlorinated dibenzo-furans (PCDFs).[14] TEF values developed by scientific groups over the past 15 years are provided in Exhibit 12-13. The most recent consensus of the scientific community (including representation by EPA scientists) is represented by the WHO 1997 values.

  TEFs based on the relative cancer potencies are used to adjust the exposure concentrations of mixture components, which are subsequently summed into a single exposure concentration for the mixture. That exposure concentration based on TEFs is then used, along with the 2,3,7,8-TCDD IUR or noncancer reference value, to estimate cancer risks or other health hazards for the mixture.

Exhibit 12-14. Toxicity Equivalence Factors for Dioxins, Furans and PCBs				
Congener	**EPA (1987)[15]**	**NATO (1989)[16]**	**WHO (1994)[17]**	**WHO (1997)[18]**
TCDDs				
2,3,7,8-TCDD	1	1		1
1,2,3,7,8-PeCDD	0.5	0.5		1
1,2,3,4,5,8-HxCDD	0.04	0.1		0.1
1,2,3,7,8,9-HxCDD	0.04	0.1		0.1
1,2,3,6,7,8-HxCDD	0.04	0.1		0.1
1,2,3,4,6,7,8-HpCDD	0.001	0.1		0.01
1,2,3,4,6,7,8,9-OCDD	0	0.001		0.0001
TCDFs				
2,3,7,8-TCDF	0.1	0.1		0.1
1,2,3,7,8-PeCDF	0.1	0.05		0.05
2,3,4,7,8-HxCDF	0.1	0.5		0.5
1,2,3,4,7,8-HxCDF	0.01	0.1		0.1
1,2,3,7,8,9-HxCDF	0.01	0.1		0.1
1,2,3,6,7,8-HxCDF	0.01	0.1		0.1
2,3,4,6,7,8-HxCDF	0.01	0.1		0.1
1,2,3,4,6,7,8-HpCDF	0.001	0.01		0.01
1,2,3,4,7,8,9-HpCDF	0.001	0.01		0.01
1,2,3,4,6,7,8,9-OCDF	0	0.001		0.0001
PCBs **IUPAC # Structure**				
77 3,3',4,4'-TCB			0.0005	0.0001
81 3,4,4',5-TCB			–	0.0001
105 2,3,3',4,4'-PeCB			0.0001	0.0001
114 2,3,4,4',5-PeCB			0.0005	0.0005
118 2,3',4,4',5-PeCB			0.0001	0.0001
123 2',3,4,4',5-PeCB			0.0001	0.0001
126 3,3',4,4',5-PeCB			0.1	0.1
156 2,3,3'4,4',5-HxCB			0.0005	0.0005
157 2,3,3',4,4',5'-HxCB			0.0005	0.0005
167 2,3',4,4',5,5'-HxCB			0.00001	0.00001
169 3,3'4,4'5,5'-HxCB			0.01	0.01
170 2,2',3,3',4,4',5-HpCB			0.0001	–
180 2,2',3,4,4',5,5'-HpCB			0.00001	–
189 2,3,3',4,4',5,5'-HpCB			0.0001	0.0001
Source: EPA's dioxin reassessment activities[19]				

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Chapter 13 Inhalation Risk Characterization

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13.1 Introduction

The last component of risk assessment, risk characterization, integrates the information from the exposure assessment (Chapter 11) and toxicity assessment (Chapter 12), using a combination of qualitative and quantitative information and including a discussion of uncertainty and variability.[1] The risk characterization and its components should be presented so that the details of the analysis are transparent, clear, consistent with EPA guidance and policy, and will generally support the conclusion that the analysis is reasonable for its intended purpose. Risk assessors aim for the risk summary and risk conclusions to be complete, informative, and useful for decision-makers. One way of accomplishing this is to make sure that major uncertainties associated with determining the nature and extent of the risk are identified and discussed.

Risk = *f* (metric of exposure, metric of toxicity)

Risk characterization combines the information from the exposure assessment and the toxicity assessment to provide a quantitative estimate of potential cancer risk and/or hazard for other adverse effects, along with a statement of confidence about the data and methods used

EPA has developed several key policies about how to characterize and present risk assessment information. EPA's *Policy for Risk Characterization*[2] specifies that a risk characterization "be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency." The purpose of the memorandum was to ensure that risk management decisions are well-supported and well-understood, both inside the EPA and outside the Agency. The confidence in the data, science policy judgments, and the uncertainties in the database should be clearly communicated. The 1995 *Guidance for Risk Characterization* has been updated by the *Handbook for Risk Characterization*, which provides more background and approaches to presenting the risk characterization results.[3] Risk assessors may want to become familiar with the information provided in both the policy and handbook before beginning a risk assessment.

A 1992 memorandum from EPA's Office of the Administrator provides guidance on describing risk assessment results.[4] This memorandum focuses on communicating the full range of information used in developing the assessment, rather than providing only point estimates of risk to the public. The risk characterization guidance and handbook[3] recommends presenting a full and complete picture of risk that includes: a statement of confidence about data and methods used to develop the assessment; greater consistency and comparability in risk assessment across EPA programs; and statement of the level of scientific judgment inherent in risk management decisions. Information should be presented on the range of exposures derived from exposure scenarios using multiple risk descriptors (e.g., central-tendency, high-end of individual risk, population risk, important sub-populations, if known). For risk management decisions, the risk estimates are compared to legally mandated or other risk objectives (see Part V of this Reference Manual).

Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high end of individual risk, population risk, important sub-populations, if known) consistent with terminology in the *Guidance on Risk Characterization*, Agency risk assessment guidelines, and program-specific guidance.

EPA *Policy for Risk Characterization*[2]

Risks are often evaluated initially for **individuals** within the potentially exposed population. **Population risks** for the exposed population may also be estimated, which may be useful in estimating potential economic costs and benefits from risk reduction. Sensitive subpopulations should also be considered, when possible. Estimates of **incidence** also are possible (see Exhibit 13-1).

Incidence is defined by the National Cancer Institute as "The number of new cases of a disease diagnosed each year." For example, a State's cancer registry might report that the statewide 5-year average incidence of lung cancer (i.e., the average number of actual people that were diagnosed by a doctor over the 5 year period) is 700 new cases per 100,000 people (5-year averages are often used to provide an estimate that is more stable over time). In comparison, air toxics risk assessments provide only a theoretical estimate of the likelihood that an individual in the exposed population will contract cancer as a result of exposure over a period of time (e.g., 50 or 100 years of a facility lifetime).

The potential risks calculated for specific inhalation exposures are typically **incremental risks**; that is, they are potential risks that are *in addition to* those risks already faced by the population under study for reasons other than exposure to air toxics (e.g., hereditary, lifestyle risks such as smoking). The risk estimates are used to answer questions concerning the general risks posed to the exposed population, the risk levels of various groups within the population, and the potential range of risks across the population (e.g., central-tendency (e.g., average) or high-end (e.g., maximum) risk for individuals within the populations of interest).

Steps in an Inhalation Risk Characterization

1. Organize outputs of inhalation exposure and toxicity assessments.
2. Derive inhalation cancer risk estimates and noncancer hazard quotients for each pollutant in each pathway for each type of receptor being studied.
3. Derive cumulative inhalation cancer risk estimates and noncancer hazards for each receptor for all chemicals in a pathway and then across pathways.
4. Identify key features and assumptions of exposure and toxicity assessments.
5. Assess and characterize key uncertainties and variability associated with the assessment.
6. Consider additional relevant information (e.g., related studies).

Risk characterization should include a risk summary and risk conclusions that are complete, informative, and useful for decision-makers, and which clearly identify and discuss the major uncertainties associated with determining the nature and extent of risk. See references 2 and 3 at the end of this chapter for more information.

Estimated cancer risks and noncancer hazards are generally developed for each chemical to which people are exposed in the study area and each exposure pathway through which exposure can occur. The results are then summed in a specific way to provide total estimates of risk and hazard. The general steps involved in risk characterization are:

- Quantify risks and hazards for each chemical through each pathway for each receptor;
- Review exposure estimates and assumptions;
- Review toxicity estimates and assumptions;
- Assess uncertainties and variability; and
- Consider additional relevant information (e.g., related studies).

Exhibit 13-1. Estimates of Risk
Individual risk. Estimates of cancer risk are usually expressed as a statistical probability represented in scientific notation as a negative exponent of 10. For example, an additional risk of contracting cancer of one chance in 10,000 (or one additional person in 10,000) is written as 1×10^{-4} (or 1E-04). This means that for every 10,000 people that are exposed, ***in the way that we have presumed***, one of those people may develop cancer over their lifetime. Likewise, a risk of one person in one million is written 1×10^{-6} (or 1E-06) and a risk or one in one hundred thousand is written 1×10^{-5} (or 1E-05).
Population Risk. Estimates of cancer risk can be expressed as the number of people in the population who may have the same risk level (e.g., 1,000,000 people in the exposed population under study may have a risk of 1×10^{-6}, 2,495 may have a risk of 1×10^{-5}, and 300 may have a risk of 1×10^{-4}).
Incidence. Estimates of cancer risk can be expressed as the incidence of cancer cases in a population. For example, the estimated incidence of cancer in a population of 500,000 individuals where the individual risk is 1×10^{-5} (based on a 100 year exposure scenario) is simply: $$Population\ Size \times \frac{Individual\ Risk}{Averaging\ Time} \times Exposure\ Duration;\ or$$ $$500{,}000\ Individuals \times \frac{1\times 10^{-5}}{70\ Years} \times 100\ Years = up\ to\ 7\ New\ cancer\ cases$$ Note that since the individual cancer risk value is a lifetime value, it is divided by 70 years (average lifetime length) prior to multiplying by the exposure period duration (100 years). It is also important to note the assumptions in this example calculation (e.g., average population size of 500,000 individuals and individual lifetime risk value of 1×10^{-5} for the 100 year period). Given these assumptions, these possible seven new cases are the expected number of cases over the total exposure duration of 100 years. If one wanted to estimate the number of new cases per year, simply use an exposure duration of one year. In our example, $$500{,}000\ Individuals \times \frac{1\times 10^{-5}}{70\ Years} \times 1\ Year = up\ to\ 0.07\ new\ cancer\ cases$$ This points out two problems with using risk estimates to derive incidence estimates. First, a fraction of a cancer case (which often results from this exercise) is not a very helpful statistic when assessing a potential air toxics problem. Second, people living in different areas with the same individual risks, but with very different exposed population sizes can end up with very different incidence rates. For example, if our population above only had 10,000 people, the incidence rate would have been predicted to be no more than 0.1 (versus seven). While the first situation indicates a higher potential population impact, the second situation nevertheless indicates identical individual risk predictions for members of the population. Both metrics are informative to the risk manager, and reflect different considerations which may have different weights in different decisions. Other ways of describing risk to an exposed population are also possible.

Risk estimates in screening-level (Tier 1) analyses typically are deterministic estimates based on point estimates of exposure and toxicity. Deterministic estimates are useful screening tools in a tiered analysis, but need to be qualified by transparent discussions of the nature and extent of uncertainties in the input variables and the subsequent likely impact on the ultimate risk characterization. Deterministic analyses with appropriate uncertainty characterization can be used to identify situations of low incremental risk and to focus on areas where additional analysis might improve the basis for selection of a risk management action. At higher tiers of analyses, risk assessors commonly describe exposure (and less frequently, toxicity) by probability distributions rather than by point values and propagate these distributions through the exposure assessment and risk characterization process. This type of probabilistic analysis, which may address uncertainty and variability as distinct issues, will result in an estimate of risk that is a probability distribution rather than a point value. A more detailed discussion of the assessment and presentation of uncertainty in the risk characterization process is provided in Section 13.3.4. Probabilistic uncertainty analysis is discussed in Chapter 31.

13.2 Quantification of Cancer Risk and Noncancer Hazard

Quantification of risk and hazard is the step where exposure concentrations in air are combined with applicable inhalation dose-response values. Predictive cancer risk estimates are presented separately from noncancer hazard quotients. Risks are quantified for the pathways, receptors, and exposure scenarios outlined in the conceptual site model.

Risk versus Hazard...What's the Difference?

Risk assessors purposefully use the term *risk* to mean the statistical probability of developing cancer over a lifetime (even if exposure only occurs over a portion of that lifetime). Noncancer "risks," on the other hand, are not expressed as a statistical probability of developing a disease. Rather they are expressed as a simple comparison of the exposure concentration to a reference concentration associated with the observable adverse health effects. To help make this distinction, the potential harm from exposure to carcinogens is called "risk" and the potential harm from noncarcinogens is called "hazard."

Information about the distribution of exposure and risk for the population is an important component of risk characterization. Distributions are often more useful than point estimates. However, since developing fully distributional estimates of risk is usually out of the scope of most risk assessments, assessors can provide a sense of the range of risks by developing both central tendency and high-end estimates.[5]

- **Central tendency** estimates are intended to give a characterization of risk for the typical individual in the population. This is usually either based on the arithmetic mean risk (average estimate) or the median risk (median estimate).

- **High-end** estimates are intended to estimate the risk that is expected to occur in the upper range of the distribution (e.g., risk above about the 90th percentile of the population distribution). For example, the maximum exposed individual (MEI) risk or maximum individual risk (MIR) might be used to estimate high-end risks.

An evaluation of the uncertainty in the risk descriptors is an important component of the uncertainty discussion in the assessment. Both quantitative and qualitative evaluations of uncertainty can be useful to users of the assessment (see Section 13.3.4 and Chapter 31).

13.2.1 Cancer Risk Estimates

Estimated individual cancer risk is expressed as the upper bound probability that a person may develop cancer over the course of their lifetime as a result of the exposures under study. This predicted risk is the **incremental risk** of cancer from the exposure being analyzed that is above the risk that the individuals in the population have already (i.e., due to non-air toxics related issues). Due to the nature of the assumptions in their derivation, inhalation unit risks (IURs) are generally considered to be "plausible upper-bound" estimates of potency. As such, the calculated risks are usually a conservative estimate (i.e., the true risk may be lower).

As described above, risks may be estimated for both the central tendency (average exposure) case and for the high-end (exposure that is expected to occur in the upper range of the distribution) case. However, for both types of estimates, the same estimate of toxicity (i.e., an IUR or reference concentration [RfC]) is generally used to calculate the risk. In other words, while the estimate of exposure may be allowed to vary to derive a sense of the range of exposures in a population, *the same estimate of toxicity* is used to calculate risk for both average and high-end risks. With few exceptions, toxicity values are not currently presented as a range.

Cancer risk characterization typically is performed first for individual air toxics, then is summed over all of the air toxics to which a person may be exposed at the same time. These steps are described in separate subsections below.

13.2.1.1 Characterization of Individual Pollutant Risk

For inhalation exposures, chronic cancer risks for individual air toxics are typically estimated by multiplying the estimate of long-term exposure concentration (EC) by the corresponding IUR for each pollutant to estimate the potential incremental cancer risk for an individual:

$$\text{Risk} = EC_L \times \text{IUR} \qquad \text{(Equation 13-1)}$$

where:

Risk	=	Cancer risk to an individual (expressed as an upper-bound risk of contracting cancer over a lifetime);
EC_L	=	Estimate of long-term inhalation exposure concentration for a specific air toxic; and
IUR	=	the corresponding inhalation unit risk estimate for that air toxic.

Performing the estimate in this way provides an estimate of the probability of developing cancer over a lifetime due to the exposure in question. Because of the way this equation is written, the underlying presumption is that a person is exposed continuously to the EC_L for their full lifetime (usually assumed to be 70 years).[(a)] The EC_L is an estimate of this long-term exposure even

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[a]EPA is currently reviewing methods for assessing cancer risk for less than lifetime exposures occurring in childhood. EPA's Draft Document *Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens* (http://www.epa.gov/sab/panels/sgacsrp.html) recommends a change to the current method for strong mutagens. This document is undergoing public and Science Advisory Board review and will be completed sometime in the future with consideration of that review. EPA's methods for air toxics assessments will be consistent with the final document.

though it is probably based on only one year's worth of monitoring data or a modeling run that covers only one year's worth of time. (As noted in Chapter 11, exposure modeling can be used, in some cases, to derive a better estimate of the amount of time people interact with contaminated air. Nevertheless, the probability of developing cancer is still averaged out over the full lifetime of the individual.)

Estimates of cancer risk are usually expressed as a statistical probability represented in scientific notation as a negative exponent of 10. For example, an additional risk of contracting cancer of one chance in 10,000 (or one additional person in 10,000) is written as 1×10^{-4} (or 1E-04). This means that for every 10,000 people that are exposed, ***in the way that we have presumed***, one of those people may develop cancer over their lifetime. Likewise, a risk of one person in one million is written 1×10^{-6} (or 1E-06) and a risk or one in one hundred thousand is written 1×10^{-5} (or 1E-05).

Because IURs are typically upper-bound estimates, actual risks may be lower than predicted (see Chapter 12), and the true value of the risk is unknown and may be as low as zero.[5] These statistical projections of hypothetical risk are intended as screening tools for risk managers and cannot make realistic predictions of biological effects. Such risk estimates also cannot be used to determine whether someone who already has cancer is ill because of a past exposure. Part VI of this volume provides an overview of the Public Health Assessment process used to evaluate whether past exposures resulted in current illness.

Risks for cancer are generally expressed as individual risks (i.e., the risk borne by an individual in a larger exposed population). The number of people in the population who have the same risk level may also be provided (e.g., 1,000,000 people in the exposed population under study have a risk of 1×10^{-6}, 2,495 have a risk of 1×10^{-5}, and 300 have a risk of 1×10^{-4}). It is also possible to calculate the number of expected cases of cancer expected over a 70-year period by multiplying the cancer risk to an individual by the number of individuals; however, even though the calculation might yield an estimate of incidence, low predicted cancer incidence rates (even vanishingly small) do not mean that individuals within the population will not get cancer because of air toxics exposures.

13.2.1.2 Characterization of Cancer Risk from Exposure to Multiple Pollutants

People may receive exposure to multiple chemicals, rather than a single chemical, at the same time. The concurrent exposure to multiple carcinogens may occur through the same pathway or across several pathways. With a few exceptions (e.g., coke oven emissions), cancer dose-response values (e.g., IURs) are usually available only for individual compounds within a mixture.

The following equation estimates the predicted cumulative incremental individual cancer risk from multiple substances, and assumes an additive effect from simultaneous exposures to several carcinogens:

$$\mathrm{Risk}_T = \mathrm{Risk}_1 + \mathrm{Risk}_2 + \ldots + \mathrm{Risk}_i \qquad \text{(Equation 13-2)}$$

where:

$Risk_T$ = total cumulative individual pathway-specific cancer risk (expressed as an upper-bound risk of contracting cancer over a lifetime); and
$Risk_i$ = individual risk estimate for the ith substance in the inhalation pathway.

In screening-level assessments of carcinogens for which there is an assumption of a linear dose-response, the cancer risks predicted for individual chemicals may be added to estimate cumulative cancer risk. This approach assumes that the risks associated with individual chemicals in the mixture are additive. In more refined assessments, the chemicals under assessment may be evaluated to determine whether effects from multiple chemicals are synergistic (greater than additive) or antagonistic (less than additive), although sufficient data for this evaluation are usually lacking. In those cases where IURs are available for a chemical mixture of concern, risk characterization can be conducted on the mixture using the same procedures used for a single compound. When more than one pathway is involved, the pathway specific risks are generally summed first, and then summed across pathways. This process is described in Part III of this reference manual. Note that for carcinogens being assessed based on the assumption of nonlinear dose-response, for which an RfC considering cancer as well as other effects has been derived, the hazard quotient approach will be appropriate (see Section 13.2.2).

Example Calculation to Estimate Cancer Risk (Hypothetical)

A Tier 1 modeling analysis was performed to estimate risk to the maximum exposed individual, assumed to reside at the point of maximum concentration for ABC Factory. Four HAPs were potentially of concern: benzene, dichloroethyl ether, formaldehyde, and cadmium compounds. Cancer risk estimates were obtained for each HAP by multiplying the estimated *annual average* EC by the IUR for each HAP. The resulting upper bound cancer risk estimates ranged from 2×10^{-6} (benzene, formaldehyde) to 8×10^{-4} (dichloroethyl ether). The cancer risk estimates for each HAP were summed to obtain an estimate of total inhalation cancer risk (9×10^{-4}). Note that 97 percent of the estimated total risk results from dichloroethyl ether, and that more than 99 percent results from dichloroethyl ether and cadmium compounds. In this hypothetical example, the risk assessor would need to decide which HAPs to carry to higher tiers by weighing the small proportion of risk posed by benzene and formaldehyde against the fact that these risks nevertheless exceeded one in one million.

HAP	EC $\mu g/m^3$	IUR $1/(\mu g/m^3)$	Cancer Risk Estimate[(a)]	Percent of Total Risk
Benzene	0.3	7.8×10^{-6}	2×10^{-6}	< 1%
Dichloroethyl ether	2.5	3.3×10^{-4}	8×10^{-4}	97 %
Formaldehyde	0.2	1.3×10^{-4}	2×10^{-6}	< 1 %
Cadmium compounds	0.01	1.8×10^{-3}	1×10^{-5}	2 %
Total			9×10^{-4}	

[(a)] Standard rules for rounding apply which will commonly lead to an answer of one significant figure in both risk and hazard estimates. For presentation purposes, hazard quotients (and hazard indices) and cancer risk estimates are usually reported as one significant figure.

13.2.2 Noncancer Hazard Estimates

For noncancer effects (as well as carcinogens being assessed based on the assumption of nonlinear dose-response), exposure concentrations are compared to RfCs, which are estimates (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive sub-populations) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime (see Chapter 12).

13.2.2.1 Characterizing Individual Pollutant Hazard for Chronic Exposures

For inhalation exposures, noncancer hazards are estimated by dividing the estimate of the chronic inhalation EC by the RfC to yield a hazard quotient (HQ) for individual chemicals:

$$HQ = EC_C \div RfC \qquad \text{(Equation 13-3)}$$

where:

HQ	=	the hazard quotient for an individual air toxic;
EC_C	=	estimate of chronic inhalation exposure to that air toxic; and
RfC	=	the corresponding reference concentration for that air toxic.

In screening inhalation risk assessments, which are routinely built around a particular year's estimate of emissions, the exposure estimate is usually based on an assumption of continuous long-term exposure using an annual average as the estimate of exposure concentration. A more refined assessment (e.g., by use of an exposure model) may generate an estimate of a more realistic exposure (e.g., by the application of an exposure model or refined emissions estimates over the longer time period).

Based on the definition of the RfC, an HQ less than or equal to one indicates that adverse noncancer effects are **not likely to occur**, and thus can be considered to have negligible hazard. Unlike cancer risks, however, HQs greater than one are not statistical probabilities of harm occurring. Instead, they are a simple statement of whether (and by how much) an exposure concentration exceeds the RfC. Moreover, the level of concern does not increase linearly or to the same extent as HQs increase above one for different chemicals because RfCs do not generally have equal accuracy or precision and are generally not based on the same severity of effect. Thus, we can only say that with exposures increasingly greater than the RfC, (i.e., HQs increasingly greater than 1), the **potential for adverse effects increases**, but we do not know by how much. An HQ of 100 does not mean that the hazard is 10 times greater than an HQ of 10. Also an HQ of 10 for one substance may not have the same meaning (in terms of hazard) as another substance resulting in the same HQ.

Example Calculation to Estimate Chronic Noncancer Hazard (Hypothetical)

A Tier 1 modeling analysis was performed to estimate chronic noncancer hazard to the maximum exposed individual, assumed to reside at the point of maximum concentration for ABC Factory. Four HAPs were potentially of concern: benzene, dichloroethyl ether, formaldehyde, and cadmium compounds. Noncancer hazard estimates were obtained for each HAP by dividing the estimated Exposure Concentration (EC) by the Inhalation Reference Concentration (RfC) for each HAP (note that the EC is expressed in units of mg/m^3 for this analysis). The resulting Hazard quotient (HQ) estimates ranged from 1×10^{-3} (formaldehyde) to 1 (cadmium compounds). Note that no RfC was available for dichloroethyl ether. The HQs for each HAP were summed to obtain an estimate of the Hazard Index (HI) of 1. Note that cadmium compounds account for 95 percent of the HI, suggesting that the other HAPs may not need further consideration (although this determination should be made in consideration of all relevant information, including uncertainties such as confidence in the exposure concentration and uncertainty factors used to derive each RfC).

HAP	EC mg/m^3	RfC (mg/m^3)	HQ[(b)]	Percent of HI
Benzene	6×10^{-4}	6×10^{-2}	1×10^{-2}	1 %
Dichloroethyl ether[(a)]	5×10^{-3}	---	---	---
Formaldehyde	4×10^{-4}	1×10^{-2}	1×10^{-3}	4 %
Cadmium compounds	2×10^{-5}	2×10^{-5}	1	95 %
Hazard Index (HI)			1	

[(a)] note that the absence of an RfC value means that we cannot quantitatively assess a HAP.
[(b)] Standard rules for rounding apply which will commonly lead to an answer of one significant figure in both risk and hazard estimates. For presentation purposes, hazard quotients (and hazard indices) and cancer risk estimates are usually reported as one significant figure.

13.2.2.2 Characterizing Multiple Pollutant Hazard for Chronic Exposures

Noncancer health effects data are usually available only for individual compounds within a mixture. In these cases, the individual HQs can be summed together to calculate a multiple-pollutant hazard index (HI):

$$HI = HQ_1 + HQ_2 + ...+ HQ_i \qquad \text{(Equation 13-4)}$$

where

HI = hazard index; and
HQ = hazard quotient for the ith air toxic.

For screening-level assessments, a simple HI may first be calculated for all chemicals of concern within the inhalation pathway (adding hazards across pathways is discussed in Part III). If the HI is less than your decision criterion, a more refined analysis is usually not performed. Adding HQs in this fashion is based on the assumption that even when individual pollutant levels are

lower than the corresponding reference levels, some pollutants may work together such that their potential for harm is additive and the combined exposure to the group of chemicals poses greater likelihood of harm. Some groups of chemicals can also behave antagonistically, such that combined exposure poses less likelihood of harm, or synergistically, such that combined exposure poses harm in greater than additive manner. Where this type of HI exceeds the criterion of interest, a more refined analysis is warranted.

Although the HI approach encompassing all chemicals in a mixture is commonly used for a screening-level study, it is important to note that application of the HI equation to compounds that may produce different effects, or that act by different toxicological mechanisms, could overestimate the potential for effects. Consequently, it is more appropriate to calculate a separate HI for each endpoint of concern for which mechanisms of action are known to be similar.

Because the assumption of dose additivity is most appropriate for compounds that induce the same effect by similar modes of action, EPA's *Guidance for Conducting Health Risk Assessment of Chemical Mixtures* and *Supplementary Guidance*[6] suggest subgrouping pollutant-specific HQs by toxicological similarity of the pollutants for subsequent calculations; that is, to calculate a **target-organ-specific-hazard index (TOSHI)** for each subgrouping of pollutants. This calculation allows for a more appropriate estimate of overall hazard.

Segregation of hazard indices by effect and mechanism of action can be complex and time-consuming because it is necessary to identify all the major effects and target organism for each chemical and then to classify the chemicals according to target organ(s) or mechanism of action. This analysis is not simple and a toxicologist with familiarity in developing TOSHIs is best suited to perform this function. If the segregation is not carefully done, an underestimate of true hazard could result.

Procedure for Segregation of HIs by Effect

Segregation of HIs requires identification of the major effects of each chemical, including those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at an EC of 20 $\mu g/m^3$ and neurotoxicity at an EC of 50 $\mu g/m^3$). Major effect categories include neurotoxicity, developmental toxicity, reproductive toxicity, immunotoxicity, and adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects).

Acute HQs are developed in the same manner as chronic HQs, with the caveat that the exposure duration associated with the exposure concentration should match the exposure duration embodied in the acute toxicity value. Whereas summing chronic HQs to a total hazard index is a relatively straightforward exercise, the issues related to developing acute HI are more subtle and complex. A toxicologist familiar with acute exposure and risk analysis should be consulted to perform this process.

13.2.2.3 Characterizing Hazard for Acute Exposures

Risk assessors can derive estimates of acute noncancer hazard for each HAP by combining the applicable short-term exposure concentration (EC) and acute dose-response value (AV) for the HAP to obtain the acute Hazard Quotient (HQ) for the HAP using the following equation:

$$HQ_A = EC_{ST} \div AV$$

where:

HQ_A = the acute hazard quotient for an individual HAP;
EC_{ST} = estimate of short-term inhalation exposure to that HAP; and
AV = the corresponding acute dose-response value for that HAP.

Note that ambient air concentrations are calculated for an exposure duration compatible with the acute dose-response value used.

Available acute dose-response values are more diverse than chronic values, because they were developed for different purposes and considering different exposure durations. The most effective characterization of acute risk often is to compare the maximum estimated hourly concentrations with a range of acute dose-response values from sources described in Chapter 12. If the ambient concentration is lower than all the acute benchmarks, it is generally reasonable to conclude that the potential for significant acute hazard is negligible. If the concentration exceeds some benchmarks but not others, the assessment should include a discussion of the implications for the chemical of interest, with attention to the details of both the exposure scenario and the benchmarks included in the analysis.

Acute noncancer health effects data are usually available only for individual HAPs within a mixture. In these cases, it may be possible to combine the individual acute HQs to calculate a multi-pollutant acute hazard index (HI) using the following formula:

$$HI_A = HQ_{A1} + HQ_{A2} + ...+ HQ_{Ai}$$

where

HI_A = acute hazard index; and
HQ_{Ai} = acute hazard quotient for the ith HAP.

Although this appears similar to the process for combining chronic HQs, the summing of acute HQs is complicated by several issues that do not pertain to chronic HQs. First, acute dose-response values have been developed for purposes that vary more widely than chronic values. Some sources of acute values define exposures at which adverse effects actually occur, while other sources develop only no-effect acute values. Second, some acute values are expressed as concentration-time matrices, while others are expressed as single concentrations for a set exposure duration. Third, some acute values may specifically consider multiple exposures, whereas others consider exposure as a one-time event. Fourth, some sources of acute values are intended to regulate workplace exposures, assuming a population of healthy workers (i.e., without children, seniors, or other sensitive individuals). Such occupational values may also consider cost and feasibility, factors that EPA considers the province of the risk manager rather than the risk assessor.

Given these differences among acute values with regard to their purposes, and the different types of acute exposure characterization that may be performed, the acute HI analysis is most informative when limited to acute values from the same source, the same level of effects, and the same duration. Analyses that mix sources, effects levels, and durations are likely to be misleading.

Risk assessors commonly evaluate acute noncancer hazard using a variety of different acute values from different sources, and discuss the resulting hazard estimates considering the purpose for which each of value was developed. This kind of evaluation should only be done by an experienced toxicologist. **The significance of these HQs and HIs would need to be considered in the context of the purpose of the risk assessment and the characteristics of the dose-response values, such as their purpose, averaging time, and health endpoints**. EPA is working to provide more comprehensive guidance on what benchmarks to rely upon and plans to develop a relevant acute benchmark methodology.

13.2.3 Quantifying Risk From Background Sources

In some cases, it may be appropriate to quantify background concentrations of the air toxics of concern. For example, background concentrations may be a critical element in determining the need for further reductions of emissions from a particular source. Background concentrations are the levels of contaminants that would be present in the absence of contaminant releases from the source(s) under evaluation. Background concentrations may occur naturally in the environment or originate from other human sources (e.g., an industrial area upwind from the sources of concern).

The general approach in risk assessments and risk management decisions has often been to assess the incremental risk posed by emissions from a particular source or group of sources. Various EPA programs, however, have taken specific approaches to considering background risks, some of which are summarized in EPA's *Residual Risk Report to Congress*.[7]

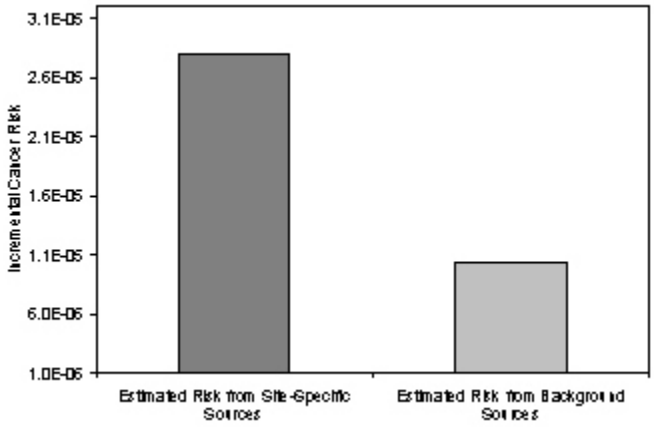
A detailed analysis of background concentrations typically would require extensive data gathering and modeling beyond that required for the incremental risk analysis. For example, numerous nearby (and possibly distant) air toxics sources of varying types would need to be characterized in sufficient detail to support release and exposure modeling. The data needs for assessment of background concentrations may differ depending on what will be done with the data. For example, if the question is simply "what is the risk to the population in a specific place," then an assessment of background may be unnecessary (monitoring data in the study area may be all that is required). On the other hand, if the question is "what is the risk and what can we do about it," then a knowledge of how much risk is contributed from both local and background sources may be necessary. If the risk is unacceptably high, but most of the risk is background in nature, there may be no appropriate risk reduction strategy (especially in regard to local sources).

Interpreting background concentrations may be difficult for anthropogenic chemicals and for chemicals formed through chemical reactions. For example, when trying to estimate background formaldehyde concentrations, it is difficult to screen out the reactive precursors which change in the study area from those that change before entering the study area. Also, if a source of nitrogen oxides (NO_x) is not present, secondary formation of formaldehyde may be slowed.

The presence of high background concentrations of anthropogenic chemicals could increase public concerns in some situations (see Part V of this reference manual for discussion of risk communication). On the other hand, knowledge of background risks could help place the air risks from a particular source or source area in better perspective.

In general, the most appropriate way to evaluate the contribution of background concentrations to the risk estimate is to simply compare the risk attributable to known or estimated (e.g., through monitoring) background concentrations in a bar chart against the risk attributable to the source(s) being evaluated (see Exhibit 13-3). Note that the study-specific risk estimate will be based on a metric of total exposure (when monitoring data are available) or incremental exposure (when modeling data are available. It generally is not appropriate to subtract background concentrations from monitored values.

Exhibit 13-3. Example Comparison of Risk Estimates from Study-specific and Background Sources



In this example, the estimated risk from the specific sources being evaluated (2.8×10^{-5}) and the estimated risk from background sources (1.0×10^{-5}) are compared side-by-side. This places the risk estimates from the sources of concern in an appropriate regional context.

13.3 Interpretation and Presentation of Inhalation Cancer Risks and Noncancer Hazards

In the final part of the risk characterization, risk assessors commonly present estimates of health risk in the context of uncertainties and limitations in the data and methodology. Exposure estimates and assumptions, toxicity estimates and assumptions, and the assessment of uncertainty are usually discussed. Additionally, information relevant to the public health context of the estimated risks is presented.

EPA's *Policy for Risk Characterization*[2] describes a philosophy of transparency, clarity, consistency, and reasonableness (TCCR), and provides detailed approaches to achieving TCCR. Exhibit 13-4 provides an overview of EPA's TCCR principles.

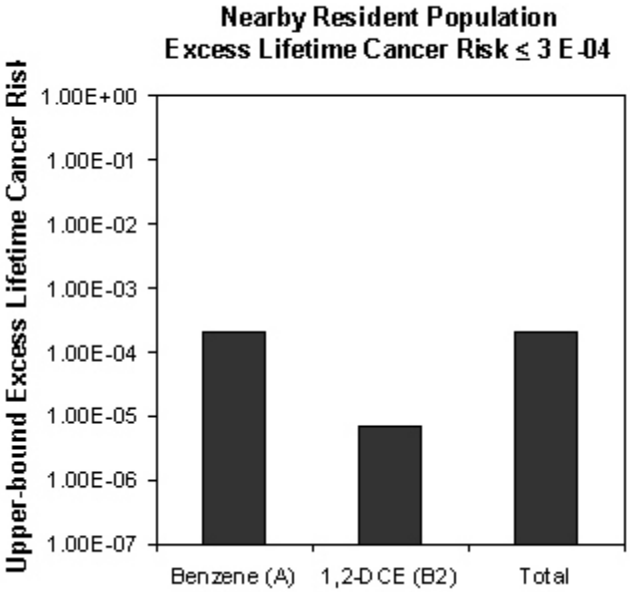
Exhibit 13-4. Transparency, Clarity, Consistency, and Reasonableness Principles		
Principle	**Definition**	**Criteria for a Good Risk Characterization**
Transparency	Explicitness in the risk assessment process	• Describe assessment approach, assumptions, extrapolations, and use of models • Describe plausible alternative assumptions • Identify data gaps • Distinguish science from policy • Describe uncertainty • Describe relative strength of assessment
Clarity	The assessment itself is free from obscure language and is easy to understand	• Employ brevity • Use plain English • Avoid technical terms • Use simple tables, graphics, and equations
Consistency	The conclusions of the risk assessment are characterized in harmony with EPA actions	• Follow statutes • Follow Agency guidance • Use Agency information systems • Place assessment in context with similar risks • Define level of effort • Use review by peers
Reasonableness	The risk assessment is based on sound judgment	• Use review by peers • Use best available scientific information • Use good judgment • Use plausible alternatives
Source: EPA *Risk Characterization Guidance*[3]		

The risk characterization document should allow the risk manager, and the public, to know why risk was assessed the way it was, by clearly summarizing the available data and its analysis, uncertainties, alternative analyses, and the choices made. A good risk characterization will state the scope of the assessment, express results clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from science policy judgments. The *Policy for Risk Characterization* calls for the explanation of the choices made to be highly visible.

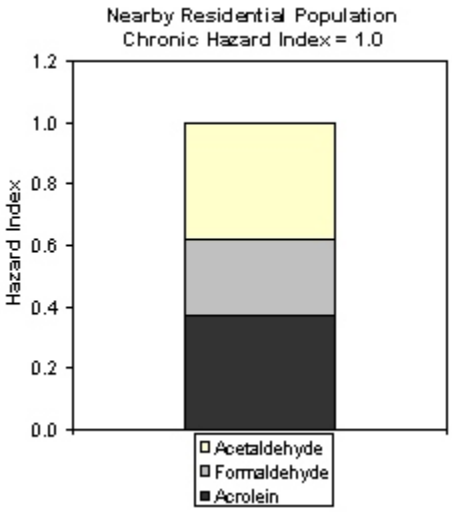
The goal of risk characterization is to clearly communicate the key findings and their strengths and limitations so that decision-makers can put the risk results into context with other information critical to evaluating risk management options (e.g., economics, social values, public perception, policies). The risk characterization will provide a means of placing the numerical estimates of risk and hazard in the context of what is known and what is not about the potential exposures and should include the elements listed in Exhibit 13-5. Exhibit 13-6 provides examples of graphical presentations of risk estimates.

Exhibit 13-5. Elements Commonly Included in the Risk Characterization Discussion
• Agreement that the key contaminants were identified • A discussion of modeled or measured air concentrations relative to background • The magnitude of the estimated cancer risks and noncancer hazard indices, and a description of the types of health risks potentially present, distinguishing between known effects in humans and those found only in experimental animals • The level of confidence in the toxicity data used to estimate risks • A presentation of qualitative information about the toxicity of substances not included in the quantitative risk assessment • Level of confidence in the exposure estimates for key exposure pathways and related exposure parameter assumptions • The major factors driving the risks (e.g., substances, pathways) • The major factors reducing the certainty in the results and the significance of these uncertainties (e.g., a change in the assumption for a certain parameter could increase/decrease the risk estimate). • The exposed population characteristics • A comparison with location-specific health studies, if available

Exhibit 13-6. Example Comparison of Risk Results for a Hypothetical Risk Assessment



The risk of developing cancer is plotted as shown. A risk of 1×10^{-4} (1 E-04) indicates a probability of one chance or less in 10,000 of an individual developing cancer. Risks of 1×10^{-5} (1 E-05) and 1×10^{-6} (1 E-06) correspond to probabilities of one chance or less in 100,000 and one million, respectively. Values in parentheses represent EPA's Weight-of-Evidence classification of the agent as a potential human carcinogen: A = human carcinogen; B2 = probable human carcinogen (with sufficient evidence in animals and inadequate or no evidence in humans).



The hazard index is equal to the sum of the hazard quotients (i.e., exposure concentration/RfC) for each chemical. It is not a probability. A hazard index ≤ 1 indicates that it is unlikely for even sensitive populations to experience adverse health effects. Thus, hazard is negligible.

13.3.1 Presenting Risk and Hazard Estimates

Risk and hazard estimates will usually be presented both to risk managers and to the public. Depending on the audience, risk characterizations can present information with different amounts of technical detail as required, although avoiding the use of technical terms generally improves clarity. Presentations may include the assumptions the risk assessment used, as well as the distribution of risks estimated for the assessment. Multiple point estimates and risk ranges could be discussed in both narrative and tabular forms. The discussion of results may include items such as:

- The range of risks estimated within specified distances from the source(s) of concern;
- An estimate of population size associated with different risk levels; and/or
- A comparison of the magnitude of the risk estimate to background risks.

Key issues and conclusions should be clearly highlighted in any summary. Exhibit 13-7 identifies several summary products that can facilitate risk communication. (See also Part V of this Reference Manual for a description of various techniques for communicating risk.)

Exhibit 13-7. Summary Products to Facilitate Risk Communication
• **Executive summary** – a summary with some technical detail, for audiences with some technical knowledge (e.g., first line managers). This executive summary may sometimes be the executive summary of the technical risk characterization itself depending on the audience. • **Bulleted list** – a list highlighting the key issues and conclusions culled from the technical risk characterization with little or no technical detail; for audiences with little or no technical knowledge (e.g., higher-level managers, decision makers). • **Briefing packages** – written products that describe key issues and conclusions for managers, decision makers, and other public officials. • **Fact sheets, press releases, and public relations notices** – written products that describe key issues and conclusions for non-technical audiences (e.g., affected or interested public). • **Slide shows, speeches, and talks** – visual presentations (perhaps accompanied by audio presentations) and transcripts of oral presentations of key issues and their context; for mostly non-technical audiences.

13.3.2 Exposure Estimates and Assumptions

For each exposure pathway evaluated in the risk assessment, check that all information needed to characterize exposure is available. For each exposure pathway evaluated, exposure estimates and assumptions should be reviewed to assure the consistency and validity of key assumptions. These assumptions may include, for example, the period of exposure and the modeling assumptions.

The risk characterization section on exposure may summarize the following exposure information:

- Estimated exposures (chronic, subchronic, and shorter-term, as appropriate); and
- Important exposure modeling assumptions, including:
  - Chemical concentration at the exposure points; and
  - Frequency and duration of exposure.

Other items that could be addressed in the risk characterization summary of the exposure assessment include:

- The most significant sources of environmental exposure:
  - Data on sources of exposure from different media (when multimedia analyses are performed);
  - Estimates of the relative contribution of different sources of exposure; and
  - Identification of the most significant environmental pathways for exposure (when multimedia analyses are performed);

- Descriptions of the populations that were assessed, including the general population, highly exposed groups, and highly susceptible groups;

- Description of the basis for the exposure assessment, including any monitoring, modeling, or other analyses of exposure distributions (e.g., probabilistic techniques – see Part VII of this Reference Manual); and

- Key descriptors of exposure:
  - Description and illustration of the (range of) exposures to: "average" individuals, "high-end" individuals, the general population, and special subpopulations such as children and the elderly;
  - Description of how the central tendency estimate was developed, including the factors and/or methods used in developing this estimate;
  - Description of how the high-end estimate was developed;
  - Description of how population estimates of risk were developed; and
  - Description of how any incidence calculations were performed.

13.3.3 Toxicity Estimates and Assumptions

During the risk characterization step, the risk assessor usually reviews whether all toxicity information needed to characterize risk is available. The risk characterization section on toxicity often summarizes the following information:

- IURs for all carcinogenic chemicals;
- Discussion of weight of evidence and classifications for all carcinogenic chemicals;
- Type of human cancer for Class A carcinogens;
- Chronic and subchronic dose-response values and shorter-term (acute) dose-response values (if appropriate) for all chemicals (including carcinogens and developmental toxicants);
- Critical effect associated with each dose-response value;

- Discussion of uncertainties, uncertainty factors, and modifying factors used in deriving each dose-response value and degree of confidence in dose-response values;
- Whether the dose-response values are expressed as absorbed or administered doses (applies primarily to ingestion exposures - See Chapter 22);
- Pharmacokinetic data that may affect the extrapolation from animals to humans for dose-response values; and
- Uncertainties in any route-to-route extrapolation.

13.3.4 Assessment and Presentation of Uncertainty in Risk Characterization

The risk estimates used in air toxics risk assessments usually are not fully probabilistic estimates of risk but conditional estimates given a considerable number of assumptions about exposure and toxicity. Air toxics risk assessments make use of many different kinds of scientific concepts and data (e.g., exposure, toxicity, epidemiology), all of which are used to characterize the expected risk in a particular environmental context. Informed use of reliable scientific information from many different sources is a central feature of the risk assessment process. Reliable information may or may not be available for many aspects of a risk assessment. Scientific uncertainty is inherent in the risk assessment process, and risk managers almost always must make decisions using assessments that are not as definitive in all important areas as would be desirable. Risk assessments also incorporate a variety of professional and science policy judgements (e.g., which models to use, where to locate monitors, which toxicity studies to use as the basis of developing dose-response values). Risk managers therefore need to understand the strengths and the limitations of each assessment, and to communicate this information to all participants and the public.[2] A critical part of the risk characterization process, therefore, is an evaluation of the assumptions and uncertainties inherent in the risk assessment in order to place the risk estimates in proper perspective.

One of the key purposes of uncertainty analysis is to provide an understanding of where the estimate of exposure, dose, or risk is likely to fall within the range of possible values. Often this is expressed as a subjective confidence interval within which there is a high probability that the estimate will fall. A related analysis, termed “sensitivity analysis” or “analysis of uncertainty importance,” is often performed to identify the relative contribution of the uncertainty in a given parameter value (e.g., emission rate, ingestion rate) or model component to the total uncertainty in the exposure or risk estimate.[8] Often this is used either to identify which parameter values should be varied to provide high-end vs. central-tendency risk estimates, or to identify parameter values where additional data collection (or modeling effort) can increase the confidence in the resulting risk estimate.

The Presidential/Congressional Commission on Risk Assessment and Risk Management (CRARM) recommends that risk assessors respect the objective scientific basis of risks and procedures for making inferences in the absence of adequate data.[9] Risk assessors should provide risk managers and other stakeholders with plausible conclusions about risk that can be made on the basis of the available information, along with evaluations of the scientific weight of evidence supporting those conclusions and descriptions of major sources of uncertainty and alternative views.

The risk characterization typically should address the following:

- Considering the hazard and the exposure, what is the nature and likelihood of the health risk?
- Which individuals or groups are at risk? Are some people more likely to be at risk than others?
- How severe are the anticipated adverse impacts or effects?
- Are the effects reversible?
- What scientific evidence supports the conclusions about risk? How strong is the evidence?
- What is uncertain about the nature or magnitude of the risk?
- What is the range of informed views about the nature and probability of the risk?
- How confident are the risk analysts about their predictions of risk?
- What other sources cause the same type of effects or risks?
- What contribution does the particular source make to the overall risk of this kind of effect in the affected community? To the overall health of the community?
- How is the risk distributed in relation to other risks to the community?
- Does the risk have impacts besides those on health or the environment, such as social or cultural consequences?
- The level of detail considered in a risk assessment and included in a risk characterization should be commensurate with the problem's importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.

Risk characterizations should include sufficient information to enable:

- Risk managers to make a useful risk management decision, and
- Stakeholders to understand the importance and context of that decision.

13.3.4.1 Practical Approaches to Uncertainty Assessment

Sources of Uncertainty

- **Scenario uncertainty**. Information to fully define exposure or risk is missing or incomplete
- **Model uncertainty**. Algorithms or assumptions used in models may not adequately represent reality
- **Parameter uncertainty**. Values for model parameters cannot be estimated precisely
- **Decision-rule uncertainty**. Policy and other choices made during the risk assessment may influence risk estimates

There are numerous sources of uncertainties in air toxics risk assessments, and each merits consideration. The degree to which these sources of uncertainty need to be quantified, and the amount of uncertainty that is acceptable, varies considerably on a study-specific basis. For a screening-level (Tier 1) analysis, a high degree of uncertainty is often acceptable, provided that conservative assumptions are used to bias potential error toward protecting human health. The use of conservative assumptions is intended to result in a situation where the risk assessor is confident that the risk estimate is unlikely to be *greater* than the point estimate of risk. In other words, the point estimate of risk is expected to be at the high-end of the range of possible values. The uncertainty characterization for a Tier 1 analysis commonly is limited to a qualitative discussion of the major sources of uncertainty and their potential impact on the risk estimate. At higher tiers of analysis, sensitivity analysis to quantify the impact of varying input parameter values (or model

algorithms) on the risk estimate, or more complete quantitative uncertainty analysis, commonly are performed to more fully describe the range of possible or plausible values.

Practical approaches to the assessment and presentation of the principal sources of uncertainty in risk assessments are summarized below.[10]

Characterize Scenario Uncertainty. There are uncertainties associated with the estimate of the magnitude and extent of chemical exposure or toxicity, the spatial and temporal aggregation of chemical concentrations to calculate the exposure concentration used in the risk characterization, the completeness of the analysis (e.g., important exposure pathways may not have been evaluated), and the manner in which the exposed population and/or exposure scenario were specified for the analysis. Ideally, the key scenario uncertainties have been discussed during planning, scoping, and problem formulation, and the analysis plan has been developed to address these uncertainties. A limited sensitivity analysis (e.g., on key assumptions associated with exposure) may indicate the magnitude of uncertainty associated with specific aspects of the scenario. At a minimum, the analysis of uncertainty should identify the key scenario uncertainties and indicate the potential impact of each on the direction and magnitude of the risk estimate.

Characterize Model Uncertainty. There are uncertainties associated with the selection of scientific models; these include dose-response models, models of environmental fate and transport, and exposure models. There is always some doubt as to how well an exposure model or its mathematical expression approximates the true relationships between site-specific environmental conditions. Ideally one would like to use a fully validated model that accounts for all the known complexities in the parameter interrelationships for each assessment. Often, however, only partially validated models are available. As a consequence, it is important to identify key model assumptions (e.g., linearity, homogeneity, steady-state conditions, equilibrium) and their potential impact on the risk estimates. In the absence of field data for model validation, the risk assessor could perform a limited sensitivity analysis (i.e., vary assumptions about functional relationships) to indicate the magnitude of uncertainty that might be associated with model form. At a minimum, the analysis of uncertainty should list key model assumptions and indicate the potential impact of each on the direction and magnitude of the risk estimate.

Characterize Model Uncertainties

- List/summarize key model assumptions
- Indicate the potential impact of each assumption on the exposure and risk estimate
  - Direction
  - Magnitude

Characterize Parameter Uncertainty. During the course of a risk assessment, numerous parameter values are included in the calculations of chemical fate and transport and human intake. Significant data gaps might have required that certain parameter values be assumed for the risk assessment. For example, no information on the time spent outdoors may be available for a specific population, and a national average may be used instead. Even if data on the parameter of interest are available, they will be uncertain because the parameter estimates are derived from a sample of the potentially exposed population. A first step in characterizing parameter value uncertainty is to identify the key parameters influencing the risk estimate. This usually can be accomplished by expert opinion or by an explicit sensitivity analysis. In a

sensitivity analysis, the values of parameters suspected of driving the risk estimates are varied, and the degree to which changes in the input variables result in changes in the risk estimates are summarized and compared. It may be possible to reduce parameter uncertainty in the most sensitive parameters by additional, selective data gathering.

Characterize Decision-Rule Uncertainty. There are uncertainties associated with policy and other choices made during the risk assessment. For example, the exposure assessment might have evaluated an exposure duration (e.g., a subchronic exposure) for which no appropriate dose-response value was available. Uncertainty would be associated with the choice of value to use in the hazard characterization (e.g., an acute versus chronic value). In this situation, it might be possible to assess hazard twice, once with the acute value, and once with the chronic value, to may indicate the magnitude of uncertainty associated with this decision. At a minimum, the analysis of uncertainty should identify the key decision-rule uncertainties and indicate the potential impact of each on the direction and magnitude of the risk estimate.

Tracking Uncertainty. Ideally, one would like to quantitatively carry through the risk assessment the uncertainty associated with each parameter in order to characterize the uncertainty associated with the final risk estimates. However, this process can be highly complex and resource intensive and the more practical approach for air toxics risk assessments may be to describe qualitatively how the uncertainties might be propagated through the risk analysis. Three different approaches to tracking uncertainty are described below:

- *Qualitative Approach*. This approach involves developing a quantitative or qualitative description of the uncertainty for each parameter and indicating the possible influence of these uncertainties on the final risk estimates given knowledge of the models used.

- *Semi-Quantitative Approach*. This approach involves: (1) using available data to describe the potential range of values that the parameters might assume; (2) performing sensitivity analysis to identify the parameters with the most impact on the risk estimate; and (3) performing sensitivity analysis to compute the range of exposure or risk estimates that result from combinations of minimum and maximum values for some parameters and mid-range values for others.

- *Quantitative Approach*. Probabilistic techniques such as Monte Carlo simulation analysis can explicitly characterize the extent of uncertainty and variability in risk assessment, especially in the exposure assessment step. Using these techniques, important variables in the exposure assessment, as well as in the other parts of the risk assessment, are specified as distributions (rather than as single values) according to what can be expressed about their underlying variability and/or uncertainty. Values are sampled repeatedly from these distributions and combined in the analysis to provide a range of possible outcomes. While this technique can offer a useful summary of complex information, it must be noted that the analysis is only as certain as the underlying data (and assumed forms of the distribution of data values in the population). It is important that the risk assessor clearly expresses individual modeled variables in a way that is consistent with the best information available. Highly quantitative statistical uncertainty analysis is usually not practical or necessary for most air toxics risk assessments. The general quantitative approach to propagating or tracking uncertainty through probabilistic modeling is described in Chapter 31.

13.3.4.2 Presentation of Uncertainty Assessment

The final discussion of the risk characterization results must place the numerical estimates of risk in the context of the uncertainties inherent in the analysis.[2] The discussion should include:

- Level of confidence in the quantitative toxicity information used to estimate risks;
- Presentation of qualitative information on the toxicity of substances not included in the quantitative assessment;
- Level of confidence in the exposure estimates for key exposure pathways and related exposure parameter assumptions;
- Major factors reducing certainty in the results and the significance of these uncertainties (e.g., adding individual risk estimates for several substances or across multiple exposure pathways); and
- Possible graphical presentation of key parameter and risk uncertainties.

13.3.5 Additional Information

Other studies relevant to the risk assessment being performed may be available, such as community health studies or previous risk assessments. For example, the Agency for Toxic Substances and Diseases Registry (ATSDR) may conduct public health assessments, health consultations, and other activities resulting in evaluations, assessments, and recommendations on specific public health issues related to actual or potential human exposure to hazardous materials (see Chapter 30). ATSDR's recommendations may include additional hazard characterization or risk reduction activities. In addition, these activities can initiate other activities within ATSDR such as exposure investigations, health studies, and health education.

If health or exposure studies have been identified and evaluated as adequate, the study findings may be incorporated into the risk characterization to strengthen the conclusions of the risk assessment. In general, a qualitative comparison of the results of available studies will usually be sufficient.

Additional References Related to Uncertainty Analysis

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Information Quality Guidelines

The U.S. Office of Management and Budget (OMB) has directed all federal agencies to develop information quality guidelines for risk-related and other information; EPA has developed draft guidelines pursuant to the OMB directive. While these guidelines do not apply to S/L/T governments, they provide useful principles for developing and communicating the information developed for the risk characterization.

The OMB guidelines denote four substantive qualifiers for information disseminated by federal agencies. **Quality** is defined as the encompassing term, of which utility, objectivity, and integrity are the constituents. **Utility** refers to the usefulness of the information to the intended users. **Objectivity** focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. **Integrity** refers to security – the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

The guidelines provide some basic principles for agencies to consider when developing their own guidelines, including:

- Guidelines should be flexible enough to address all communication media and variety of scope and importance of information products.
- Some agency information may need to meet higher or more specific expectations for objectivity, utility, and integrity.
- Ensuring and maximizing quality, objectivity, utility, and integrity comes at a cost, so agencies should consider using a cost-benefit approach.
- Agencies should adopt a common-sense approach that builds on existing processes and procedures. It is important that agency guidelines do not impose unnecessary administrative burdens.

EPA developed draft information quality guidelines in response to the OMB directive (www.epa.gov/oei/qualityguidelines). EPA's guidelines include two components of particular relevance to air toxics risk management: (1) guidelines to ensure and maximize the quality of "influential" information; and (2) guidelines to ensure and maximize the quality of "influential" scientific risk assessment information.

Source: Office of Management and Budget. 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*. 67 *Federal Register* 36:8451. February 22, 2002 (www.whitehouse.gov/omb/fedreg/reproducible.html).

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PART III

HUMAN HEALTH RISK ASSESSMENT: MULTIPATHWAY

Chapter 14 Overview and Getting Started: Planning and Scoping the Multipathway Risk Assessment

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14.1 Introduction

Part II of this Reference Manual discussed how to plan for and conduct a human health risk assessment via the direct inhalation pathway. Part III provides the same general discussion of the various aspects of the risk assessment process; however, the discussion is focused specifically on multipathway human health risk assessment. ***As noted earlier, all air toxics risk assessments evaluate the direct inhalation pathway. In addition, multipathway risk assessment may be appropriate generally when air toxics that persist and which also may bioaccumulate and/or biomagnify are present in releases. These generally will focus on the persistent bioaccumulative hazardous air pollutant (PB-HAP) compounds (Exhibit 14-1), but specific risk assessments may need to consider additional chemicals that persist and which also may bioaccumulate and/or biomagnify***. For these compounds, the risk assessment generally will need to consider exposure pathways other than inhalation – in particular, pathways that involve deposition of air toxics onto soil and plants and into water, subsequent uptake by biota, and potential human exposures via consumption of contaminated soils, surface waters, and foods. Substances that persist and bioaccumulate readily transfer between the air, water, and land. Some may travel great distances, and linger for long periods of time in the environment.

The discussion of multipathway risk assessment follows the same general framework presented in Part II. This chapter presents an overview of multipathway risk assessment and discusses the initial planning, scoping and problem formulation activities. The remaining chapters of this Part focus on Exposure Assessment (Chapters 14 to 20), Toxicity Assessment (Chapter 21), and Risk Characterization (Chapter 22). The discussions presented here supplement the information provided earlier – readers are encouraged to refer back to the corresponding Chapters in Part II for additional background materials.

Bioconcentration is the net accumulation of a substance by an organism as a result of uptake directly from an environmental medium (e.g., net accumulation by an aquatic organism as a result of uptake directly from ambient water, through gill membranes or other external body surfaces).

Bioaccumulation is the net accumulation (storage in tissue and/or organs) of a substance by an organism as a result of uptake from all environmental sources – the medium in which they live, the water they drink, and the diet they consume – over a period of time.

Biomagnification or Biological Magnification is the process whereby certain substances, such as pesticides or heavy metals, transfer up the food chain and increase in concentration. A biomagnifying chemical deposited in rivers or lakes absorbs to algae, which are ingested by aquatic organisms, such as small fish, which are in turn eaten by larger fish, fish-eating birds, terrestrial wildlife, or humans. The chemical tends to accumulates to higher concentration levels with each successive food chain level. Biomagnification is illustrated in Chapter 23.

Exhibit 14-1. PB-HAP Compounds			
PB-HAP Compound	**Pollution Prevention Priority PBTs**	**Great Waters Pollutants of Concern**	**TRI PBT Chemicals**
Cadmium compounds		X	
Chlordane	X	X	X
Chlorinated dibenzodioxins and furans	X[a]	X	X[b]
DDE	X	X	
Heptachlor			X
Hexachlorobenzene	X	X	X
Hexachlorocyclohexane (all isomers)		X	
Lead compounds	X[©]	X	X
Mercury compounds	X	X	X
Methoxychlor			X
Polychlorinated biphenyls	X	X	X
Polycyclic organic matter	X[d]	X	X[e]
Toxaphene	X	X	X
Trifluralin			X

[a] "Dioxins and furans" ("" denotes the phraseology of the source list)
[b] "Dioxin and dioxin-like compounds"
[c] Alkyl lead
[d] Benzo[a]pyrene
[e] "Polycyclic aromatic compounds" and benzo[g,h,i]perylene
See Appendix D for a discussion of the derivation of this list of PB-HAPs.

14.2 Overview of Multipathway Air Toxics Risk Assessment

The multipathway risk assessment is organized in the same way as the direct inhalation risk assessment into three general phases:

1. Planning, scoping, and problem formulation;
2. Analysis, consisting of exposure assessment and toxicity assessment; and
3. Risk characterization.

14.2.1 Planning, Scoping, and Problem Formulation

The planning, scoping, and problem formulation phase of multimedia risk assessment focuses on developing a common understanding of what needs to be added to the risk assessment (beyond the direct inhalation assessment) to assess risks associated with pathways involving deposition (i.e., transfer of the compounds to soil, water, sediment, and biota) and subsequent ingestion exposure. The scope of the multimedia risk assessment generally is more extensive than that for inhalation assessment, and therefore significant additional effort is likely.

For purposes of this Reference Manual, we discuss planning, scoping, and problem formulation for multipathway human health risk assessment separately from the corresponding phase for inhalation risk assessment. In reality, the planning, scoping, and problem formulation phase for the multipathway assessment would be integrated with the inhalation analysis as early as feasible.

It may be necessary to include on the **planning and scoping team** experts in multimedia modeling, bioaccumulation, human exposure factors, and ingestion toxicology. The focus on additional exposure pathways may influence many aspects of the risk assessment, including the size of the study area; emission sources to be considered; the temporal and spatial resolution required; the appropriate level of detail and documentation; trade-offs between depth and breadth in the analysis; QA/QC requirements; analytical approaches to be used; and the staff and monetary resources to commit. The **study-specific conceptual model** would also reflect the specific concerns of air toxics that persist and which also may bioaccumulate. As with the inhalation risk assessment, the planning, scoping, and problem formulation process is an iterative process that reflects changing information and concerns as the multimedia risk assessment unfolds.

The reader should become familiar with Part II of this manual before reading this Part, since Part III focuses primarily on those aspects of the risk assessment that are unique to multipathway analyses, including:

- How the study area is defined;
- Potentially exposed populations;
- Exposure pathways and exposure routes;
- How exposure is assessed;
- Dose-response values for non-inhalation pathways; and
- How risks are characterized.

14.2.2 Analysis

The analysis phase of the multipathway assessment is divided into two components: exposure assessment and toxicity assessment. **Exposure assessment** is likely to be considerably more complicated than the corresponding inhalation exposure assessment for several reasons:

- People can be exposed to air toxics in many more ways, including in the food they eat, the milk they drink, and the soils on which they play.

- Time is a critical variable. Air toxics that persist and which also may bioaccumulate can slowly build up in soils, sediments, and biota over time. With sufficient time, even relatively small releases have the potential to result in high exposures.

- The spatial distribution of the air toxics can be complex. Chemicals can move away from deposition points due to runoff, erosion, and the movement of contaminated animals. Chemicals deposited over a wide area (e.g., a watershed) can concentrate in smaller areas (e.g., a pond).

- Multimedia models often use more extensive input variables.

- Sampling and analysis may involve a wider range of media (e.g., soil, sediment) and different types of biota (e.g., fish, shellfish, plants). Each type of sampling and analysis has its own methods, protocols, and QA/QC procedures.

- Whereas the exposure concentration in air is the quantitative metric of exposure for inhalation, intake is the quantitative metric of ingestion exposure in multipathway analyses. To quantify intake, it is necessary to (1) estimate the concentrations of chemicals of potential concern (COPC) in water, soil, sediment, and/or food items; (2) determine how much water, soil, sediment, and food are ingested; (3) determine the duration and temporal patterns over which ingestion occurs; and (4) adjust for body weight, to account for the different types of people in the population who interact with the contaminated media. Multimedia exposure assessment uses a number of different **exposure factors** that provide quantitative estimates of the physical and behavioral attributes of potentially exposed populations (e.g., how much fish a person eats per day). Exposure factors can be treated as either constants or variables in the exposure assessment, depending on whether a deterministic or probabilistic analysis is being performed.

The multipathway **toxicity assessment** is similar to the toxicity assessment for inhalation. It considers the same general information: (1) the types of potential adverse health effects associated with chemical exposures; (2) dose-response relationships; and (3) related uncertainties such as the weight of evidence for carcinogenic effects. There are two primary differences:

- A chemical's toxicity is influenced by the route of exposure. That is, the same chemical can result in different toxic effects (and have different dose-response values) depending on whether the chemical is inhaled or ingested. There are a number of reasons why this may occur. For example, when a chemical is inhaled into the respiratory tract, the primary toxic effect may occur in the respiratory tract as a result of the inhaled chemical (a portal of entry effect). When swallowed, on the other hand, many chemicals are absorbed into the

bloodstream through the gastrointestinal tract where they are carried directly to the liver. Chemicals in the liver are often metabolized extensively (either to more or less toxic substances) before being transported by the bloodstream to other parts of the body.

- The specific dose-response values used for the ingestion pathway – reference doses (RfDs) for non-cancer effects and oral cancer slope factors (CSFs) – differ in form and derivation from those used for inhalation assessments. Specifically, RfDs and CSFs are developed to match the metric of exposure for ingestion and are expressed (usually) in terms of amount of chemical ingested per unit of body weight per day (i.e., mg/kg-d for RfDs) and risk per amount of chemical ingested per unit body weight per day (i.e., $(mg/kg\text{-}d)^{-1}$ for CSFs).

14.2.3 Risk Characterization

The risk characterization for multipathway assessments also may be more complicated than that for the inhalation risk assessment.

- Ingestion risk estimates are first added across all ingestion pathways and then added to inhalation risk estimates to calculate total (i.e., cumulative) risk. Although the summation process is relatively simple for screening-level analyses, it can become complex for more advanced tiers of risk assessment.

- The uncertainty analysis for multipathway risk assessments may be considerably more complex if multiple pathways are important because many more exposure factors and variables will be involved in the quantification of risk. As noted earlier, many more specific exposure factors can be treated as variables for probabilistic multipathway risk assessments.

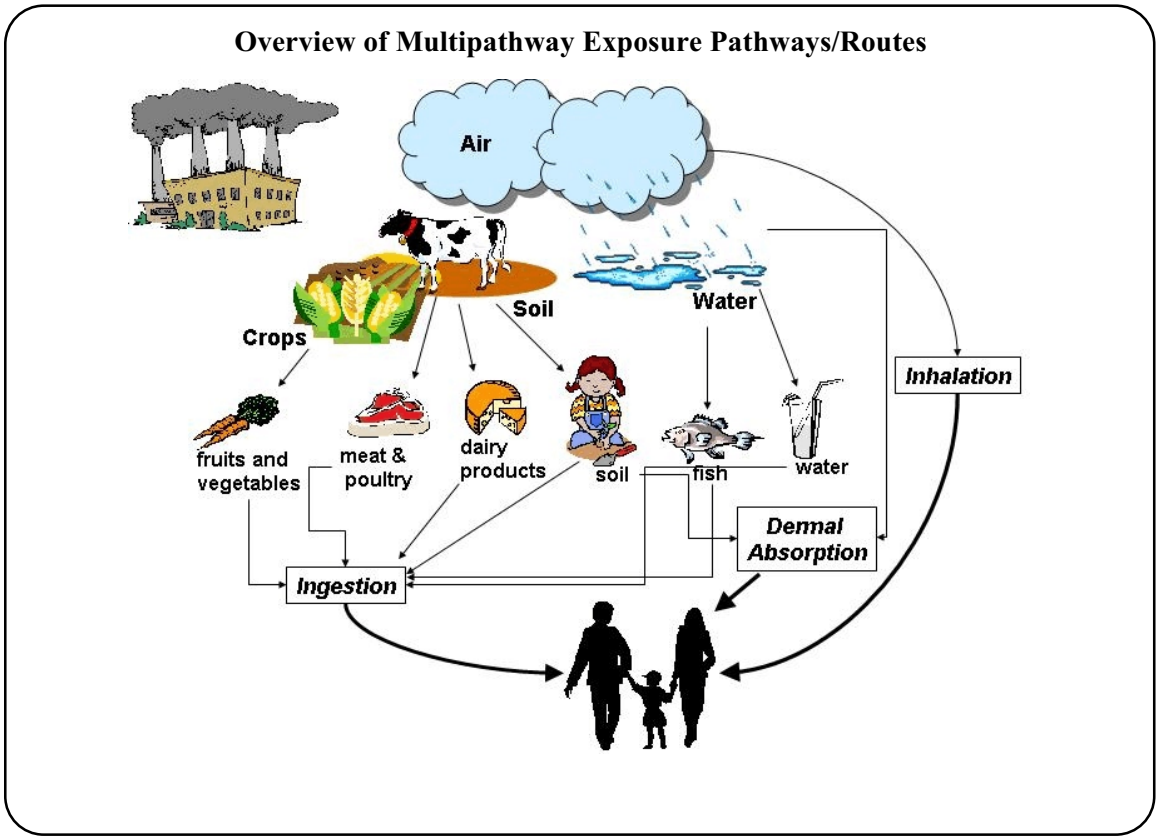
- The uncertainty analysis for multipathway analysis is also much more complex due to the larger number of pathways assessed and the larger number of measurement and modeling inputs that are needed.

14.3 Overview of Multipathway Exposure Assessment

As with inhalation risk assessments, the exposure assessment for multipathway risk assessments includes identifying sources, characterizing releases to the air, estimating concentrations of air toxics in the environment, characterizing potentially exposed populations, and developing metrics of exposure. This section provides an overview of exposure assessment for multipathway risk assessments. Familiarity with EPA's *Guidelines for Exposure Assessment*[1] prior to beginning the multipathway exposure assessment would be helpful.

The multipathway exposure assessment covers a broader scope and may be more complex than direct inhalation exposure assessment.

- Exposure pathways to be evaluated include multiple media (soil, water, sediment, biota) and exposure routes in addition to inhalation (e.g., ingestion). Therefore, the exposure setting may need additional characterization (e.g., the location and nature of water bodies and/or agricultural crops).



- The evaluation of chemical fate and transport accounts for the transfer of contaminants from air to soil and water and subsequent transport and transfer to other media. For example, air toxics that persist and which also may bioaccumulate are deposited onto soils and can enter surface waters via runoff; some of the compounds that deposit into water predominantly partition into sediments. **Bioaccumulation** – a concentration of contaminants in biological tissues – and subsequent transfer to humans via ingestion often play a major role in the exposure assessment. Multimedia models can be used to describe contaminant fate and transport through the use of partition coefficients and mass-balance techniques (see Chapter 6). Different monitoring methods (e.g., sediment or fish tissue sampling and analysis) may be included to augment or assist in the evaluation of modeling outputs.

- In contrast to the direct inhalation assessment, in which the quantitative metric of exposure is the ambient air concentration at the exposure point, ingestion exposures are quantified using the **chemical intake rate** – the amount of chemical ingested per unit time – generally expressed in units of milligrams of chemical per kilogram of body weight per day. Calculation of chemical intake rate requires information on COPC concentrations in items ingested as well as information about the type and amount of different items eaten each day, body weight, and exposure durations for the sub-populations of interest. **Intake rate** is simply the amount of food (or other media), containing the contaminant of interest, that an individual ingests during some specific time period (units of mass/time). Intake rate can be expressed as a total amount (e.g., mg); as a dose rate (e.g., mg/day); or as a rate normalized to body mass (e.g., mg/kg-day). For most chemicals, the dose-response value (e.g., reference dose, or RfD) is based on the potential dose (i.e., the amount of chemical taken in), with no

explicit correction for the fraction absorbed. For some chemicals, it may be necessary to adjust for such differences using physiologically based pharmacokinetic (PB-PK) models, mathematical dosimetry models, and/or adjustment factors (see Chapter 8).

Because exposure is quantified using chemical intake rate, different types of people within a population (e.g., childhood exposures) may need to be considered explicitly. Consumption rates, dietary preferences, and body weight vary with age and would be accounted for in the risk assessment. (Note that not only age, but sex, ethnicity, cultural and religious practices may also strongly influence the exposure patterns of people within a potentially exposed population.)

Although it is possible to evaluate acute exposures for the ingestion pathway, EPA does not generally perform acute exposure assessments, because it is unlikely that PB-HAP compounds would concentrate to acutely toxic levels under any typical release scenario that did not pose a much more substantial chronic risk. However, each assessment would consider the available evidence in making this judgement. At a minimum, the risk characterization would state the reasons why an analysis of acute health effects for non-inhalation pathways was not performed.

The multipathway exposure assessment focuses on two general categories of ingestion pathways: incidental ingestion and food chain (Exhibit 14-2). Incidental ingestion pathways consider exposures that may occur from ingestion of soils or surface water while an individual is engaged in other activities (e.g., ingestion of soil while gardening or playing outside; ingestion of surface water while swimming). Food chain pathways consider exposures that may occur if PB-HAP compounds accumulate in the food and water people consume.

Exhibit 14-2. Human Exposure Pathways Considered for Multipathway Air Toxics Assessments

Incidental Ingestion Pathways:

air → soil → human
air → surface water → human

Food Chain Pathways:

air → water → human
air → soil → water → human
air → vegetation → human
air → animal → human
air → vegetation → animal → human
air → soil → vegetation → human
air → soil → animal → human
air → soil → water → animal → human
air → soil → water → fish → human
air → soil → water → sediment → fish → human
air → water → animal → human
air → water → fish → human
air → water → sediment → fish → human

As Exhibit 14-2 suggests, the focus of the multipathway assessment is on ingestion pathways. Other exposure pathways may be important for particular risk assessments, including dermal exposures (i.e., direct contact with contaminated soils, surface waters, or surface water sediments during outside activities such as gardening or swimming); resuspension of dust (e.g., from wind blowing across contaminated soils, or agricultural activities such as tilling) and subsequent inhalation of the dust particles; and ingestion of contaminated groundwater. However, EPA does not have sufficient experience with multipathway air toxics risk assessments to identify the circumstances for which exposures via these additional pathways may represent a potential concern.

- If site-specific circumstances suggest that dermal pathways may be of concern, EPA's *Risk Assessment Guidance for Superfund (RAGS), Part D, Standardized Planning, Reporting and Review of Superfund Risk Assessments*,[2] includes a relatively straightforward methodology for dermal exposure and risk assessment, starting with soil concentrations. The Planning Tables in the document are simple to use and incorporate into the multipathway analysis.

- Relative to the direct inhalation pathway, inhalation of soil resulting from dust resuspension by wind erosion generally is not thought to be a significant pathway of concern for air toxics risk assessments. If site-specific circumstances suggest that resuspension of dust may represent a potential concern, EPA's *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combuster Emissions* (MPE) (Chapter 5 Dust Resuspension) discusses the methods for evaluating this pathway.[3]

Analysis of Groundwater Pathways

EPA's Office of Solid Waste has considerable experience in modeling and monitoring the movement of contaminants in groundwater. Much of that experience is based on exposure assessments associated with land-based disposal units (i.e., where the source of contamination is in the subsurface). For example, EPA's Center for Exposure Assessment Modeling (CEAM) distributes multimedia models designed to quantify the movement and concentration of contaminants (from land-based releases at hazardous waste sites) traveling through groundwater, surface water, and food chain media (available at http://www.epa.gov/ceampubl/). In these models, releases to the atmosphere from the subsurface may be considered, but transfer from the air through the subsurface are not.

EPA does not have sufficent experience with air toxics multipathway analysis to identify situations in which the groundwater may be contaminated. EPA's *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure*[3] identifies three site-specific conditions that might lead to greater groundwater impacts:

- Deposition rates that are several times greater than the average;
- The existence of more soluble HAPs in emissions; and
- Higher recharge rates such as would occur in areas with very permeable soil and bedrock near the surface.

- If site-specific circumstances suggest that groundwater may represent a potential concern (e.g., the presence of extremely shallow aquifers used for drinking water purposes or a karst environment in which the local surface water significantly affects the quality of ground water used as a drinking water source), Total Risk Integrated Methodology - Fate, Transport, and

Ecological Exposure Module (TRIM.FaTE) has the ability to assess chemicals moving into the groundwater pathway. EPA's *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*[3] and EPA's *Draft Technical Background Document for Soil Screening Guidance* discusses methods for evaluating the groundwater pathway.

14.4 Planning and Scoping

As with inhalation analyses, the key steps in the planning and scoping process include (1) identifying the concern; (2) identifying who will be involved; (3) determining the scope of the risk assessment; (4) describing why there may be a problem; and (5) determining how the concern will be evaluated. The planning and scoping process for multipathway risk assessment focuses on developing a common understanding of what needs to be evaluated to assess risks via deposition and transfer of the air toxics to soil, water, and biota, and subsequent ingestion. More detailed discussions of the planning and scoping process can be found in Part II of this Volume and in guidance documents developed by EPA.[4]

14.4.1 Identifying the Concern

The driving concern for the multipathway risk assessment generally would be the same as that for the inhalation risk assessment (e.g., regulatory requirement, community need, health concern). However, a number of additional specific concerns may arise. For example, the potential for bioaccumulation in food and subsequent ingestion may raise specific concerns about areas where people farm, economic issues such as recreational fishing, or additional exposure pathways of potential concern (e.g., infants ingesting mother's milk).

14.4.2 Identifying the Participants

The participants for the multipathway risk assessment generally would be the same as those for the inhalation risk assessment. However,

- A broader range of risk managers would be involved. For example, if there is a potential for a fishery or farm crops to become contaminated with air toxics, different persons or groups may have the authority to make the risk management decisions – the state, local, or tribal (S/L/T) fish and game department or the agriculture department may become involved.

- The risk assessment technical team would include additional experts (e.g., in the areas of multimedia modeling, bioaccumulation, soil chemistry).

- The specific set of interested or affected parties may change or expand (e.g., farmers and fishermen may be more concerned/involved).

14.4.3 Determining the Scope of the Risk Assessment

At a minimum, the scope of the risk assessment will include additional exposure pathways, exposure routes, and potentially exposed populations or sub-populations. The details of scope are developed during the problem formulation step (see Chapter 15).

14.4.4 Describing the Problem

As with inhalation, participants would develop a **problem statement** that clearly articulates the perceived problem to be evaluated. The problem statement may also provide statements of what is and is not included in the multipathway risk assessment and why. (Note that, in general, only one problem statement is necessary to describe all exposure pathways, including inhalation. A separate problem statement for each exposure pathway is not usually necessary.)

14.4.5 Determining How Risk Managers Will Evaluate the Concern

As with inhalation, the multipathway risk assessment would be designed to provide input to risk managers to help inform the decisions they must make. Part of the planning and scoping process is developing an understanding of the types of information needed by the risk managers and the level of uncertainty in that information that can be tolerated.

Example Multipathway Problem Statement

Air toxics emissions may be causing increased long-term health risk to people who eat fish in Puffer Pond that may be contaminated with mercury compound releases from the Big Air Manufacturing Company. A multipathway risk assessment will be performed to evaluate potential long-term human health impacts associated with consumption of contaminated fish. Ingestion risks will be assessed for recreational fishers who eat fish caught in Puffer Pond. In addition, a modeling risk assessment using air dispersion modeling will be conducted to estimate inhalation risks for populations within 50 km of the Acme property boundary using residential exposure conditions.

14.5 Tiered Multipathway Risk Assessments

EPA guidance generally recommends that a tiered approach to risk assessments be taken to identify the key chemicals, sources, and pathways that contribute most to the risk being evaluated.[5] A tiered approach can be particularly valuable for multipathway risk assessments because of the potential complexity commonly associated with such analyses. Often, screening-level analyses assume relatively high exposure factors (e.g., all of the fish a person eats comes from a potentially contaminated pond) to determine whether risk associated with a specific pathway appears to be significant enough to warrant more robust analysis. Subsequent tiers of analysis, using more realistic exposure factors and perhaps involving more complex modeling and perhaps sampling and analysis, are generally undertaken only if lower-tier analyses continue to indicate the potential for risk. As with inhalation risk assessments, an iterative process of evaluation, deliberation, data collection, work planning and communication is used to decide:

- Whether or not the risk assessment, in its current state, is sufficient to support the risk management decision(s); and

- If the assessment is determined to be insufficient, whether or not progression to a higher tier of complexity (or refinement of the current tier) would provide a sufficient benefit to warrant the additional effort.

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Chapter 15 Problem Formulation: Multipathway Risk Assessment

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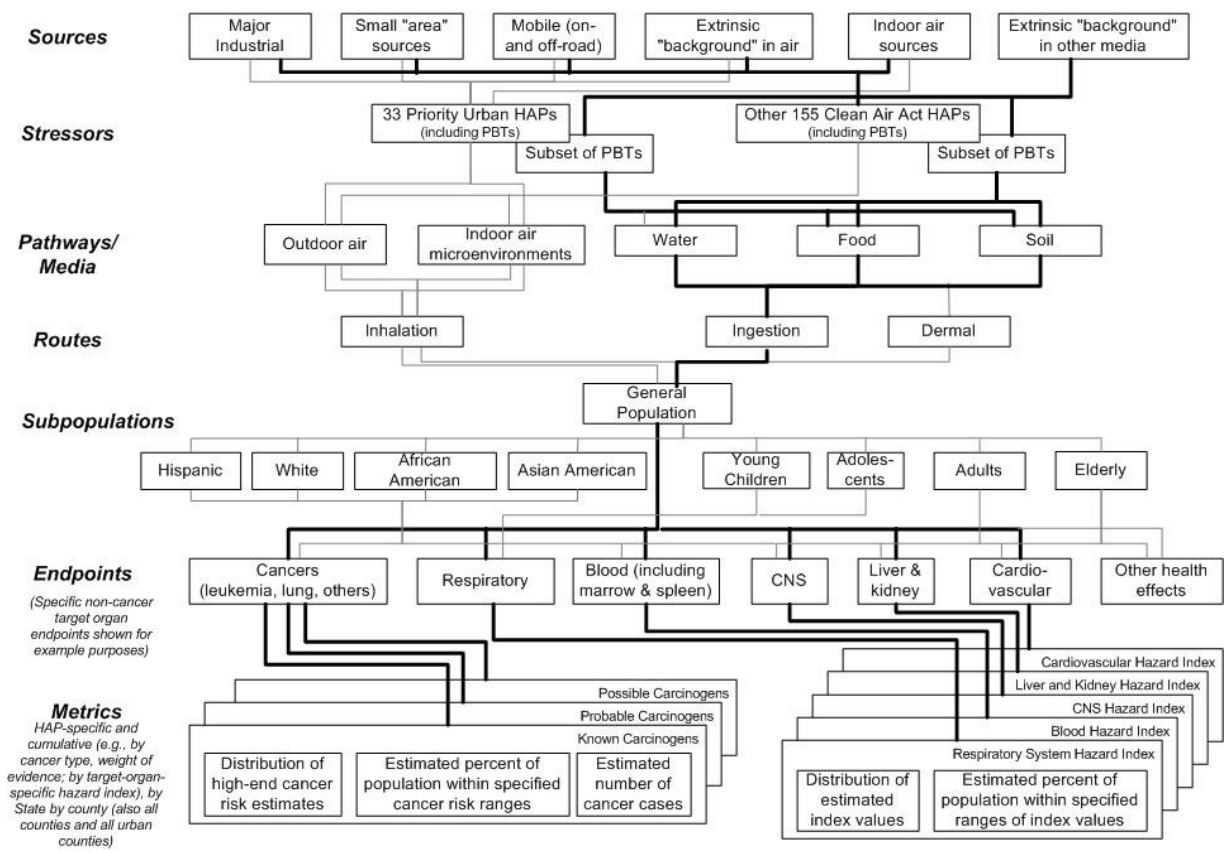
15.1 Introduction

This chapter discusses the problem formulation step of the multipathway risk assessment, which takes the results of the planning and scoping process and translates them into two critical products: the conceptual model, and the analysis plan.

15.2 Developing the Multipathway Conceptual Model

As with inhalation analyses, the conceptual model (Exhibit 15-1) focuses the multipathway risk assessment on several key elements, including sources, chemicals released, fate and transport mechanisms, potentially exposed populations, potential exposure pathways and routes of exposure, and potential adverse effects. Although discussed separately here, as noted in Chapter 6, ***the elements of the conceptual model that are unique to the multipathway human health risk assessment should be integrated with those for the inhalation assessment as early as feasible***.

Exhibit 15-1. Generalized Conceptual Model for Multipathway Analyses



This figure highlights the multipathway components of the general air toxics risk assessment conceptual model introduced in Chapter 6. The conceptual model for a specific multipathway risk assessment may consider only part of this general model, or may focus more closely on specific sub-populations of concern.

Elements of the conceptual model that may be unique to the multipathway assessment include:

- **Sources**. The specific sources included in the analysis may be focused on the subset of all sources that release most or all of the identified air toxics that persist and which also may bioaccumulate.

- **Chemicals of potential concern**. The specific COPC will focus on those air toxics that persist and which also may bioaccumulate (i.e., persistent bioaccumulative hazardous air pollutants (PB-HAPs) and other non-HAP chemicals that may be of concern for persistence and bioaccumulation).

- **How the COPC move through the environment**. The conceptual model will need to consider the mechanisms by which PB-HAPs move through the environment, which include dispersion in the air; deposition (including vapor phase transfer) to soils, surface waters, and plant surfaces; erosion and other runoff phenomena; and uptake and bioconcentration by biota. The physical boundaries of the study area may need to include geographic areas where COPC may be transported after deposition (e.g., PB-HAPs may have the potential to be deposited in a watershed and be carried out of the geographic area defined for the inhalation pathway modeling).

- **The exposure pathways/media of concern**. The potential exposure pathways will include a number of different ingestion pathways and, in some cases, dermal absorption pathways.

- **The human populations potentially receiving exposure**. The potentially exposed populations may need to include persons who do not live within the study area but consume food products that have the potential to become contaminated (e.g., recreational fisher). Additionally, different sensitive sub-populations may be identified (e.g., people who consume large amounts of locally-caught fish because of cultural reasons).

- **The potential adverse health effects (endpoints) that may result from exposure**. The general types of chronic health risks (cancer, non-cancer) may or may not change, depending on the specific COPC being evaluated. However, acute exposures generally are not a concern for multipathway analyses because it would be unlikely for air toxics to accumulate in soil, sediment, or food items to concentrations that would pose, in the absence of a chronic hazard, an acute hazard through the ingestion or dermal pathway.

- **Metrics**. The metrics used to characterize exposure and estimate risk may or may not be different from those used in the inhalation risk assessment. For example, the inhalation assessment may stop at a Tier 1 analysis, while the multipathway assessment may go all the way to a Tier 3 analysis.

15.3 Developing the Multipathway Analysis Plan

As noted in Chapter 6, the analysis plan matches each element of the conceptual model with the analytical approach that the assessor will use to develop data about that element. This section describes the elements of the analysis plan that are unique to the multipathway assessment, including (1) identification of sources; (2) identification of COPC; (3); identification of exposure

pathways/routes; (4) identification of exposed populations; and (5) identification of endpoints and metrics.

15.3.1 Identification of the Sources

This part of the analysis plan identifies the sources to be included in the risk assessment. As noted earlier, the focus of multipathway analysis is on sources of the air toxics that persist and which also may bioaccumulate. Within that subset, certain sources may be most important for a specific risk assessment. A tiered approach is recommended for focusing the risk assessment from the initial set of sources to the sources that will drive risk management decisions. The initial tier of analysis generally includes all sources of PB-HAPs. In subsequent tiers of analysis, it may be possible to remove specific sources from the analysis that contribute a very small fraction to the total risk estimate.

15.3.2 Identification of the Chemicals of Potential Concern

This part of the analysis plan identifies the chemicals that will be evaluated in the risk assessment. As noted earlier, the focus of multipathway analysis is on the subset of air toxics that persist and which may also bioaccumulate. Within that subset, certain chemicals may be most important for a specific risk assessment. A tiered approach is recommended for focusing the risk assessment from the initial list of COPC to the set of contaminants that will drive risk management decisions. The initial tier of analysis generally includes all of the air toxics released from the identified important sources. In subsequent tiers of analysis, it may be possible to remove specific chemicals from the analysis if they contribute a very small fraction to the total risk estimate.

15.3.3 Identification of the Exposure Pathways/Routes

This part of the analysis plan identifies the exposure pathways/routes to be evaluated. As noted in Chapter 6, an exposure pathway consists of four elements:

- A source and mechanism of chemical release;
- One or more environmental media (i.e., air, water, soil) in which the chemical is transported from the source;
- A point of potential human contact with the contaminated medium (referred to as the exposure point); and
- An exposure route (e.g., inhalation, ingestion) at the contact or exposure point. The route may be actual or potential, depending on the purpose of the assessment.

The exposure pathway is complete if all four elements can be identified; otherwise the exposure pathway is incomplete and not considered further (see Exhibit 14-2, which presents the potential exposure pathways considered for multipathway assessments).

The exposure points selected for the multipathway risk assessment also will depend on the choice of multipathway assessment approach and may or may not be identical to those used in the inhalation risk assessment. In the example presented in Chapter 11, Mr. McDonald's house was selected as the point of maximum inhalation concentration at a receptor location. The multipathway assessment would likely also evaluate potential exposures via crops, meat, milk,

and other foods. However, the focus would be on other exposure points or areas within the farm (e.g., the area where forage fed to dairy cows is grown or where vegetable crops are planted), not on the farmer's house.

15.3.3.1 Characteristics of the Assessment Area

The physical setting is important both in developing the study-specific conceptual model and selecting and providing input parameters for the appropriate multimedia models. As described earlier, the physical setting includes information such as urban vs. rural setting, simple vs. complex terrain, climate and meteorology, and other important geographic features (see Chapter 6). The most important additional information required for multipathway analyses is information on land use, soils, and surface water bodies within the assessment area.[(a)] Many of the general physical characteristics of the setting will influence the scope of multimedia modeling required. For example, if the sources being evaluated are located in heavily industrialized area, there may be few, if any, agricultural areas or water bodies close enough to receive significant deposition. In this example, deposition to soils in nearby residential areas and subsequent exposure pathways may be the most significant exposure pathways to examine.

- **Land use**. Information on land use is an important part of the physical characteristics of the assessment area discussed in Chapter 6. For multipathway analyses, it is important to identify specific types of land uses that may lead to exposures via ingestion pathways, especially agriculture, fishing, recreation, and residential (indoor and outdoor, including gardening), as well as the location of particular areas where exposures via soil may be of concern (e.g., playgrounds, schools, day care centers). Sources for land use data are discussed in Chapter 6.

- **Soils**. The type and characteristics of soils (e.g., sandy, organic, acidic, alkaline) in the assessment area affects physical phenomena such as soil erosion rates, the types and density of plants supported by the soils, and the physical and chemical characteristics that govern contaminant fate and transport. For example, the bioavailability of a compound may depend partially on soil pH. The specific information needed will depend in part on the input requirements of the multimedia fate and transport models selected for the analysis (see Chapter 19).[(b)]

- **Water bodies and their associated watersheds**. Water bodies and their associated watersheds are important factors in evaluating some of the major exposure pathways/routes considered in multipathway analyses. For example, the identification of surface water bodies at locations in the assessment area receiving deposition from emission sources indicates the potential for exposures to contaminants from ingestion of fish, and possibly drinking water (drinking water is usually evaluated only if the local population obtains drinking water from

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[a]Maps, aerial photos, and tools such as Geographic Information Systems (GIS) can be very helpful tools for characterizing the exposure setting (see Part VI of this Reference Manual).

[b]Sources of this information may include any existing site descriptions, preliminary risk assessments, county soil surveys, wetlands maps, aerial photographs, U.S. Geological Survey topographic maps, U.S. Department of Agriculture Soil Conservation Service reports, and information from state natural resources agencies.

surface water sources).[c] Information on fishing activity will also be useful in characterizing the potentially exposed population.

Land use and human activities should be characterized in much the same way as Chapter 6 described, except that a broader range of activities/uses needs to be considered. It is important to identify all activities within the assessment area that could result in exposure to contaminants via non-inhalation pathways. These would include hunting, fishing, growing crops (e.g., commercially, as animal feed, or for private consumption), and incidental ingestion of soils. As noted earlier, the multipathway assessment may need to specifically address special populations that are located in impacted areas because of unique characteristics of the exposure setting or to address particular community concerns. For example, a day care center or traditional Tribal fishing/hunting area may be located in an area that is impacted by releases from a facility or source area. Consequently, due to the site-specific exposure characteristics, exposure to children at the day care center or tribal members may need to be addressed, because they may be especially sensitive to the adverse effects and/or the exposure setting may be particularly conducive to exposure. EPA has developed a policy focused on consistently and explicitly evaluating environmental health risks to infants and children in all risk assessments.[1]

15.3.3.2 Scale of the Assessment Area

For inhalation assessments, the study area generally is limited to a 50-km radius from the emissions sources (based on the dispersion models being used). The study area for the multipathway risk assessment generally will be limited similarly to the area in which deposition is modeled. However, certain potential exposure scenarios may require expansion of the study area beyond the modeled deposition area. Examples include:

- The watershed for a lake or pond is within the modeled deposition area, but the lake or pond (where contaminants may accumulate) is outside the deposition area.
- A commercial farm is within the deposition area, and a portion of the crops are consumed by persons living outside the deposition area.
- A popular fishing area is located within the deposition area, and people from outside the deposition area come there to fish.

15.3.3.3 Use of Modeling vs. Monitoring

As this document has previously noted, risk assessors can base estimates of current exposure concentrations on either actual

Multimedia Assessments: Modeling vs. Monitoring

Most multimedia air toxics risk assessments will develop estimates of exposure concentration for non-inhalation pathways primarily through modeling. In some instances, analysts may use monitoring to evaluate the model. In more rare instances, however, analysts will use monitoring to develop exposure concentrations.

[c] Use, area, and location of water bodies and their associated watersheds can typically be identified by reviewing the same land-use land classification maps, topographic maps, and aerial photographs used in identification of land use discussed in Part II of this Reference Manual. Additional information on water body use can also be obtained through discussions with local authorities (e.g., state environmental agencies, fish and wildlife agencies, or local water control districts) about viability to support fish populations and drinking water sources, or current postings of fish advisories.

measurements (i.e., monitoring data) or modeling (in this case, multimedia models). In many cases, monitoring can be helpful in reducing uncertainties in the exposure assessment, because multimedia modeling is more complex and involves more uncertainties. Note, however, that the scope of potential monitoring for multipathway analysis is considerably greater than that for inhalation analyses. A wide range of types of sampling and analysis could be conducted, including sampling of soils, surface waters, sediments, and biota (human food items). Each type of sample has its own methods, protocols, and QA/QC requirements (see Chapter 19). Multimedia sampling and analysis may require additional expertise and effort. The analysis plan, including the quality assurance protection plan (QAPP), will need to be modified accordingly.

15.3.3.4 Quantitation of Exposure

In contrast to the inhalation assessment, in which the quantitative metric of exposure is the ambient air concentration at the exposure point, ingestion exposures are quantified using the **chemical intake rate** – the amount of chemical ingested per unit time – generally expressed in units of milligrams of chemical per kilogram of body weight per day. The fundamental equation for dietary intake and ingestion pathways in general is given as:

$$I = \frac{EC \times CR}{BW} \times \frac{EF \times ED}{AT} \qquad \text{(Equation 15-1)}$$

where

I = Chemical intake rate, expressed in units of mg/kg-day. For evaluating exposure to non-carcinogens, the intake is referred to as average daily dose (*ADD*); for evaluating exposure to carcinogenic compounds, the intake is referred to as lifetime average daily dose (*LADD*).

EC = Exposure concentration of the chemical in the medium of concern for the time period being analyzed, expressed in units of mg/kg for soil and food or mg/L for surface water or beverages (including milk).

CR = Consumption rate, the amount of contaminated medium consumed per unit of time, event, or other measure. (e.g., kg/day for soil and food; L/day for water).

EF = Exposure frequency (number of days exposed per year).

ED = Exposure duration (number of years exposed).

BW = Average body weight of the receptor over the exposure period (kg).

AT = Averaging time, the period over which exposure is averaged (days). For carcinogens, the averaging time is usually 25,550 days, based on an assumed lifetime exposure of 70 years; for non-carcinogens, averaging time equals *ED* (years) multiplied by 365 days per year.

As noted above, modeling and/or monitoring (sampling and analysis) can be used to determine the exposure concentration (EC) at specified exposure points. However, a variety of approaches and assumptions can be used to determine the remaining variables in the equation, as will be discussed in subsequent chapters. For example, calculation of the intake rate requires assumptions about diet (i.e., how much the exposed individual eats and drinks each day) and body weight (how much the individual weighs). Dietary assumptions need to be specific to the type of food consumed (e.g., fish, milk, beef).

As noted in Section 6.3.3.4, the exposure duration (ED) used to calculate chemical intake rate (I) will have an impact on the choice of toxicity values (e.g., acute vs. chronic) used to characterize risk and hazard. As a general rule, the ED values should match the exposure assumptions used in developing the dose-response values.

15.3.3.5 Evaluation of Uncertainty

As with the inhalation assessment, the evaluation of uncertainty includes both a **summary** of the values used to estimate exposure, including their range, midpoint,and other values; and a qualitative or quantitative **discussion** that evaluates which variables or assumptions have the greatest potential to affect the overall uncertainty in the exposure assessment.

15.3.3.6 Preparation of the Documentation

The analysis plan needs to specify the approach used to document the multipathway exposure assessment, as discussed in Chapter 20.

15.3.4 Identification of the Exposed Population

This part of the analysis plan identifies the exposed population that will be evaluated in the risk assessment. The procedure for characterizing the potentially exposed population generally will be similar to that described for the inhalation pathway (Chapter 6). As noted previously, it may be necessary to include individuals who live outside the modeled deposition area. The manner in which potentially exposed populations are characterized depends on the general approach used for the multipathway assessment (see Section 15.4 below).

15.3.5 Identification of Endpoints and Metrics

This part of the analysis plan identifies the specific human health endpoints that will be evaluated in the risk assessment and the metrics used to quantify exposure and risk. The multimedia assessment uses the same general endpoints (i.e., cancer and non-cancer) and presents the central tendency and high-end tendency descriptors required as the range of risk estimates of the distribution. Risk characterization is discussed in more detail in Chapter 22.

15.4 Exposure Assessment Approach

A variety of approaches are available for multipathway exposure assessments. This section describes two representative approaches that range from a relatively simple approach based on scenarios to a very complex and data-driven approach based on mass-balance models. This discussion is intended to illustrate some of the potential approaches available for multipathway exposure assessment. A given risk assessment might incorporate features of either of the two approaches outlined below, or might feature a different approach.

Regardless of the specific approach taken, EPA recommends a tiered approach to multipathway exposure assessment, in which the exposure assessment moves from relatively simple to more complex as warranted by the quality of available information and its ability to be used to support the risk management decision(s). Chapter 3 provides an overview of tiered approaches to risk assessment.

Childhood exposures need to be considered explicitly in any non-inhalation scenario. This can be done with a separate scenario (e.g., a "resident child") or by incorporating changes in consumption rates, dietary preferences, and body weight with age in the exposure factors incorporated into the scenario. EPA's Risk Assessment Forum recently published guidance on selecting appropriate age groups for assessing childhood exposures.[2]

15.4.1 Scenario Approach

Multipathway exposures may be evaluated by developing a number of scenarios that describe the potential human exposures that might occur via each of the potential exposure pathways identified in the conceptual model. An **exposure scenario** is a combination of exposure pathways by which a single defined human receptor might be exposed to air toxics that persist and which also may bioaccumulate. The specific exposure scenarios defined for a given risk assessment would be based on the characteristics of the exposure setting, potential exposure pathways, potential exposure points or areas, and predominant land uses and activities associated with the potentially exposed population. For example, if the study area included a small lake where fishing might occur, the assessment might include a "fisher" scenario that included ingestion of fish caught in the lake.

The scenario approach generally involves relatively simple modeling and fewer data requirements as modeling inputs. This can be performed by using "linked modeling systems" which can either be relatively simple or incorporate highly sophisticated single-medium models into a single multimedia system. However, these types of models do not assure conservation of mass and therefore may under- or over-estimate exposure concentrations for particular scenarios. The general scenario approach involves:

- Identifying the potential exposure pathways that may be important, including the areas where contaminants have the potential to accumulate in soils, surface waters, sediments, and biota; and specific activities that may result in ingestion of these contaminants (either via incidental ingestion of soil while in the contaminated areas or by consuming the contaminated plants, animals, or surface water).

- Developing a set of scenarios that describe reasonable sets of potential exposure pathways, given the types of people and activities that occur within the study area. The scenarios would include specific exposure factors (e.g., body weight, fish consumption) based on the particular activities identified above. The exposure scenarios should consider children, either as a separate scenarios (e.g., a "resident child") or as part of an overall scenario (e.g., someone who is born in the exposure area and lives there for 30 years, and thus experiences exposure both during childhood and as an adult). The exposure factors could be set initially at conservative levels for screening-level assessments and then at more site-specific levels for higher tiers of analysis. Each exposure scenario also should appropriately consider study-specific sub-populations that may experience different exposure conditions (e.g., because they eat different foods or parts of foods at different rates than the general population).

- Using relatively simple multimedia modeling techniques (e.g., "linked modeling systems" described in Chapter 18) to estimate exposure concentrations in the media and biota of interest to each scenario. Monitoring (sampling or analysis) could be used to augment the modeling effort. For screening-level analyses, the scenarios can be based on the locations

with the highest modeled concentrations or deposition rates. For example, a scenario involving consumption of fish could be based on the same location as a residential scenario. In some cases, it may be appropriate to evaluate an exposure scenario assuming exposure through ingestion of fish from one water body and drinking water from a different water body. Such assumptions may need to be refined in subsequent modeling tiers.

- Quantifying the dietary intake for each scenario based on the modeled or estimated exposure concentrations and the specific exposure factors for each scenario.

Several exposure scenarios are commonly used in multipathway risk assessments (Exhibit 15-4). A recent description of several scenarios is provided in EPA's risk assessment guidance for hazardous waste incinerators.[3] In addition to the commonly assessed scenarios provided in Exhibit 15-4, other scenarios may be appropriate, depending on study-specific conditions. For example, if a contaminated surface water body is used for bathing and swimming, incidental ingestion, and dermal exposure from these activities may need to be considered. As another example, the resuspension of contaminated soils (i.e., windblown dust) may be important in some study areas. Note also that exposure of an infant to chlorinated dioxins/furans (and other lipophilic contaminants) via the ingestion of breast milk may be evaluated as an additional exposure pathway, separately from adult exposures, in each of the scenarios outlined below. ***Note also that in each of these scenarios, the risk assessment needs to look at both an adult and child (for example, the "farmer" includes both an adult farmer and a farmer child)***.

Farmer. The farmer scenario is commonly evaluated to account for the combination of exposure pathways to which a person may be exposed in a farm or ranch exposure setting. As indicated in Exhibit 15-4, the farmer is commonly assumed to be exposed to air toxics through one or more of the following exposure pathways:

- Direct inhalation of vapors and particles;
- Incidental ingestion of soil;
- Ingestion of drinking water from surface water sources;
- Ingestion of homegrown produce;
- Ingestion of homegrown beef;
- Ingestion of dairy products from homegrown livestock;
- Ingestion of homegrown chicken;
- Ingestion of eggs from homegrown chickens;
- Ingestion of homegrown pork; and
- Ingestion of breast milk (evaluated separately for an infant [for PCBs, dioxins, and furans]).

In a Tier 1 assessment, the farmer commonly is assumed to consume a certain amount daily (e.g., grams/day) of each food group (beef, pork, poultry, eggs, and milk) to make up a total consumption rate, and amounts consumed are assumed to be homegrown. If site-specific information is available that demonstrates that a farmer does not raise beef, poultry, or pork, and that raising any of these livestock would not occur for a reasonable potential future farmer at a location, then elimination of one or more of these exposure pathways could be justified. The farmer scenario often does not include the fish ingestion exposure pathway. However, in some areas of the country, it is common for farms to also have stock ponds which are fished on a regular basis for the farmer's consumption. Also, ingestion rates (e.g., food, incidental soil ingestion) often are age-dependent.

Exhibit 15-4. Common Exposure Scenarios Used in Multipathway Exposure Assessments				
Exposure Pathways	**Scenarios[a]**			
	Farm Resident	**Resident**	**Resident with Garden**	**Local Fish Consumers**
Inhalation of Vapors and Particulates[b]	•	•	•	•
Incidental Ingestion of Soil	•	•	•	•
Ingestion of Drinking Water from Surface Water Sources	•	•	•	•
Ingestion of Homegrown Produce	•	–	•	•
Ingestion of Homegrown Beef	•	–	–	–
Ingestion of Milk from Homegrown Cows	•	–	–	–
Ingestion of Homegrown Chicken	•	–	–	–
Ingestion of Eggs from Homegrown Chickens	•	d	d	d
Ingestion of Homegrown Pork	•	–	–	–
Ingestion of Fish	d	d	d	•
Ingestion of Breast Milk	c	c	–	c

Notes:

- • Pathway is included in exposure scenario.
- – Pathway is not included in exposure scenario.
- [a] Exposure scenarios are defined as a combination of exposure pathways evaluated for a receptor at a specific exposure scenario location. Note that these scenarios are not exhaustive (i.e., additional or other scenarios may be relevant to a particular exposure assessment). Note also that within each scenario, the quantitative exposure estimates will vary across age groups.
- [b] Note that inhalation is included in the overall exposure assessment, but the inhalation exposure assessment is performed separately (as described in Part II of this Reference Library).
- [c] Infant exposure to dioxins and/or furans via the ingestion of their mother's breast milk is evaluated for infants as an additional, separate exposure pathway.
- [d] Regional specific exposure setting characteristics (e.g., presence of ponds on farms or within semi-rural residential areas, presence of livestock within semi-rural residential areas) may warrant inclusion of this exposure pathway when evaluating a recommended exposure scenario.

Resident. The resident scenario is commonly evaluated to account for the combination of exposure pathways to which a person may be exposed in an urban or rural (non-farm) setting. As indicated in Exhibit 15-4, the resident is commonly assumed to be exposed to air toxics through the following exposure pathways:

- Direct inhalation of vapors and particles;
- Incidental ingestion of soil;
- Ingestion of drinking water from treated surface water sources; and
- Ingestion of breast milk (evaluated separately for an infant [for PCBs, dioxins, and furans]).

The resident scenario often does not include the fish ingestion exposure pathway. However, in some areas of the country, ponds within semi-rural residential areas support fish for human consumption.

Resident with Garden. The resident with garden scenario is commonly evaluated to account for people who may be exposed while gardening or through the consumption of produce grown in their garden in an urban or rural (non-farm) setting. As indicated in Exhibit 15-4, the resident with garden is commonly assumed to be exposed to air toxics through the same exposure pathways as the resident scenario, with one additional exposure pathway:

- Ingestion of homegrown produce.

Local Fish Consumer. The local fish consumer scenario is evaluated to account for the combination of exposure pathways to which a receptor may be exposed in an urban or rural setting where fish is the main component of the person's diet. As indicated in Exhibit 15-4, the local fish consumer is commonly assumed to be exposed to air toxics through the following exposure pathways:

- Direct inhalation of vapors and particles;
- Incidental ingestion of soil;
- Ingestion of drinking water from surface water sources;
- Ingestion of homegrown produce;
- Ingestion of fish; and
- Ingestion of breast milk (evaluated separately for an infant [for PCBs, dioxins, and furans]).

In many cases, local fish consumers are assumed to grow some of their own produce, but this may or may not be relevant to a particular risk assessment. Also note that in some parts of the country, a primary reliance on fishing as a source or dietary protein is common - a circumstance known as "subsistence fishing." Subsistence hunting may also be important for some groups.

15.4.2 Population-Based Approach

Multipathway exposures may be evaluated by tracking individual members of a population and their inhalation and ingestion through time and space. Such analyses may incorporate a user-specified number of **simulated individuals** or population groups (**cohorts**) to represent the population in the study area. A cohort is defined here as a group of people within a population with the same demographic variables who are assumed to have similar exposures. In this approach, the exposure analysis process consists of relating chemical concentrations in environmental media (e.g., air, soil, water) to chemical concentrations in the exposure media with which a person or population has contact (e.g., soil, food, household dust). Exposure is estimated by tracking the movement of a population cohort through locations where chemical exposure can occur according to a specific activity pattern.[4] Models such as the Stochastic Human Exposure and Dose Simulation Model (SHEDS), Calendex, the Hazardous Air Pollution Exposure Model (HAPEM), and the Total Risk Integrated Methodology, Exposure Event Model (TRIM.Expo) incorporate this approach (see Chapter 19). The general approach, which is analogous to the inhalation exposure modeling techniques described in Chapter 9, involves:

- Defining **exposure districts** – geographic locations within the study area where there is potential contact between humans and a pollutant – and estimating chemical concentrations within each exposure district (through modeling and/or measurement).

- Preparing inventories of chemical concentrations in each microenvironment in each exposure district at selected time intervals (e.g., days, hours). These inventories may be developed using mass-balance approaches that predict the partitioning of chemicals throughout the environment or through the use of microenvironment factors.

- Identifying the characteristics and activity patterns of each population cohort or set of representative individuals (e.g., the demographic characteristics of the individual; the locations where the individual lives, works, etc.; the amount of time spent in each location, and the individual's activities within a location). These activity patterns should be representative of the exposed population of concern. For representative individuals or cohorts, each simulated person/cohort is represented by a "personal profile" or "activity pattern" developed by selecting from a set of variables that include:

  – Demographic variables (e.g. age, sex), which are generated based on census data;
  – Residential variables (e.g., where the person lives, works, etc., which are generated based on sets of distribution data;
  – Daily varying variables (e.g., how long a person works in a garden), which are generated based on distribution data that change daily during the simulation period;
  – Physiological variables (e.g., height, weight), which are generated based on age group-specific distribution data; and
  – Dietary variables (e.g., amount and type of food consumed), which are generated based on sets of distribution data.

  Profiles or activity patterns may be developed using probability density functions, allowing the analysis to incorporate probabilistic techniques such as Monte Carlo analysis (see Part VII of this reference manual).

- Summing the exposures for each exposure event over the assumed duration of exposure (e.g., lifetime or portion of a lifetime).

The primary advantage of the population-based approach is that it is a more realistic exposure assessment that simulates how people actually live and work within the study area. It therefore can provide a more complete characterization of the spatial and temporal patterns of exposure. The primary disadvantage of the cohort approach is the time and resources it requires, including significant input data requirements.

References

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2. U.S. Environmental Protection Agency. 2003. *Guidance on Selecting the Appropriate Age Groups for Assessing Childhood Exposures to Environmental Contaminants (External Review Draft)*. Risk Assessment Forum, Washington, D.C., February 1, 2003. EPA/630/P-03/003A. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55887

3. U.S. Environmental Protection Agency. 1998. *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Volume 1. Peer Review Draft*. Office of Solid Waste and Emergency Response, Washington, D.C., July 1998. EPA/530/D-98/001A. Available at: http://www.epa.gov/combustion/risk.htm.

4. See the Human Exposure Modeling page of EPA's Fate, Exposure and Risk Analysis (FERA) website: http://www.epa.gov/ttn/fera/human_gen.html.

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   U.S. Environmental Protection Agency. 1999. *Total Risk Integrated Methodology. TRIM.Expo Technical Support Document. External Review Draft*. Office of Air Quality Planning and Standards, Research Triangle Park, NC, November 1999. EPA/453/D-99/001. Available at http://www.epa.gov/ttn/fera/trim_fate.html#1999historical.

Chapter 16 Quantification of Exposure: Development of the Emissions Inventory for the Multipathway Risk Assessment

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16.2 Developing the Emissions Inventory 1

16.1 Introduction

Chapter 7 provides an overview of the process used to develop an emissions inventory for an air toxics risk assessment. As noted in that chapter:

- Emissions data are a source term for the risk assessment, primarily as a key input for computer models that estimate the transport of chemicals in the atmosphere; if and how they will be transformed by chemical or physical processes; how and where they will be deposited; and how they will continue to partition and move through environmental media following deposition.

- Developing the emissions inventory involves identifying the specific air toxics released from the source and quantifying release characteristics (e.g., release rates, temperature, release velocity).

- Local enhancements of existing air toxics emissions inventories may be advantageous to a particular air toxics assessment effort as a very critical initial step, because air toxics inventories are not always at the quality that would provide the results desired in a modeling assessment.

16.2 Developing the Emissions Inventory

The process used to develop the emissions inventory for the multipathway risk assessment is similar to the process for inhalation analyses (see Chapter 7 for a description of this process). However, there are a few additional considerations that may apply to a given multipathway analysis (e.g., information on particulate/particle-bound/vapor fractions if ISCST3 is used). See Chapter 18 for more discussion on inputs for models used in multimedia assessment.

Chapter 17 Quantification of Exposure: Chemical and Physical Properties Affecting Multimedia Fate and Transport

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17.1 Introduction

This chapter provides both an overview of the physical and chemical properties of chemicals that persist in the environment long enough to be of potential concern for multimedia exposure and information on their potential to bioaccumulate in biological tissues to levels that may result in significant exposures. This chapter also provides a brief discussion of various approaches for evaluating persistence and bioaccumulation in an air toxics exposure assessment.

- The term **persistence** refers to air toxics that are slow to degrade in the atmosphere or in the soils, water, and/or sediments onto which they deposit and partition. Under certain circumstances, persistent chemicals can increase in concentration over time. In addition, some of these pollutants can bind tightly to soils and sediment and move from place to place by erosion. Examples of persistent chemicals are metals (which never degrade) and polychlorinated biphenyls (which degrade, but only over very long periods of time). Measures of persistence are described in Section 17.1.1.

- The term **bioaccumulation** refers to persistent chemicals that build up in the tissues of living organisms to concentrations that are higher than in the surrounding environment. These pollutants are often lipophilic in nature, which allows them to be taken up in and stored by fat tissues. As an example, the group of chemicals known collectively as dioxins (usually some mixture of chlorinated dioxins and furans) persists for long periods of time in the environment and is strongly lipophilic. Repeated exposure to dioxin in food can lead to increased body burdens in fat tissue and human milk. Measures of bioaccumulation are discussed in 17.1.2.

- The term **biomagnification** refers to persistent chemicals that increase in concentration as they transfer up the food chain so that they accumulate to higher concentration levels with each successive food chain level (see Section 17.1.2).

The air pollutant's physical and chemical properties and the characteristics of the environment to which the pollutant is emitted affect its potential to persist and bioaccumulate. One of the most important determinants in predicting persistence and accumulation in biota and other environmental media is the partitioning behavior of the pollutant. Partitioning refers to where in the environment a chemical will tend to reside and in what relative quantities. When released to the air, chemicals may partition to air, water, soils, sediments, or biota, depending on a number of chemical and site-specific factors. Section 17.2 highlights measures of partitioning and other chemical and physical properties. Section 17.3 discusses how measures of persistence, bioaccumulation, and partitioning are used in exposure assessment.

17.1.1 Measures of Persistence

Estimating the persistence of chemicals in the environment is a challenging exercise. Persistence depends on basic processes such as how the chemicals are released (i.e., which environmental media they are released to initially, in this case, air); how they move in the environment (i.e., to which environmental media they tend to partition); and their tendency to degrade within those specific media (i.e., their persistence in air vs. in water). These basic processes, in turn, depend on a number of chemical-specific properties and site-specific conditions. However, despite the

complexity of the overall process, some general screening methods are available to get a sense of persistence of chemicals in certain media.

Within each environmental medium, several different degradation processes can influence the persistence of chemicals. However, regardless of the specific degradation process, what generally occurs is that organic chemicals (or organo-metallic compounds) are reduced in size and complexity, and, if complete degradation occurs, converted to carbon dioxide, methane, ammonia, water, sulfates, phosphates, nitrates, and other end products. Explanations of the specific degradation processes and their applications within different environmental media are summarized below and in Exhibit 17-1:

- **Aerobic biodegradation** is the breakdown of chemicals by microorganisms that utilize oxygen;
- **Hydrolysis** is the breakdown of chemicals by reaction with water;
- **Photolysis or photodegradation** is the process by which chemicals can be degraded by the energy in artificial light or sunlight;
- **Oxidation or reduction (or redox)** reactions involving the exchange of electrons between the pollutant and reactive compounds found in the environment;
- **Photooxidation** is a process by which oxidation and photolysis work jointly to break down chemicals and refers to a reaction with oxygen in the presence of light (usually sunlight); and
- **Anaerobic biodegradation** is the breakdown of chemicals by microorganisms without the use oxygen (for example, in sediments).

Exhibit 17-1. Degradation Processes in Environmental Media

Environmental Medium	Applicable Degradation Process(es)
Air	Photolysis
	Photooxidation
Surface water	Aerobic biodegradation
	Hydrolysis
	Photolysis
	Photooxidation
Soils	Aerobic biodegradation
	Hydrolysis
	Photolysis (surface soil)
	Oxidation - reduction reactions
Sediments	Anaerobic biodegradation

Persistence is usually described using a term called **half-life**, which is the time required for one-half of the original mass of the chemical to be degraded, transformed, or destroyed in a given medium. Half-life values may be measured directly or estimated (e.g., with computer models that predict half-life based on chemical structure). Alternatively, the literature may report a degradation or transformation **rate constant** in units such as 1/day or day^{-1}. Assuming the reaction is first-order, the rate constant can be converted to the half-life and vice versa using the equation $t_{½} = 0.693/k$, where $t_{½}$ is the half-life (days) and k is the first-order rate constant (day^{-1}). Exhibit 17-2 provides a list of data sources for degradation half-life or rate constant values.

Exhibit 17-2. Data Sources for Half-Life and Rate Constant Values		
Data Source	**Data Elements**	**Comments**
Howard et al. Handbook	• High and low compartment half-life values for soil, air, surface water, and sediment/ground water based on measurements and modeling estimations; and • High and low measured and estimated process-specific half-life values, including hydrolysis, reduction, photolysis, photooxidation (in water and air), and biodegradation.	Howard et al.[1] compiled measured and estimated environmental degradation rates for organic chemicals, including polycyclic aromatic hydrocarbons (PAHs), pesticides, and solvents.
Mackay et al Handbooks	• Measured and estimated half-life and rate constant data for air, water, soil, and sediment.	Mackay et al.[2] compiled measured and estimated environmental degradation rates for organic chemicals, including monoaromatic hydrocarbons, chlorobenzenes, polychlorinated biphenyls, polynuclear aromatic hydrocarbons, polychlorinated dioxins and dibenzofurans, volatile organic compounds (VOCs), pesticides, and oxygen, nitrogen, and sulfur organic compounds.
Verschuren	• Measured and estimated half-life values in surface water, ground water, sediment, soil, and biota.	Verschuren[3] compiled measured and estimated degradation rates for organic chemicals.
Mercury Study Report to Congress	• Measured demethylation rate constants converted to half-life data for mercury (water, soil, sediment).	The *Mercury Study Report to Congress*[4] was developed for a rulemaking and has undergone extensive Agency peer review.
HYDROWIN	• Estimated hydrolysis rate for water.	HYDROWIN, the hydrolysis estimation program, is part of EPA's Estimation Program Interface (EPI) Suite.[5] HYDROWIN uses a chemical's structure to estimate the acid- and base-catalyzed rate constants for certain chemical classes (esters, carbamates, epoxides, halomethanes, and certain alkyl halides). Chemicals can be catalyzed (broken down) by acids (hydronium) or bases (hydroxide ions). The rate constants are used to calculate hydrolysis half-lives at selected pHs.

Half-life values for the same substance in different media, and for different substances in the same medium, can differ by several orders of magnitude. This is illustrated in Exhibit 17-3.

Exhibit 17-3. Example Illustrating Ranges of Half-life Values in Different Environmental Media

HAP	Measured or Estimated Half-life Value (Hours)[a]			
	Air	Water	Soil	Sediment
acrolein	19	672	672	1,776
benzene	276	252	252	9,984
chlorobenzene	401	2,616	50	1,800
formaldehyde	4	192	96	384
methyl bromide	8,980	420	420	1,680
2,3,7,8-TCDD	200	768	12,096	14,400

Note: Values are for Illustrative Purposes Only

(a) Values represent the maximum measured or estimated values from the references cited in Exhibit 17-2.

The fate and transport models used for characterizing multipathway exposure use metrics of persistence to account for loss of the chemical through degradation or transformation processes described above. Typically, for each modeled media compartment, the fate and transport models require an overall metric of persistence for that media compartment (e.g., a half-life value for air, a half-life value for soil, a half-life value for surface water). The media compartment half-life is the half-life associated with the most important or fastest degradation process or reaction. That is, the process-specific half-life of the fastest degradation process is usually selected as the overall media compartment half-life.

Metals may transform among different compounds or species (e.g., divalent mercury can undergo methylation to yield methyl mercury, and it can be reduced to form elemental mercury). Some metal species are more persistent and/or may be more toxic than others. Transformation half-life values in different media are more useful for evaluating the persistence of metal pollutants of concern. The speciation of metals is highly dependent on geochemical environment (and in some cases, the presence of certain microbes). One species may dominate in water of one pH, Eh, DOC concentration, etc., and an entirely different species may dominate in water of different geochemistry. [Also note that a further complicating factor is that analytical laboratories often report the total amount of a metal present in a sample, rather than the amount of the various individual metal species present (e.g., Cr^{6+} versus Cr^{3+}), which usually have different toxicities and different persistence values. An understanding of the concentrations of various metal species is therefore desirable; however, it is often not analytically achievable.][6] There are a number of concerns regarding the assessment of risks posed by metals in the environment. Information on this subject can be found at the following website: http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=51736.

What is a Persistent Chemical?

Because environmental persistence is a complicated phenomenon, no single value is universally accepted as indicating a "persistent" chemical. EPA has used a half-life value of two months (1,440 hours) in the Toxics Release Inventory (TRI) PBT final rule and the Premanufacturing Notice evaluation process.[7] Other authors have suggested a half-life value of one month (720 hours), using the following logic: Assuming that a chemical will degrade in approximately six half lives (when less than two percent of the mass remains), a chemical with a half-life of one month would persist in the environment for six months. This six month period would be long enough to encompass the sensitive developmental life stages of many organisms.[8]

Note that **the use of any single threshold value to define "persistent" chemicals may be misleading**. An important consideration is data quality (e.g., whether the half-life value is measured or predicted and the overall quality of the experimental study or computer algorithm used to develop the value). Assessors must consider other factors including the tendency of the chemical to partition into various media. For example, vinyl chloride has a half-life of six months in surface water and two years in sediment – values that might suggest this chemical is "persistent." However, its half-life in air is 53.4 hours and in soil is 10 days. Thus, depending on its relative tendency to partition between air, soil, water, and sediment, a significant amount of the mass in air emissions might be degraded (in the air and/or soil) prior to the chemical reaching surface water and sediment.

Ultimately, it is often difficult to select a single and reliable half-life because the half-life of a chemical depends not only on its physical properties (see section 16.4), but also on the environmental conditions of the site to which the chemical is emitted. Temperature, sunlight intensity, the nature of the microbial community, and concentrations of reactive species such as oxygen radicals can all affect the reactivity of a compound.[3]

17.1.2 Metrics of Bioaccumulation

Several chemical-specific metrics can be used to evaluate the potential for a chemical to bioaccumulate in plants and animals and biomagnify in food webs.[9] These values may be measured in laboratory tests or estimated with computer models based on chemical structure. These metrics include:

Note that BAFs and BCFs are not calculated for humans; rather, they are sometimes used to estimate air toxics concentrations in the food items eaten by people.

- **Bioaccumulation Factor (BAF)**. The concentration of a substance in tissue of an organism divided by its concentration in an environmental medium in situations where the organism and its food are exposed (i.e., accounting for food chain exposure as well as direct chemical uptake). Such values are often used to characterize the transfer of pollutants through consumption of fish, beef, or dairy products.[10]

- **Bioconcentration Factor (BCF)**. The concentration of a substance in the tissue of an organism divided by the concentration in an environmental medium (e.g., the concentration of a substance in an aquatic organism [µg/kg body weight] divided by the concentration in the ambient water [µg/L water], in situations where the organism is exposed through the water only). The most commonly given value is an estimate of the relative concentrations in water and whole fish (or, in some cases, fish fillets, since most people in the U.S. do not eat

whole fish), but BCFs for other organisms are also available. For plants, the Root Concentration Factor (RCF) indicates how readily pollutants are taken up from soil into underground tissues.

- **Octanol/water partition coefficient**. The ratio of a chemical's solubility in n-octanol to its solubility in water at equilibrium (in this test, n-octanol is used as a surrogate for lipophilic tissue). This metric, usually expressed as a logarithm (log K_{ow} or log P), is often used as a surrogate for (and is an important basis for estimating) BAF or BCF.

As with persistence, bioaccumulation is a complicated phenomenon, and no single value is universally accepted as indicating that a chemical has a high tendency to bioaccumulate, although EPA's Office of Pollution Prevention and Toxics has used a threshold BCF value of 1,000 in evaluating new and existing chemicals.[11] Exhibit 17-4 provides a list of sources for bioaccumulation data.

Importance of Trophic Levels in Evaluating Bioaccumulation in Aquatic Food Chains

An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. Certain pollutants have the potential to biomagnify, or increase in concentration at successive trophic levels through a series of predator-prey associations. Chapter 5 (Bioaccumulation) of EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* provides guidance about deriving trophic level-specific bioaccumulation factors.[17]

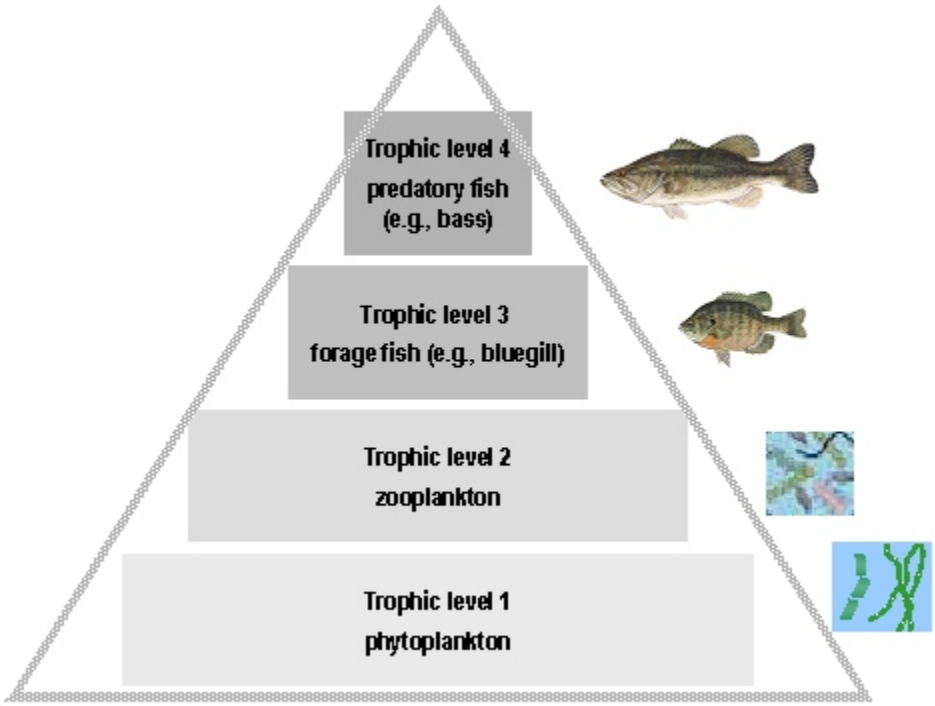

Exhibit 17-4. Sources of BCF and BAF Values		
Data Source	**Data Element**	**Comments**
HWIR Technical Support Document	Measured BAF Measured BCF Predicted BAF Predicted BCF	The Hazardous Waste Identification Rule (HWIR) Technical Support Document[12] data were developed for a rulemaking. Estimates are available for different classes of organisms (fish and invertebrates).
Mercury Study Report to Congress	Measured BAF for mercury	The *Mercury Study Report to Congress*[4] was developed for a rulemaking and has undergone extensive Agency peer review.
Ambient Water Quality Criteria documents	Measured BCF	Ambient Water Quality Criteria documents[13] are developed for rulemakings that establish concentration limits for chemicals in the surface waters of the United States. They have undergone extensive Agency peer review.
AQUIRE Database	Measured BCF	EPA's Office of Research and Development, Environmental Research Laboratory in Duluth, MN, maintains a database of citations and aquatic bioassay data including residue measures.[14]
BCFWIN	Predicted BCF	BCFWIN, the Bioconcentration Factor Estimation Program, is part of EPA's EPI Suite.[5] This program estimates BCFs based on log K_{ow} data using the estimation methodology presented in a 1997 study prepared for EPA by Meylan et al.[15] The methodology was formulated using a training set of 694 compounds with measured BCF values for fish. In order of preference, the program uses (1) the log K_{ow} entered by the user, (2) the experimental log K_{ow} from the experimental log K_{ow} database for KOWWIN, and (3) the KOWWIN estimated log K_{ow} value.

BAF or BCF values are used in some fate and transport models to calculate how much of the chemical will partition into organisms, such as fish or shellfish, that are consumed by humans or ecological receptors of concern. The concentrations in these biota can then be used to calculate the intake of the chemical by humans or ecological receptors of interest. It is recommended that BAFs be derived separately for species of different trophic levels to account for different levels of accumulation for members of different trophic levels.[16] EPA presents specific guidelines for deriving BAF values, including how to estimate BAFs using BCF values in its revised methodology for developing Ambient Water Quality Criteria.[17] National-level BAFs developed by the Office of Water can be used in screening analyses. These can be refined based on site-specific characteristics in subsequent tiers of the assessment, if necessary.

As with half-life values, BCF values vary significantly among air toxics. Exhibit 17-5 presents a few representative BCF values for several HAPs. Note that these represent the highest values identified in the references cited in Exhibit 17-4 and are meant for illustrative purposes only.

Exhibit 17-5. Example BCF Values	
HAP	**BCF Value[a]**
acrolein	3
carbon tetrachloride	30
chloroform	6
pentachlorophenol	776
2,3,7,8-TCDD	5,754
Note: values are for illustrative purposes only	
(a) Values represent the maximum measured or estimated values from the references cited in Exhibit 17-4.	

Note that **the use of any single threshold value to define "bioaccumulative" chemicals may be misleading**. As with persistence, data quality is an important consideration (e.g., measured vs. predicted values; quality of the underlying study/algorithm used to develop the value). Moreover, the specific organisms and tissues in which bioaccumulation is measured or predicted are important determinants of the relevance of a given BCF or BAF value for the exposure assessment. Many substances that bioaccumulate tend to accumulate in lipid tissues (e.g., fat, organs), which may not be the tissues that most people eat (e.g., fish fillet). Therefore, a high BCF may not actually result in high exposures to humans.

17.2 Chemical and Physical Properties that Affect Persistence and Bioaccumulation

Exhibit 17-6 identifies both direct metrics of persistence (i.e., half-life values), as well as the physical and chemical properties that are most important in determining persistence and bioaccumulation.

In Exhibit 17-6, **solubility** and **vapor pressure** determine the propensity for pollutants to dissolve in water and volatilize into the air, respectively. The **Henry's Law constant**, which is simply the ratio of the chemical's water solubility to its vapor pressure, indicates whether a compound will partition into air or water at equilibrium. The speed with which the equilibrium occurs is affected by the diffusion constants in air and water.

The coefficients that are abbreviated with a capital "K" (e.g., the octanol-water partition coefficient, K_{ow}) in Exhibit 17-6 provide information on how strongly organic and inorganic compounds are likely to bind to soil or sediment particles, or to partition into lipid versus aqueous phase liquids. Strong binding indicates a high potential to persist and accumulate in soils and sediments; soil/sediment binding also tends to be correlated with the potential to bioaccumulate.

The 1998 Peer Review Draft of EPA's *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (HHRAP) provides (Appendix A) tables of recommended rate constants and chemical/physical parameters for a large number of air toxics.[18] Also, the user's guide for EPA's Risk Screening Environmental Indicators (RSEI) tool includes physicochemical properties for TRI chemicals and chemical categories.[19] Note, however, the values in these sources may need to be updated.

Exhibit 17-6. Chemical and Physical Property Definitions		
Property	**Definition**	**Significance/Comments**
Name	Unique identifier	Not always reliable (many synonyms)
CAS No.	Unique identifier	Much more reliable than the chemical name; some chemicals have no CAS number; some CAS numbers refer to mixtures
MW	Molecular weight	In absence of data, can be used to calculate D_a, D_w, etc.
V_p	Vapor pressure	Indicates volatility
S	Solubility	Indicates maximum concentration of a chemical that will dissolve in water
H	Henry's Law constant	Ratio of vapor phase concentration to the liquid phase concentration of a gas; high values indicate tendency to volatilize from water solution
D_a	Diffusion coefficient in air	Used to calculate rate of volatilization from air
D_w	Diffusion coefficient in water	Used to calculate rate of volatilization from water
K_{ow}	Octanol-water partition coefficient (log K_{ow} is frequently tabulated)	High value (> 1000, log K_{ow} > 3) indicates strong tendency to bioconcentrate
K_{oc}	Organic carbon partition coefficient (log K_{oc} often tabulated)	High value indicates strong tendency to bind to soil/sediment; K_{oc}, K_{ow} can be estimated from each other
Kd_{soil}	Soil dissociation constant	Indicates potential of inorganic ions/compounds to bind to soil; varies for different ionic species, pH, soil types
Kd_{sed}	Sediment dissociation constant	Indicates potential of inorganic ions/compounds to bind to sediment (similar to Kd_{soil})
$t_{1/2soil}$	Half-life in soil	Indicates persistence in soil; generally soil type, conditions, and degradation pathway(s) must be specified
$t_{1/2sed}$	Half-life in sediment	Indicates persistence in sediment; same considerations as for $t_{1/2soil}$
$t_{1/2sw}$	Half-life in surface water	Indicates persistence in surface water; for moderate to high-vapor pressure compounds
BAF	Bioaccumulation factor	Indicates accumulation of a compound into tissues of an organism from contact with contaminated water, contaminated sediments, and ingestion of contaminated food
BCF	Bioconcentration factor	Indicates accumulation of a compound into tissues of an organism from contact with a contaminated medium.
RCF	Root concentration factor	Ratio of root to soil concentration, measures propensity to take up pollutant from soil for defined plant species
B	Biotransfer factors	Describes propensity of pollutant to be transferred through food chain; defined for specific crops and consuming organisms (e.g., alfalfa => dairy cattle); generally correlates with BCF, K_{ow}; used primarily for detailed pathway modeling

Fugacity as a Determinant in the Fate and Transport of a Pollutant

Once a contaminant is emitted from its source, the fate of the contaminant is determined by a number of factors (e.g., molecular weight, solubility, partition coefficients). In order to characterize the fate of the pollutant, modelers have developed the concept of fugacity[20] to define the tendency of the gas to escape to another phase in order to reach a steady-state equilibrium. This tendency to migrate then leads to partitioning of the pollutant across environmental media based on its chemical and physical characteristics. Fugacity models are distribution-based models incorporating all environmental compartments (media) and are used to quantify steady-state fluxes of pollutants across compartment interfaces. There exist three levels at which fugacity may be modeled. The Level I model depicts the distribution of a known quantity of a chemical in a closed environment at equilibrium, in which no degrading reaction occurs and no advective gain or loss is attained. A Level II model describes a situation in which a chemical is continuously discharged at a constant rate and achieves steady-state equilibrium, at which the input and output rates are equal. In Level II models, reaction and advection may occur. A Level III model is similar to a Level II model in that the modeled chemical is continuously discharged at a constant rate and achieves a steady state condition, in which the input rate equals the output rate. Yet, a Level III model differs in that fugacity for the given chemical is equal within a single compartment for all defined subcompartments, but is not equal between compartments. Therefore, individual inputs for each medium must be defined separately in order to determine appropriate pollutant partitioning among environmental compartments.

17.3 Evaluating Persistence and Bioaccumulation in Exposure Assessments

Characterizing the movements of air toxics that persist and which also may bioaccumulate through various environmental media such as air, soils, water, sediments, and biota can be a highly complex task, and generally available methods for evaluating these fate and transport pathways have only recently been developed. Specifically, EPA and other regulatory agencies have developed a number of models that estimate the concentrations of persistent and bioaccumulative compounds over time in the various environmental "compartments" subsequent to defined patterns of deposition. These models simulate both physical and chemical processes such as air deposition to soil, runoff, leaching (dissolution), soil/sediment adsorption, and chemical speciation (oxidation/reduction, precipitation reactions). Some models also evaluate the biodegradation of organic pollutants by bacteria and other organisms in soil, sediment, and surface water. These models require a large number of site-specific inputs and many measures of the physical and chemical properties of pollutants. It is beyond the scope of this chapter to discuss in detail all the processes that may be modeled in the assessment of indirect exposure pathways; however, Mackay and his colleagues provide a good overview of the multimedia fate and transport[20] and Conell and Emlay describe the principles governing the bioaccumulation of pollutants in the environment.[21] Also, Chapter 18 provides a description of available multimedia models that are generally recommended for use in air toxics risk assessment. The documentation for these models provides detailed descriptions of the specific processes and methods used in each model.

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Chapter 18 Quantification of Exposure: Multimedia Modeling

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18.1 Introduction

This chapter summarizes the concepts and tools available for multimedia modeling to support a multipathway human health risk assessment. The discussion is divided into three sections:

- Section 18.2 discusses multimedia fate and transport modeling used to estimate chemical concentrations in abiotic and biotic media that indirectly result from air emissions;
- Section 18.3 discusses key parameters used as inputs to multimedia models; and
- Section 18.4 presents examples of the use of multimedia models in air toxics risk assessments.

18.2 Multimedia Fate and Transport Modeling

Although the primary route of exposure to many air toxics is via inhalation, non-inhalation exposure through soil, water, and food pathways can be a potential health concern for those air toxics that persist and which also may bioaccumulate (see Chapter 4 for the list of persistent bioaccumulative hazardous air pollutants (PB-HAP) chemicals). Therefore, risk assessments for these substances often include multimedia modeling to predict the movement of these air toxics in the environment. This section provides an overview of the multimedia fate and transport models commonly used by EPA.

18.2.1 Basis of Multimedia Models

Multimedia fate and transport models take into account various physical and chemical processes to predict the movement of pollutants within and between environmental media. Multimedia models can be grouped into the following basic categories.

- **Linked modeling systems** are composed of several independent single-medium models. These systems typically consist of a "one-way" process through a series of linked single-medium models or algorithms; that is, they calculate fate and transport by running a single-medium model (e.g., an atmospheric model) and using the output as the input for the next single-medium model (e.g., a soil or surface water model). One of the primary advantages of linked modeling systems is that they can incorporate several highly sophisticated single-medium models into a single modeling system. The primary drawbacks of these types of models are (1) they do not always assure conservation of mass; (2) they lack dynamic "feedback" loops; and (3) secondary pollutant transfers are not treated in a fully coupled manner.

- **Fully coupled, mass-conserving models** estimate the fate and transport of pollutants between and within media and are able to fully account for the distribution of pollutant mass within a defined modeling region. In these types of models, each of the included media (e.g., soil, air, biota) are modeled simultaneously (i.e., fully coupled), and thus these models can simulate dynamic "feedback" loops and secondary pollutant transfers. The primary drawback of these types of models is that they typically involve some simplification relative to sophisticated single-medium models due to the computational demands associated with modeling multiple media simultaneously.

18.2.2 Multimedia Exposure Models

To date, EPA has used primarily the Multiple Pathways of Exposure (MPE) model and variations of the MPE approach to conduct multimedia fate and transport modeling for air toxics. More recently, EPA developed the Fate, Transport, and Ecological Exposure (TRIM.FaTE) model as a component of the Total Risk Integrated Methodology (TRIM).[1] This section provides a summary of the MPE model, the variations of the MPE approach, and the TRIM.FaTE model. During the development of the TRIM.FaTE model, EPA conducted a comprehensive review of those multimedia fate and transport models that estimate exposures and risks from emissions of air toxics that EPA and other organizations in the United States use. Exhibit 18-1 provides a summary of the models included in this review, with models grouped into the two basic categories described in the previous section. The TRIM.FaTE documentation provides a description of each of these models. Also presented at the end of this section is a multimedia model developed by the State of California called CalTOX.[2]

Exhibit 18-1. Multimedia Models Reviewed During TRIM.FaTE Development

Linked Modeling Systems	Fully Coupled, Mass-Conserving Models
• Indirect Exposure Methodology (IEM)/Multiple Pathways of Exposure (MPE), developed by EPA's National Center for Environmental Assessment • Multimedia Environmental Pollutant Assessment System (MEPAS), developed by the U.S. Department of Energy	• CalTOX, California Department of Toxic Substance Control's Multimedia Risk Computerized Model • SimpleBOX, developed by the Netherlands National Institute of Public Health and the Environment • Modeling Multimedia Environmental Distribution for Toxics (Mend-Tox)/ISMCM), developed by EPA's Office of Research and Development

<u>Multiple Pathways of Exposure Model (MPE)</u>

The Multiple Pathways of Exposure model, formerly known as the Indirect Exposure Methodology (IEM), primarily consists of a set of multimedia fate and exposure algorithms developed by EPA's Office of Research and Development (ORD).[a] ORD issued an interim document describing this methodology in 1990, a major addendum was issued in 1993, and an updated guidance document was issued in 1999 in response to comments it received during a 1994 Science Advisory Board review of the addendum.[3] The MPE documentation describes fate and transport algorithms, exposure pathways, receptor scenarios, and dose algorithms.

The MPE approach includes procedures for estimating human exposures and health risks resulting from the transfer of emitted pollutants from air to soil and surface water bodies and the

[a] Note that the MPE model and many of its variations are conceptual models used to describe fate and transport, not "ready-to-run" computer models. Typically, users incorporate these conceptual models into spreadsheets or other computer frameworks to create a usable model.

subsequent uptake by vegetation, animals, and humans. The methodology specifically addresses exposures via inhalation; ingestion of food, water, and soil; and dermal contact. The MPE model was designed to predict long-term, steady-state impacts from continuous sources, rather than short-term, time-series estimates. It consists of a "one-way process" through a series of linked models and algorithms, beginning with the modeling of the transport of pollutant emissions in air and the subsequent deposition to soil and surface water and culminating in the uptake of the emitted pollutant(s) into biota. The aspects of the MPE model that address exposure estimation are described in more detail in Section 18.4 below.

EPA designed the MPE model to assess human exposures to air toxics emitted from stationary combustors, although analysts can apply most aspects of the approach to other types of stationary sources. One can apply this model to one or more sources at a single facility simultaneously to estimate exposures within 50 kilometers of the facility. The MPE model will allow modeling of only one chemical at a time, and there is no tracking (i.e., carry through the analysis) of transformation products of the modeled chemical. To apply the MPE approach, users must provide a significant number of site-specific inputs, such as source emission rate, wind speed and direction, soil loss constant, and pollutant degradation rate.

> The *Draft Guidance on the Development, Evaluation, and Application of Regulatory Environmental Models* recommends best practices to help determine when a model, despite its uncertainties, can be appropriately used to inform a decision. The Knowledge Base (KBase) is a web-accessible database of information on some of EPA's most frequently used models. The draft guidance recommends what information about models to document, while the Knowledge Base is the repository where this information is documented. Both products are available at the CREM internet site at http://www.epa.gov/crem.

EPA modified the MPE approach to multimedia fate and transport modeling for use in two additional EPA models and modeling approaches. These models and approaches are as follows.

- **IEM2M**. In 1997, Office of Air Quality Planning and Standards (OAQPS) modified the then-current version of the IEM model to create IEM2M. This revised version of IEM added the functionality necessary to model transformation between the three key species of mercury and track the concentrations throughout the modeled system for each of these species. This model was applied to estimate nationwide exposures to mercury for the *Mercury Study Report to Congress*.[4]

- **Human Health Risk Assessment Protocol (HHRAP)**. EPA's Office of Solid Waste and Emergency Response (OSWER) developed the HHRAP to provide guidance for conducting multipathway exposure and risk assessments of emissions of air toxics from hazardous waste combustion facilities. The suggested protocol for assessing multipathway exposures was adapted from the MPE approach and the documentation of this protocol[5] compiles detailed information on many of MPE's input parameters and algorithms.

Two additional models and approaches used by EPA to assess multipathway exposures to air toxics use many of the same fate and exposure algorithms and methodologies used in the MPE model.

- **Dioxin Reassessment Methodology**. Many of the algorithms used in the MPE model have been used for ongoing EPA efforts to characterize exposure and risks from dioxins, particularly chlorinated dibenzodioxins and dibenzofurans, as part of the Dioxin Reassessment project.[6]

- **Multimedia, Multipathway, Multi-receptor Exposure and Risk Assessment Model (3MRA)**. The 3MRA model is currently being developed by EPA's Office of Solid Waste and Emergency Response to support their Hazardous Waste Identification Rule (HWIR). Many of the fate and exposure algorithms used in 3MRA are similar to those used in MPE.

TRIM.FaTE

EPA developed the TRIM Fate, Transport, and Ecological Exposure (TRIM.FaTE) model[7] to describe the movement and transformation of pollutants over time, through a user-defined, bounded system of environmental compartments (i.e., abiotic media and organisms). The design of the compartment system can encompass spatial interconnections (with some similarities to grid-type Eulerian models) and ecological exposure-related relationships. TRIM.FaTE is designed to generate both media concentrations relevant to human pollutant exposures and exposure estimates relevant to ecological risk assessment primarily for air pollutants for which non-inhalation exposures are important.

In contrast to the IEM/MPE approach, TRIM.FaTE is a fully coupled multimedia model that estimates the flow of pollutant through time among environmental compartments. TRIM.FaTE offers the following important features that are not available using IEM/MPE.

- TRIM.FaTE is able to model mass-balanced "feedback" loops between media as well as secondary emissions (e.g., re-emission of deposited pollutants).

- TRIM.FaTE has the ability to provide detailed time-series estimates of pollutant concentrations in the environmental compartments.

- TRIM.FaTE maintains a full mass balance of the pollutant mass in the system (i.e., all the pollutant introduced into the system is accounted for among all the environmental compartments).

- TRIM.FaTE can model sensitivity of model results to variations in input parameters and perform probabilistic modeling such that uncertainty and variability in model results can be characterized.

- TRIM.FaTE is designed with the flexibility to allow for implementation of nearly limitless configurations (e.g., spatial resolution, types of biota), algorithms, and approaches. Simulations can range from quite simple analyses of pollutant distribution across abiotic media and biota to more complex, spatially-refined assessments, with associated implications with regard to user requirements.

TRIM.FaTE can model multimedia fate and transport of air toxics from any type of stationary source. It can be applied to multiple facilities, sources, and chemicals simultaneously to track the fate and transport of emitted pollutants as well as transformation products of the emitted

pollutants. The amount of input data required by TRIM.FaTE is directly related to the complexity of the user-specified modeling system; however, TRIM.FaTE analyses typically require more input data than similar analyses conducted using the MPE approach. As noted in Exhibit 18-2, TRIM.Expo is the exposure component of the TRIM modeling system (see Section 18.2.2.2).

California Total Exposure Model for Hazardous Waste Sites (CalTOX)

The Department of Toxic Substances Control (DTSC), within the California Environmental Protection Agency, has the responsibility for managing the State's hazardous-waste program. As part of this program, the DTSC funded the development of the CalTOX program.[2] CalTOX has been developed as a set of spreadsheet models and spreadsheet data sets to assist assessing human exposures and defining soil clean-up levels at uncontrolled hazardous wastes sites. More recently, CalTOX has been modified for use in establishing waste classification for landfills and hazardous waste facilities in California. CalTOX addresses contaminated soils and the contamination of adjacent air, surface water, sediments, and ground water. The modeling components of CalTOX include a multimedia transport and transformation model, exposure scenario models, and add-ins to quantify uncertainty and variability. The multimedia transport and transformation model is a dynamic model that can assess time-varying concentrations of pollutants introduced initially to soil layers or for pollutants released continuously to air, soil, or water. This model assists the user in examining how chemical and landscape properties impact both the ultimate route and quantity of human contact. Multimedia, multiple pathway exposure models are used in CalTOX to estimate average daily doses within a human population. The exposure modeling part of CalTOX is described further in Chapter 20.

18.3 Key Parameters/Inputs for Multimedia Models

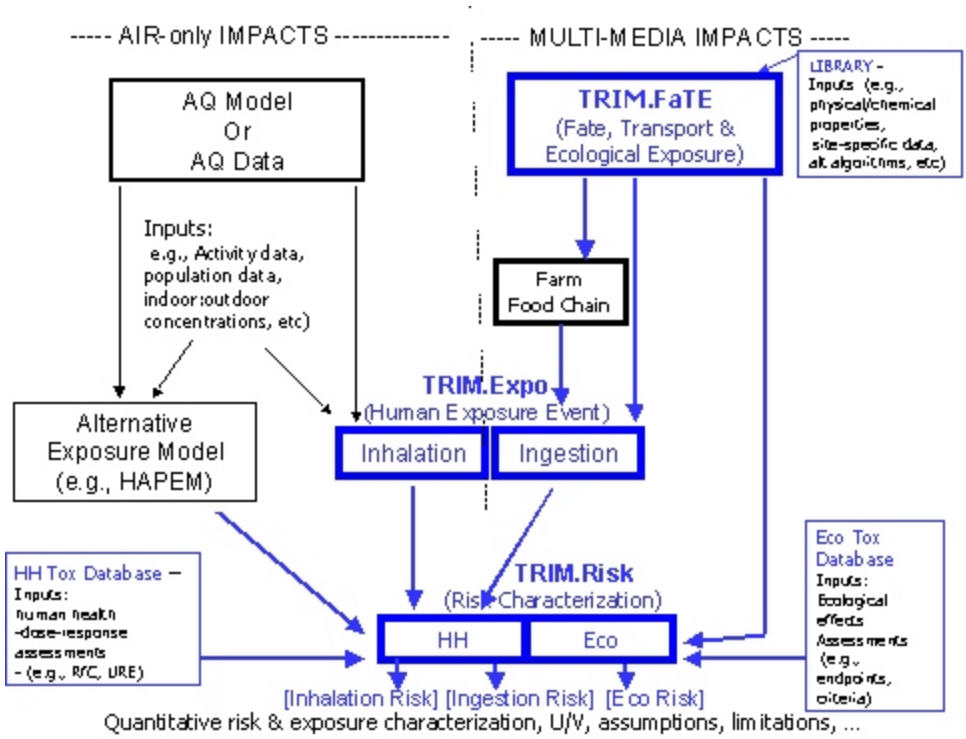
For most air risk applications, multimedia modeling results are strongly dependent on the **emission rate** of pollutants emitted to the air from the facility. For the MPE framework and TRIM.FaTE model, transport of modeled pollutants and accumulation in media of interest result directly from the emission of the chemical into the air from the facility, the dispersion or advection of chemical through the air, and the subsequent deposition of the chemical onto land, water, or other surfaces in the modeled region. In addition to emission rate, several other types of data are often required by multimedia models to characterize the pollutants and site being modeled. Generally, the data requirements for multimedia fate and transport models fall into the following categories.

- **Source characteristics** for the sources that are modeled, such as location, emission rates for the modeled pollutant(s), stack height, exit gas velocity, and exit gas temperature.

- **Environmental setting characteristics** for the abiotic media included in the modeling scenario, such as water body dimensions, surface soil characteristics (e.g., organic carbon content, porosity), and data related to local meteorology and hydrology (e.g., precipitation, erosion, runoff rates).

- **Abiotic chemical/physical data** for the chemicals included in the modeling scenario, such as Henry's law constant and soil-water partition coefficients. EPA's draft HHRAP provides default values for many of these parameters.[5]

Exhibit 18-2. Role of the TRIM Modeling System



The Total Risk Integrated Methodology (TRIM) modeling system can be used to assess human inhalation, human ingestion, and ecological risks. TRIM.FaTE accounts for movement of a chemical through a comprehensive system of discrete compartments (e.g., media and biota) that represent possible locations of the chemical in the physical and biological environments of the modeled ecosystem and provides an inventory, over time, of a chemical throughout the entire system. In addition to providing exposure estimates relevant to ecological risk assessment, TRIM.FaTE generates media concentrations relevant to human ingestion exposures that can be used as input to the ingestion component of the Exposure-Event module, TRIM.Expo. Measured concentrations also can be used as inputs to TRIM.Expo. In the inhalation component of TRIM.Expo, human exposures are evaluated by tracking randomly selected individuals that represent an area's population and their inhalation and ingestion through time and space. $TRIM.Expo_{Inhalation}$ can accept ambient air concentration estimates from an external air quality model or monitoring data. In the Risk Characterization module, TRIM.Risk, estimates of human exposures or doses are characterized with regard to potential risk using the corresponding exposure- or dose-response relationships. The TRIM.Risk module is also designed to characterize ecological risks from multimedia exposures. The output from TRIM.Risk is intended to include documentation of the input data, assumptions in the analysis, and measures of uncertainty/variability, as well as the results of risk calculations and exposure analysis. Information on TRIM can be accessed at: http://www.epa.gov/ttn/fera/.

- **Non-chemical-specific characteristics of biota** for any organisms included in the modeling scenario, such as feeding rates, body weight, and population density.

- **Biotic chemical-specific data** for any organisms included in the modeling scenario, such as bioaccumulation and/or bioconcentration factors or assimilation efficiency values.

The Multiple Pathways of Exposure (MPE) model,[8] a commonly used model for multipathway analyses, requires air concentrations, deposition rates, which are typically obtained via Industrial Source Complex (e.g., ISCST3) modeling (see Chapter 9 for descriptions of these models). Risk assessors would execute the ISCST3 modeling for multipathway in a similar fashion to how they executed the modeling for inhalation. Specifically, the sources would be characterized in the same way (e.g., vent height and diameter, release temperature and velocity, flow rate). The user would provide the inputs necessary to calculate the deposition rates properly (e.g., particle size distribution, scavenging coefficient). However, for multipathway analyses, the user should execute the ISCST3 model with the "depletion option" (i.e., telling the model to subtract out the mass of chemical deposited).

The user would need to know the particulate/particle-bound/vapor fractions of the emissions for ISCST3 to calculate wet and dry deposition of vapors and particles. These would probably be considered source-related, since although they are chemical-dependent, they also vary by source (i.e., the industrial process affects the emissions profile).

For dry deposition of particles, the user would supply the following inputs (in addition to the normal ISC inputs), including the:

- Array of particle diameters of the emissions;
- Array of mass fractions corresponding to the different particle diameters; and
- Array of particle densities corresponding to the different particle diameters.

For wet deposition of particles, the user would supply the following inputs (in addition to the normal ISC inputs), including the:

- Particle scavenging coefficients for liquid precipitation corresponding to the different particle diameters; and
- Particle scavenging coefficients for frozen precipitation corresponding to the different particle diameters.

For wet deposition of gases, the user would supply the following inputs (in addition to the normal ISC inputs), including the:

- Gaseous scavenging coefficient for liquid precipitation; and
- Gaseous scavenging coefficient for frozen precipitation.

The ISC user's guide[9] provides more detailed information on the deposition algorithms and required input data. There also is guidance for application of ISC for multipathway assessment in the latest MPE documentation.[8]

The only facility-related/source term data points used by the **TRIM Fate, Transport, and Ecological Exposure (TRIM.FaTE)** model are chemical emission rate, location (lat/long, UTM), and emission height, which are available from the inhalation modeling. TRIM.FaTE calculates all values internally for determining vapor/particle fractions and deposition rates based on chemical-specific (**not** source-specific) properties.

Other multimedia models may require specific source characterization data and other documentation that were not obtained for the inhalation analysis (the various user's guides for these models should be consulted for appropriate inputs).

It is important to note that the number and refinement of inputs to a multimedia model may vary depending on the outputs of interest and level of detail entailed in the modeling.

18.4 Examples of Multimedia Modeling

TRIM.FaTE Test Case Application. As a test case application, the TRIM.FaTE model was used to predict multimedia concentrations of mercury at a chlor-alkali facility in the northeastern United States. Speciated mercury concentrations were calculated for various abiotic media (e.g., surface soil, surface water, lake sediment) and biota (e.g., fish for various trophic levels, birds, mammalian predators) for the ecosystem surrounding the facility. A sensitivity and uncertainty analysis using TRIM.FaTE tools and a model comparison involving the 3MRA modeling system were also performed. The complete report on the test case will be available at the TRIM.FaTE page of EPA's Fate, Exposure, and Risk Analysis (FERA) website: http://www.epa.gov/ttn/fera/trim_fate.html.

Paints Hazardous Waste Listing Determination Analysis. On April 4, 2002, EPA issued a final determination not to list as hazardous certain wastes generated from the production of paint. EPA made this determination pursuant to the Resource Conservation and Recovery Act (RCRA), which directs EPA to determine whether certain wastes from the paint production industry may present a substantial hazard to human health or the environment. EPA proposed concentration-based listings for certain paint waste solids (K179) and liquids (K180) on February 13, 2001 (66 *Federal Register* 10060). However, following a review of the public comments and supplemental analyses based on public comments, EPA determined that the paint wastes identified in the February 13, 2001, proposal did not present a substantial hazard to human health or the environment. EPA conducted a multipathway risk assessment in support of this determination.[10] EPA used a series of models to estimate concentrations of Chemicals of Potential Concern (COPCs) in the environment with which human and ecological receptors may come into contact. The analysis used a source partioning model to estimate environmental releases of each COPC from a waste management unit for each waste stream, as appropriate. These estimated environmental releases provided input to the fate and transport models to estimate media concentrations in air, soil, surface water, and groundwater. A farm food chain model was used to estimate COPC concentrations in produce, beef, and dairy products. Aquatic bioconcentration factors were used to estimate concentrations in fish.

Chlorinated Aliphatics Hazardous Waste Listing Determination. In support of a hazardous waste listing determination for wastewaters and wastewater treatment sludges generated from the production of certain chlorinated aliphatic chemicals, EPA conducted a multipathway human health risk assessment.[11] EPA used the ISCST3 model to estimate dispersion and deposition of vapors emitted from wastewater treatment tanks and landfills, and vapors and particulates emitted from sludge land treatment units. EPA used a series of indirect exposure equations based on the MPE approach to quantify the concentrations of contaminants that pass from contaminated environmental media to the receptor indirectly. For example, EPA examined risks associated with contaminant transport in air; deposition onto plants and soil; accumulation in forage, grain,

silage, and soil; subsequent ingestion by beef cattle and dairy cattle; and human ingestion of contaminated beef and dairy products.

Hazardous Waste Combustor MACT Standard Analysis. A human health and ecological risk assessment was performed in support of developing a Maximum Achievable Control Technology (MACT) standard for hazardous waste combustor facilities.[12] The risk analysis included a multimedia, multipathway assessment that addressed direct exposures to constituents released into the atmosphere by hazardous waste combustor units and indirect exposures due to the movement of air toxics in the food chain. The risk assessment addressed both human health risks (cancer effects and noncancer effects) as well as ecological risks. Constituents assessed were seven congeners of chlorinated dioxin and 10 congeners of chlorinated furan; three species of mercury; 14 metals (antimony, chromium III, chromium VI, arsenic, lead, barium, nickel, beryllium, selenium, cadmium, silver, thallium, cobalt, copper, and manganese); particulate matter; hydrochloric acid; and chlorine gas. To the maximum extent possible, this risk assessment followed the latest risk guidelines adopted by EPA and used the most recent data available.

Columbus Waste-to-Energy Study. A risk assessment study using fate modeling was performed by EPA's NCEA for dioxin emissions at the Columbus, Ohio, Waste-to-Energy incinerator facility.[13] In 1994, EPA headquarters, the Office of Research and Development, and Region 5 conducted a screening assessment of indirect impacts, leading to the conclusion that continued emissions "may pose an imminent endangerment to public health and the environment." Fate modeling used to support EPA's position utilized the air-to-beef model described in the draft Dioxin Exposure document (i.e., based on the principles included in the MPE framework) and assumed a subsistence farming family scenario. Exposure pathways considered beef, milk and vegetable ingestion; soil dermal contact and childhood soil ingestion; and breast milk ingestion. The exposure duration for adults was assumed to be seventy years. Air concentrations used were the average from nine dairy farms located between five and twelve miles from the incinerator. Overall exposure and cancer risk were estimated for each of the exposure pathways, with cancer risk being highest for beef consumption (2×10^{-4}) and lowest for soil dermal contact (9×10^{-9}). Exposure from breast milk ingestion was determined to be higher by one order of magnitude than exposure from beef and milk consumption, and higher by two orders of magnitude than exposure from inhalation. Breast milk exposure near the incinerator site ranged between two and more than seven times the background dioxin levels. A TRIM.FaTE case study has been developed based on this analysis, including a direct model comparison component on the air-soil outputs, and will be available at: http://www.epa.gov/ttn/fera/trim_fate.html.

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Chapter 19 Quantification of Exposure: Multimedia Monitoring

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19.1 Introduction

As noted earlier, modeling is generally the recommended approach for estimating exposure concentrations for air toxics risk assessments (for both inhalation and other pathways). However, there may be circumstances in which monitoring is requested or recommended for a particular multipathway risk assessment. This chapter provides an overview of multimedia monitoring, including the reasons for monitoring (Section 19.2), planning and implementation issues (Section 19.3), and available monitoring methods (Section 19.4).

19.2 Why Monitor?

The reasons for monitoring for a multipathway risk assessment are identical to those noted earlier for inhalation risk assessments (Chapter 10):

- Measuring existing concentrations of air toxics in specific locations (e.g., soils in a schoolyard) and/or food items (e.g., fish from a lake within the study area) for purposes of developing estimates of exposure;
- Developing or refining values for specific parameters needed by multimedia models;
- Evaluating the predictions of a model in specified circumstances (e.g., estimates of sediment concentrations resulting from deposition and runoff);
- Closing gaps that might be present in existing data (e.g., gaps in emissions inventory); and
- Providing compliance/enforcement information as to whether a given facility or set of sources is meeting regulatory or permit requirements.

Monitoring for Evaluation of Multimedia Modeling

For multipathway risk assessments, monitoring is a valuable tool for evaluating model predictions because multimedia modeling is more complicated and involves more uncertainties than does air quality modeling. When using samples to evaluate model predictions, however, it is important to realize that **monitored concentrations may be greater than model predictions** because sources other than those being modeled may have contributed to the contamination.

19.3 Planning and Implementing Issues

The planning and implementation processes for multipathway risk assessment monitoring programs are similar to those for air monitoring programs discussed in Chapter 10. The planning process involves a step-wise integration of data quality and data sampling and analysis processes that are consistent with the study-specific conceptual model (CM), quality assurance project plan (QAPP), and data quality objectives (DQO) process. Many of the general planning and implementation issues for air monitoring programs also apply to multimedia modeling. Some additional considerations arise because the sampling and analysis program might include soils, surface waters, sediments, fish, meat, vegetables, milk, and other human food items. The scale and scope of monitoring could be much greater (e.g., multiple media could be sampled), and issues specific to ingestion need to be considered (e.g., what parts of plants and animals do people eat?).

- **Monitoring or sampling methods should be appropriate for the compounds and environmental media to be measured**. They must have the sensitivity needed to monitor at the levels likely to be of health and/or regulatory concern.

- **Monitoring sites and frequency of monitoring should be appropriate for the spatial and temporal variation of the chemical being measured and the monitoring objective**. Typically, an exposure location (e.g., a water body, a property, an agricultural field) or source (e.g., milk from cows on a specific farm) is defined for the risk assessment. The monitoring program should be adequate to represent the spatial and temporal variation within the location or source, given the particular measure(s) used to support the risk management decision to be made (e.g., average exposure, maximum exposure). However, several aspects of spatial and temporal variation are unique to air toxics that persist and which also may bioaccumulate. For example:
  - The temporal patterns of releases from sources may be less important because the chemicals may slowly accumulate in media and biota over time;
  - Spatial "hot spots" of contamination may occur (for example, if soils erode and collect in low-lying areas);
  - Chemicals generally accumulate in different tissues at different rates; therefore, concentrations may be higher in certain parts of the plant or animal (which may or may not be the parts that people tend to eat, and vice versa);
  - Certain seasonal effects (e.g., growing season for plants, migratory movements in animals) may be important sources of variation; and
  - Age of the plant or animal being sampled may be important if it takes many months or years for contaminants to reach equilibrium in biological tissues (or if equilibrium is never reached). For example, mercury concentrations in fish tend to be higher in older, larger fish.

- **The monitoring effort should consider the relative contributions of the four main sources of variability in measurements**. As noted in Chapter 10, these are analytical, sampling, temporal, and spatial.

- **Standard operating procedures should be defined and followed** both in the field (during sample collection) and in the laboratory (during sample analysis). These include procedures related to sample collection, sample transport and storage (including prevention of sample degradation), sample analysis, "chain of custody," audits, data validation, and data reporting. These procedures may be quite varied due to the range of possible media and biota that could be sampled.

- **Limits of quantitation or detection should be determined and compared** against relevant decision needs, including health benchmarks and likely environmental levels.

- **Measurement processes should be properly calibrated** to ensure the accuracy of the method.

- **Results must be adequately recorded and archived**. The best monitoring program can be compromised by a failure to keep proper records that can be made part of the public record.

A periodic, random check of the archived records (e.g. computer files) should be made against "hard copies" to ensure the integrity of the process of recording the data.

Soil Depth: Issues for Sampling

The depth over which surface soils are sampled should reflect the type of exposure expected in the study area, the type of receptors expected in the study area, the depth of biological activity and the depth of potential contamination. Careful consideration of the size, shape, and orientation of sampling volume is important since they have an effect on the reported measured contaminant concentration values.[1] Selection of sampling design and methods can be accomplished by use of the Data Quality Objectives (DQO) process discussed in Chapter 6. Additional soil sampling guidance that may be consulted includes EPA's *Preparation of Soil Sampling Protocols: Sampling Techniques and Strategies* and *Guidance for Data Usability in Risk Assessment* and *Soil Screening Guidance*, available at: http://www.epa.gov/superfund/programs/risk/tooltrad.htm#dbhh.[2]

19.4 Monitoring and Sampling Methods, Technologies and Costs

19.4.1 Method Selection

Method selection for sample collection and analysis programs that are applicable to multipathway human health risk assessments are dependent on numerous aspects of the project. Factors such as media, sample types, sample program designs, lead regulatory authority, and concentration ranges of concern all can impact the selection of the appropriate methods. While it is not possible for this chapter to review all of the monitoring methods available for this broad range of applications, several of the more important factors that generally influence decisions on methods selected are discussed below.

The primary determining factor in selection of sample collection and analysis methodologies is the sample media to be evaluated. Exhibit 19-1 presents several examples of the types of media that might be sampled for a multipathway human health risk assessment.[a] Other factors that affect selection of sample collection methods are sample type and sample program design. Specific factors in selection of sample collection methods may also be construction material of the sampling devices, its design, decontamination, and proper use, site-specific conditions, relative cost, and data quality limitations.

Sample collection methods may be categorized by sample type as discussed in Chapter 10. However, the distinction is not always clear (e.g., a single fish tissue sample might be considered a grab sample because it is collected at a single location and time; however, because the contaminant concentrations in its tissues accumulate over time, the sample could also be considered a time-integrated sample). The more common types of samples used for non-air sampling are provided below:

- **Grab samples** (also known as discrete samples) are collected at a specific location (and generally instantaneous) time. Any technique where the sampling container is filled to represent a snapshot of the concentration of target contaminants at a single specific time is

[a] Air sampling also may be conducted; however, that is discussed in Chapter 10.

considered a grab sample. Where the population to be represented is demonstrated to be homogenous or consistent, grab samples provide the maximum information.

- **Time-integrated samples** are collected at a single location but over an extended period of time. Similar to grab samples, analysis of time-integrated samples provides a snapshot of that range of time and location as a single value. Only the total pollutant collected is measured, and so only the average concentration during the sampling period can be determined.

Exhibit 19-1. Examples of Environmental Media that May be Sampled for Multipathway Human Health Risk Assessment [(a)]

Medium	Comments
Surface Water	Generally sampled only if used as a drinking water source
Soils	Generally sampled within the top few inches of the surface, where ingestion exposure or erosion may occur, but other considerations may require a different soil sampling depth
Sediments	Generally sampled to support assessments of bioaccumulation in aquatic systems (in more rare instances, sediments might support a dermal assessment of exposure to the sediments themselves)
Fish	Generally focused on species and parts of the fish that people eat (although this may vary regionally; e.g., some native cultures may routinely eat the entire fish)
Vegetables and other crops	Generally focused on the plants and parts of plants that people eat and/or are fed to livestock
Dairy products and other foods	Generally focuses on milk and other dairy products; eggs and meat are also sometimes evaluated

[(a)] Note that this list is not exhaustive; additional types of samples might be appropriate for a given risk assessment.

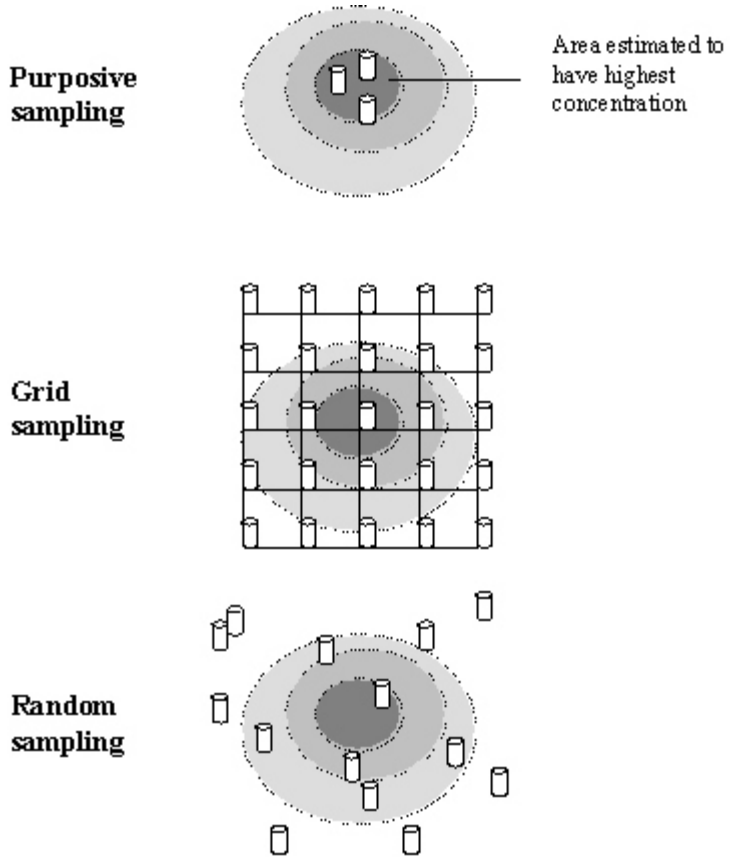
- **Composite samples** represent combinations of discrete samples, which may be collected either at different times or from different locations, that are combined into a single sample for analysis. Composite samples can be helpful when the amount of material that can be obtained from a single sample is very small (e.g., fish tissue), and the analytical quantitation limit can be lowered if the sample mass is increased (e.g., by combining multiple samples into a single composite sample for analysis). Composite samples also can be helpful when resources for laboratory analysis are limited, as they provide an estimate of average concentration across multiple samples, with the analysis cost of only one sample. The greatest drawback to composite samples is that they do not allow for an understanding of the variation in concentration values among the individual samples collected.

- **Continuous samples** provide essentially real-time measurements over time from a single, specific location. Continuous measurements typically involve real-time measurements, because samples cannot be practically collected to provide true continuous data. Continuous monitoring data frequently are evaluated as a function of concentration over the time period

analyzed. Depending on the application, maximum, median, time-weighted average, or distribution curves may be applied to reduce the large amount of results obtained from true continuous data to usable results which can be compared to decision criteria.

Sample collection methods may also be determined by the sample collection design methodology (Exhibit 19-2). Sample design impacts method selection often by determining the number of samples being collected.

Exhibit 19-2. Common Types of Sampling



Purposive sampling focuses the sampling effort in specific locations (in this example, the area estimated to have the highest concentration). Grid sampling consists of regularly-spaced samples in a predetermined grid. Random sampling consists of samples in locations selected by chance.

- **Purposive** sampling involves focused sample collection based on previous knowledge of release event locations. Purposive (also called biased) sampling is named such because the person taking the sample willfully takes that sample at a time or place where, based on prior knowledge, it is expected that concentrations will generally be biased high. Purposive sampling may be desired in programs looking to verify expected model results. Purposive sampling often targets maximum contaminant conditions to evaluate maximally impacted areas. However, it may be used for reasons such as targeting specific species to calibrate bioaccumulation models or defining the spatial extent of contamination.

- **Systematic** sampling consists of collecting samples at locations and times according to specific patterns (e.g., grid sampling). Systematic sampling may use previous knowledge to set frequency, density, or coverage of sampling.

- **Random** sampling involves collecting samples from locations in a manner such that each location has an equal probability of being sampled and analyzed. Random sample collection designs are an important aspect of certain statistical data evaluations.

The factors which primarily affect selection of preparation and analysis methods include target contaminants, required reporting limits (i.e., concentration range of decision criteria), number of samples, data quality limitations, method/instrument portability, previous data comparability, acceptance/approval by regulators and stakeholders, and relative cost and availability.

- **Target contaminants**. The specific contaminants being sampled may have a significant impact on both budget and overall approach. For example, sampling and analytical procedures for metals are different than those for organic chemicals. Careful evaluation before inclusion of unwarranted parameters and establishment of a procedure for identification and removal of chemicals of potential concern (COPCs) is critical to an effective monitoring program.

- **Required reporting limits**. Assessors should select analytical methods so that the reporting limits (usually the estimated quantitation limits) are less than the effects concentrations of interest. If the assessor does not select an adequately sensitive analytical method, the quantitation limit for a given chemical could exceed the chemical's effects benchmark concentration of interest; in that case, monitoring information would not provide meaningful input to the risk assessment.

- **Number of samples**. A sampling program that involves screening-level assessment of a large number of samples may drive selection of certain methods for the bulk of samples in order to allocate limited resources. In the opposite case, determination of low heterogeneity of sample media, and extremely low risk-based concentrations of interest as decision criteria may require fewer samples and more highly sophisticated methodologies.

- **Data quality limitations**. High data quality requirements imposed by high uncertainty or other factors may influence the choice of sampling methods such as procedures that are more stringent and more costly than usual procedures.

- **Method/instrument portability**. In-field or on-site analysis has begun to replace laboratory-based analysis in many monitoring programs. Certain preparation and analysis methodologies are more portable than others, in part because of the sensitivity of the instrumentation. However, considerable expertise in sampling and analysis is needed to decide whether in-field or laboratory-based analysis is appropriate for the study.

- **Previous data comparability**. Previous data sets can affect selection of appropriate methods. All other factors being equal, data comparability goals and objectives are more easily met by use of consistent methods.

- **Stakeholder input**. Stakeholder preferences may influence method selection.

- **Relative Cost/Availability**. The reality of limited resources often impacts method selection. Certain monitoring methods are commonly performed and available at numerous laboratories or by readily available field instrumentation. Other more obscure methods may better meet the needs of the project but are only available from highly specialized laboratories. In addition to cost impact, low availability of some specific monitoring methods can impact data quality due to lack of practice, market competition, appropriate standards, or certifications.

19.4.2 Available Methods

Hundreds of specific sampling, test, analysis, and quality assurance methods and procedures exist for soil, water, sediment, and biota. The list of available methods changes frequently as new methods are introduced and older methods are retired. It is not possible for this chapter to review all of the monitoring methods available. Instead, this section provides an overview of several key EPA resources and provides a listing of web sites that serve as sources of additional information. Key EPA resources include the *EPA Test Methods Index*; the Contract Laboratory Program (CLP); and the Fish and Wildlife Advisories Program.

- ***EPA Test Methods Index*** (http://www.epa.gov/epahome/Standards.html). EPA has developed hundreds of specific sampling, test, analysis, and quality assurance methods and procedures. In response to frequent requests for agency test methods, Region 1 Library staff developed a methods index as a tool to help locate copies. Confirming that there was no single volume containing all agency methods and no comprehensive list of them, the project commenced and in 1988 printed the first *EPA Test Methods Index*.[3] It has been updated periodically to reflect new procedures and revoked methods, and the current edition includes about 1,600 method references. The index includes only EPA methods, and its primary goal remains as a reference tool to identify a source from which the actual method can be obtained, either free or for a fee.

- **EPA Contract Laboratory Program**. The Contract Laboratory Program (CLP) is a national network of EPA personnel, commercial laboratories, and support contractors whose fundamental mission is to provide data of known and documented quality, primarily for the Superfund program (http://www.epa.gov/superfund/programs/clp/about.htm). The Analytical Operations/Data Quality Center (AOC) provides several tools to assist CLP clients, laboratories, and samplers (http://www.epa.gov/superfund/programs/clp/tools.htm). These tools were designed to use the Internet to facilitate many of the essential functions of the CLP.

Available Guidance from EPA's Contract Laboratory Program

Contract Laboratory Program National Functional Guidelines for Low Concentration Organic Data Review EPA-540-R-00-006 June 2001

Contract Laboratory Program National Functional Guidelines for Organic Data Review EPA-540/R-99-008 (PB99-963506) October 1999

Contract Laboratory Program National Functional Guidelines for Inorganic Data Review EPA 540-R-01-008 July 2002

Contract Laboratory Program National Functional Guidelines for Chlorinated Dioxin/Furan Data Review EPA-540-R-02-003 August 2002

Contract Laboratory Program Guidance for Field Samplers (Draft-Final) EPA-540-R-00-003 April 2003

This information, as well as methodology information is available from the CLP at: http://www.epa.gov/superfund/programs/clp/services.htm

- **EPA's Fish and Wildlife Advisories Program** (http://www.epa.gov/waterscience/fish/). EPA's Office of Science and Technology provides technical and outreach material that support efforts by state, local, and tribal (S/L/T) governments to protect their residents from the health risks of consuming contaminated noncommercially caught fish. S/L/T governments do this by issuing consumption advisories for the general population as well as for specific vulnerable sub-populations. These advisories tell the public when high concentrations of chemical contaminants have been found in local fish. They also include recommendations to limit or avoid eating certain fish species from specific water bodies or water body types. The program also provides *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories* (http://www.epa.gov/waterscience/fish/guidance.html), a set of four volumes that provides guidance for assessing health risks associated with the consumption of chemically contaminated non-commercial fish and wildlife. The set includes Third Editions of Volume 1: *Fish Sampling and Analysis* and Volume 2: *Risk Assessment and Fish Consumption Limits*.

Exhibit 19-3 provides links to information on specific sampling and analysis methods, summarized from key EPA compendia of methods. Methods are divided into four categories (General, Analytical Method Index, Sample Collection, and Quality Assurance). Keywords are added to help readers get to the area they are concerned with. Additional effort may be required to "drill into" each site to view the relevant information. These links generally are limited to government sites. Some non-EPA sites are included (e.g., Occupational Safety and Health Administration (OSHA), National Institute of Standards and Technology (NIST), and National Institute for Occupational Safety and Health (NIOSH)) to help fill specific information gaps.

Exhibit 19-3. Sources for Information on Specific Sampling and Analysis Methods	
Keywords	**Description and URL Link**
General References	
Sample collection, analysis method, criteria, water	General EPA Water page with links to analytical methods, sampling guidance, and criteria for assessment of contamination. http://www.epa.gov/waterscience/
Analysis methods	EPA' s Office of Ground Water and Drinking Water (OGWDW) links to analysis methods. http://www.epa.gov/OGWDW/methods/methods.html
Sample collection, analysis methods, reference	NIOSH pocket guide to chemical hazards contains information by analyte which can support field sample collection, analysis, and determination of relevant criteria. http://www.cdc.gov/niosh/npg/npg.html
Sample collection, analysis methods, reference	NIST web book contains information by analyte which can support field sample collection, analysis, and basic chemical parameters from thermodynamic constants to reference mass spectra. http://webbook.nist.gov/chemistry/
Sample collection, analysis methods, reference	General EPA environmental test methods and guidelines page with numerous links to other areas of information throughout EPA web sites. http://www.epa.gov/epahome/Standards.html
Analysis Method Index	
Analysis methods, sample collection	Region I list of methods available as hardcopy and partial links to analysis methods. http://www.epa.gov/epahome/index/
Analysis methods, sample collection	Searchable online database of analysis methods. NEMI is a project of the National Methods and Data Comparability Board, a partnership of water quality experts from Federal agencies, States, Tribes, municipalities, industry, and private organizations supported by EPA and the U.S. Geological Survey. http://www.nemi.gov
Analysis methods, sample collection	National Exposure Research Laboratory (NERL) formerly EMSL, Manual of Manuals links to information about analysis methods; summaries and ordering information for eight laboratory analytical chemistry methods manuals published by the former Environmental Monitoring Systems Laboratory-Cincinnati (EMSL-Cincinnati) between 1988 and 1995. http://www.epa.gov/nerlcwww/methmans.html
Analysis Methods	
Analysis methods, water	EPA's Office of Water link to analysis methods. Laboratory analytical methods that are used by industries and municipalities to analyze the chemical and biological components of wastewater, drinking water, sediment, and other environmental samples that are required by regulations under the authority of the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). http://www.epa.gov/waterscience/methods/
Analysis methods, water, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 624, 625, 1624, 1625	Methods for organic chemical analysis under the authority of the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). http://www.epa.gov/ostwater/methods/guide/methods.html

Exhibit 19-3. Sources for Information on Specific Sampling and Analysis Methods	
Keywords	**Description and URL Link**
Analysis methods, drinking water	Recent drinking water methods from EPA's Office of Research and Development, National Exposure Research Laboratory (NERL), formerly the Environmental Monitoring Systems Laboratory (EMSL). http://www.epa.gov/nerlcwww/ordmeth.htm
Organic, analysis methods, drinking water	Organic method index with hyperlink to method by analyte in drinking water as maintained by Office of Ground Water and Drinking Water. http://www.epa.gov/OGWDW/methods/orch_tbl.html
Inorganic, metal, analysis methods, drinking water	Inorganic and metal analysis methods in drinking water as maintained by Office of Ground Water and Drinking Water. http://www.epa.gov/OGWDW/methods/inch_tbl.html
Analysis methods, drinking water, radionuclides	Radionuclides in drinking water as maintained by Office of Ground Water and Drinking Water. http://www.epa.gov/OGWDW/methods/rads.html (EPA) http://www.epa.gov/OGWDW/methods/indrads.html (non-EPA)
Analysis methods, drinking water,	Approved methods for unregulated contaminants in drinking water as maintained by Office of Ground Water and Drinking Water. http://www.epa.gov/OGWDW/methods/unregtbl.html
Analysis methods, drinking water,	Secondary contaminants in drinking water as maintained by Office of Ground Water and Drinking Water. http://www.epa.gov/OGWDW/methods/2nd_tbl.html
Analysis methods, immunoassay	Region 1 guidance on immunoassay methods. http://www.epa.gov/region1/measure/ia/iaguide.html
Analysis methods, CLP, organic, dioxin, inorganic, water, soil	Contract Laboratory Program (CLP) methods for organics, inorganics, and dioxins/furans. http://www.epa.gov/superfund/programs/clp/methods.htm
Analysis methods, air	EPA Emissions Measurement Center (EMC) for methods related to determination of airborne pollutants. http://www.epa.gov/ttn/emc/
Analysis methods, pesticide, soil, water	EPA' Office of Pesticide Programs (OPP) database of environmental chemistry, residual, and antimicrobial analysis methods. http://www.epa.gov/oppbead1/methods/
Analysis methods, water, soil, sediment, waste, air	EPA's OSWER provides online updated SW-846 waste sampling and analysis methods manual which is the source of many related methods used in environmental sampling and analysis. http://www.epa.gov/epaoswer/hazwaste/test/main.htm
Sample collection, analysis methods, air	Occupational Safety and Health index of sampling and analysis methods alphabetically by parameter and general information on selection of methods and laboratories. http://www.osha-slc.gov/dts/sltc/methods/index.html
Sample collection, analysis methods, air	EPA's Organic (TO) Compendium of methods for air toxics and EPA's Inorganic (IO) Compendium methods. http://www.epa.gov/ttn/amtic/airtox.html
Sample Collection	
Sample collection, analysis, fish, shellfish, biota	Methods for sampling and analyzing contaminants in fish and shellfish tissue. http://www.epa.gov/waterscience/fishadvice/volume1/index.html

Exhibit 19-3. Sources for Information on Specific Sampling and Analysis Methods	
Keywords	**Description and URL Link**
Sample collection	Current manuals and protocols prepared by NERL-Cincinnati scientists. NERL is the EPA's scientific lead for the following stream and source monitoring indicators: fish, macroinvertebrates, periphyton, zooplankton, functional ecosystem indicators, water and sediment toxicity and fish tissue contaminants. As part of their indicator lead responsibilities NERL-Cincinnati scientists prepare and update field and laboratory protocol and methods manuals for these indicators. http://www.epa.gov/nerleerd/methman.htm
Sample collection, monitoring wells, low stress	Guidance for RCRA/Superfund groundwater sample collection methodologies and the logical process for determining an approach fit to site specifics. http://www.epa.gov/tio/tsp/download/gw_sampling_guide.pdf
Sample collection, monitoring wells, low stress	Generally well accepted low stress (low flow) ground water sample collection guidance from EPA Region I. Several versions exist across EPA regions and within other governmental and State guidelines. http://www.epa.gov/region1/measure/well/wellmon.html
Sample collection, field analysis	EPA Environmental Response Team provides numerous sampling and field analysis Standard Operating Procedures (SOPs) often encountered in environmental responses including otherwise atypical sample collections SOPs such as drum, wipe, and waste pile sampling techniques. http://www.ertresponse.com/sops.asp
Sample collection, field analysis, program design	EPA's Office of Technology Innovation provides a web site with information on proper sampling program design, QA/QC concerns, and use of field methodologies to expedite information collection without loss of data quality. http://clu-in.org
Quality Assurance	
Quality assurance	EPA Agency-wide quality system documents for EPA and non-EPA organizations plus general guidance. Documents are available as PDFs. http://www.epa.gov/quality/qa_docs.html
Quality assurance	Region I guidance includes quality assurance documents. http://www.epa.gov/region1/lab/qa/qualsys.html

References

1. U.S. Environmental Protection Agency. 2000. *Draft Ecological Soil Screening Level Guidance*. Office of Emergency and Remedial Response. July 10, 2000.

2. U.S. Environmental Protection Agency 1992. *Guidance for Data Useability in Risk Assessment (Part A)*. Office of Emergency and Remedial Response, Washington, D.C., April 1992. Publication 9285.7-09A, PB92-963356. Available at: http://www.epa.gov/superfund/programs/risk/datause/parta.htm

   U.S. Environmental Protection Agency 1992. *Preparation of Soil Sampling Protocols: Sampling Techniques and Strategies*. Office of Research and Development. EPA/600/R-92/128. Available at: http://www.epa.gov/superfund/programs/risk/tooltrad.htm#dbh

   U.S. Environmental Protection Agency 1996. *Soil Screening Guidance: User's Guide*. Office of Solid Waste and Emergency Response. Washington, D.C., July 1996. EPA540/R-96/018. See especially Attachment B, *Soil Screening DQOs for Surface Soils and Subsurface Soils*. Available at: http://www.epa.gov/superfund/resources/soil/index.htm#user

   U.S. Environmental Protection Agency. 2002. *Supplemental Guidance For Developing Soil Screening Levels for Superfund Sites*. Office of Solid Waste and Emergency Response, Washington, D.C., December 2002. OSWER 9355.4-24. Available at: http://www.epa.gov/superfund/programs/risk/tooltrad.htm#dbh

3. U.S. Environmental Protection Agency. 1988. *EPA Test Methods Index*. EPA 901/388/001.

Chapter 20 Exposure Metrics for Multimedia Assessment

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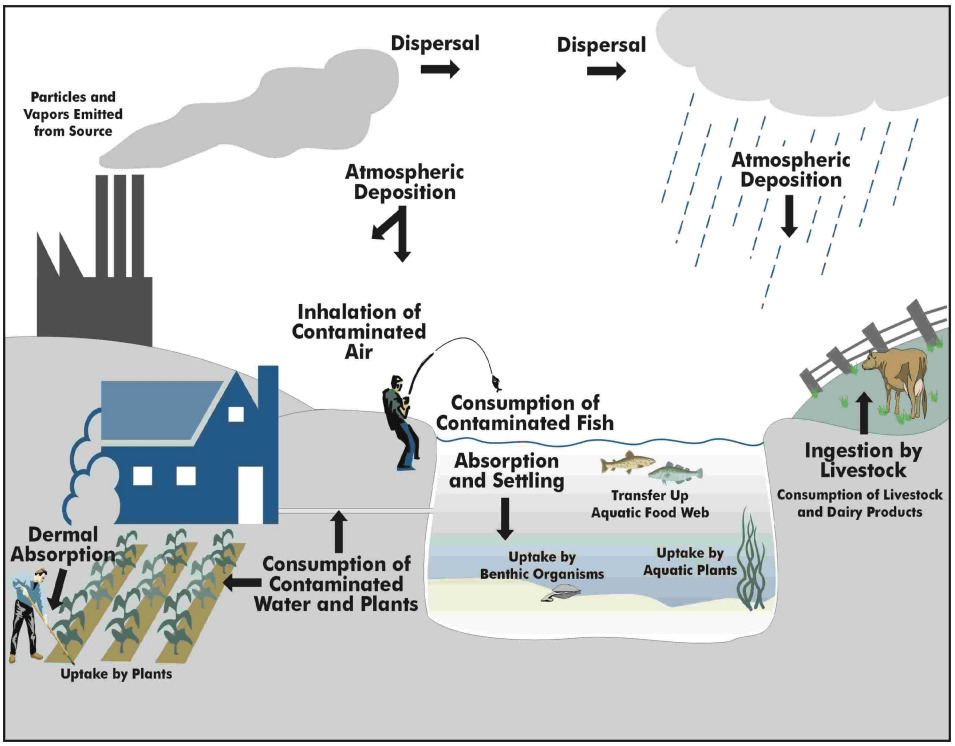
20.1 Introduction

This chapter concludes the exposure assessment component of the multipathway risk assessment by describing how to develop estimates of intake (i.e., the metric of exposure) for the ingestion pathways selected for analysis. Estimates of chemical intake via the inhalation pathway were presented in Chapter 11. Exhibits 14-2 and 20-1 provide an overview of the potential multimedia exposure pathways by which air toxics that persist and potentially bioaccumulate may reach ecological and human receptors, respectively. Determination of chemical intake via the ingestion exposure route combines the estimates of chemical of potential concern (COPC) levels in food items and drinking water (discussed in Chapter 7) with estimates of consumption rates (food, water), exposure frequency and duration, averaging time, and body weight to derive estimates of the **chemical intake rate** (expressed generally as mg/kg-day).[1]

Exhibit 20-1. Potential Multimedia Exposure Pathways of Concern



This graphic illustrates many of the potential multimedia pathways of concern for air toxics. Air toxics released from a source disperse through the air and eventually fall to the earth (atmospheric deposition) via settling and/or precipitation. Air toxics deposited to soil may be absorbed by plants that are then harvested for human consumption. Humans may be exposed via ingestion of contaminated plants and soils, or by consuming contaminated terrestrial animals (e.g., beef, for those air toxics that bioaccumulate and transfer up the terrestrial food web). Air toxics deposited to water may be dissolved in the water column and/or may settle and be absorbed into aquatic sediments. Air toxics in sediments and the water column may be absorbed by aquatic plants (uptake). Aquatic organisms (e.g., fish) may be exposed directly to air toxics in the water column and/or by consuming other contaminated aquatic organisms (for those air toxics that bioaccumulate and transfer up the aquatic food web) or sediments. People may be exposed to air toxics by eating contaminated aquatic plants, fish, or shellfish and/or by drinking contaminated water. Note also that, while in the atmosphere, air toxics may also have direct impacts to humans via inhalation.

Chapter 7 described two general approaches for deriving the exposure concentration (EC) for an inhalation risk assessment: (1) use of ambient air concentrations as a surrogate for the EC, and (2) exposure modeling that combines estimates of ambient air concentrations with information about the population of interest, including the types of people present (e.g., ethnicity, age, sex), time spent in different microenvironments, and microenvironment concentrations. **The first approach (i.e., use of ambient concentrations in abiotic media such as soil, water, or sediments) generally is not used for multipathway air toxics risk assessments. Instead, a multipathway exposure assessment must involve some type of exposure modeling** (e.g., at a minimum simple scenarios to characterize persons who are exposed and the amount and duration of their contact with the abiotic and biotic media).

Note that EPA has derived some human health screening-level concentration benchmarks for surface water and soil (i.e., the Office of Water's Ambient Water Quality Criteria for the Protection of Human Health,[2] and the Superfund Program's soil screening levels[3]). However, these human health benchmarks are based on specific scenarios (e.g., how much water a person drinks each day, how much they weigh) that were selected to meet different programmatic goals and statutory requirements. Therefore, the scenarios on which these benchmarks are based may not be appropriate for a specific air toxics risk assessment.

The way a chemical enters the body and eventually reaches the target organ is a complex process (see box below). For most chemicals, however, it is not necessary to quantify anything beyond the chemical **intake rate**, because the dose-response value (e.g., Reference Dose [RfD] or Cancer Slope Factor [CSF]) is also based only on the amount of chemical ingested and not the amount of chemical that has been absorbed into the bloodstream.

Exposure and Intake via Ingestion

The process of a chemical entering the body can be described in two steps: **exposure** (contact), followed by **entry** (crossing the boundary). **Intake** involves physically moving the chemical in question through an opening in the outer boundary (usually the mouth), typically via eating or drinking. Normally the chemical is contained in a medium that comes into contact with the body, such as food or water, and the concentration of the chemical at this point of contact is called the **exposure concentration**. The estimate of how much of the chemical enters into the body is based on how much of the carrier medium enters the body. The **chemical intake rate** is the amount of chemical crossing the outer boundary per unit time, and is the product of the exposure concentration times the ingestion rate. **Ingestion rate** is the amount of the carrier medium crossing the boundary per unit time, such as the number of kilograms of food ingested/day or liters of water consumed/day. Ingestion rates typically are not constant over time (they can vary over time and among individuals) and are usually given (for deterministic analyses) as an average intake rate over some period of time. In addition, the intake rates are usually normalized to body weight. Thus, a common intake rate would take the form of milligrams of pollutant ingested per kilogram of body weight per day (or mg/kg-d). A different ingestion rate would be developed for each type of person in the population under study. For example, one intake rate could be developed to represent the average adult (male and female) while a separate intake rate could be developed to represent children between the ages of birth to four years old.

The remainder of this chapter focuses on how to quantify ingestion exposure (intake) for multipathway air toxics risk assessments. The corresponding chapter for inhalation analyses

(Chapter 11) discusses how to evaluate uncertainty in the exposure assessment and how to present the exposure assessment results; this applies to all exposure evaluations (i.e., inhalation and ingestion).

20.2 Generic Equation for Dietary Intake

Equation 20-1 is the generic equation used to calculate dietary chemical intake:[4]

$$I = \frac{EC \times CR}{BW} \times \frac{EF \times ED}{AT} \qquad \text{(Equation 20-1)}$$

where

I = Chemical intake rate, or the amount of pollutant ingested per unit time per body weight (mass), expressed in units of mg/kg-day. For evaluating exposure to noncarcinogens, the intake is referred to as Average Daily Dose (*ADD*); for evaluating exposure to carcinogenic compounds, the intake is referred to as Lifetime Average Daily Dose (*LADD*).

Chemical-related variable:

EC = Exposure concentration of the chemical in the medium of concern for the time period being analyzed, expressed in units of mg/kg for soil and food or mg/L for surface water or beverages (including milk).

Variables that describe the exposed population (also termed "intake variables"):

CR = Consumption rate, the amount of contaminated medium consumed per unit of time or event (e.g., kg/day for soil and L/day for water).
EF = Exposure frequency (number of days exposed per year).
ED = Exposure duration (number of years exposed).
BW = Average body weight of the receptor over the exposure period (kg).

Assessment-determined variable:

AT = Averaging time, the period over which exposure is averaged (days). For carcinogens, the averaging time is 25,550 days, based on an assumed lifetime exposure of 70 years; for noncarcinogens, averaging time equals *ED* (years) multiplied by 365 days per year.

The values of some exposure factors depend on site conditions as well as the characteristics of the potentially exposed population (e.g., child vs. adult). Because of differences in physiology and behavior, exposures among children are expected to be different than exposures among adults. For example, body weight and consumption rate differ for children and adults. For the evaluation of non-carcinogenic effects, intakes for children generally are estimated separately (often for ages 0-6) than for adults (often from ages 6-beyond). For the evaluation of carcinogenic effects, intake estimates are averaged over the assumed lifetime (70 years).

20.3 Estimating Exposure Concentrations

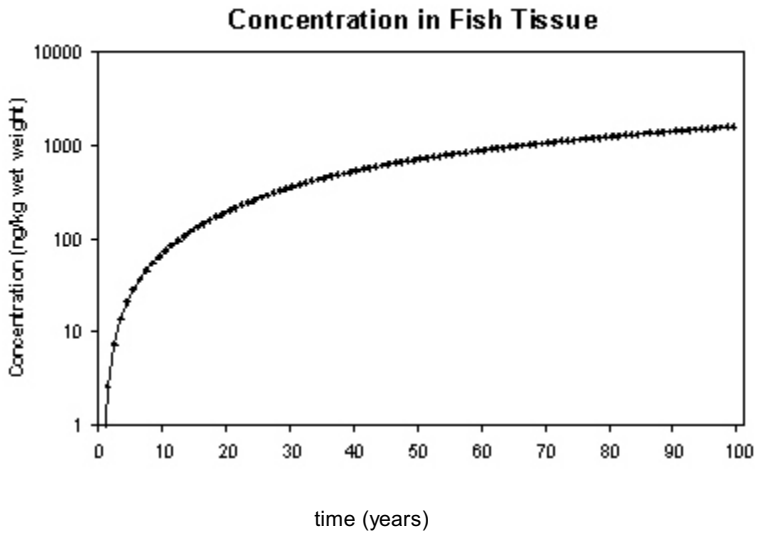
The exposure concentration for a chemical is calculated separately for each food item and environmental medium of concern. The value of these variables may be determined by modeling (Chapter 18), monitoring (Chapter 19), or a combination of both. The specific algorithms for determining these concentrations will depend on the specific models and/or sampling and analysis techniques used. For example, EPA has developed methodologies for estimating EC values in soil, water, sediment, and various food items for releases from hazardous waste combustion facilities (see Appendix L).[5]

For ingestion pathways, the specific media concentration values obtained from a multimedia modeling simulation for use in deriving exposure concentrations depends on several important decisions made during problem formulation, including:

- Choice of modeling duration for a model run;
- Choice of the year or years of the model run on which to base the EC; and
- Choice of a specific ED.

Exhibit 20-2 presents several different examples relevant to different purposes/objectives for an assessment.

Exhibit 20-2. Example Decisions in Assessing Exposures Resulting From Distribution of Air Toxics into Other Media



In this hypothetical example, a modeling analysis was used to predict the concentrations of a persistent bioaccumulative hazardous air pollutant (PB-HAP) in fish tissue during a 100-year emissions scenario (annual average was estimated each year and is plotted here using a logarithmic scale). As discussed below, the exposure scenario assessed will reflect several key choices including:

(1) choice of modeling duration for model run;
(2) choice of year or years of model run on which to base EC (i.e., the model outputs); and
(3) choice of specific ED.

Exhibit 20-2 (continued)

The modeling duration is a separate decision from the ED and is not related to the average human lifespan.

Note that in this example, the analyst assumed that the starting concentration was zero (i.e., the tissue concentrations reflect only the sources being modeled). Some multimedia models (e.g., TRIM.FaTE) can start with an initial concentration.

Modeling Duration. The analyst can choose to run a multimedia model for any period of time. Duration will usually be chosen to reflect the expected duration of emissions from the source(s) being evaluated or, perhaps, that duration expected in order to reach steady-state conditions. A common duration is 30 or 40 years (e.g., the expected lifespan of many facilities or processes). For this example, a 100-year duration was selected.

Selection of Model Outputs. Usually the modeling duration will have been chosen with consideration of the model outputs on which the exposure scenario is to be based and the exposure duration. Some common examples follow:

- **Year of maximum concentration**. Screening-level analyses often use the maximum concentration reached during the modeling period which, for a constant emissions scenario, will usually be the final year of the modeling simulation. For this example (see figure), it would be the 100th year (at such time as the fish concentration was approximately 2,000 ng/kg).
  - **Exposure Duration.** With use of the maximum model result, the analysis presumes no change in fish concentration over the exposure duration (i.e., in this example EC = 2,000 ng/kg throughout the exposure period).

- **Initial years of simulation.** In this case the exposure being assessed is that beginning with initiation of emissions and extending through the duration selected for assessment.
  - **30-year Exposure Duration**. In this case, the analyst is basing the exposure duration near the 95 percentile of how long people live in the same home.[(6)] If the analyst chose to examine changing concentrations over time, the ECs would vary, reflecting the concentration outputs from the first 30 years of the modeling duration.
  - **70-year Exposure Duration.** In this case, the analyst is using a lifetime exposure assumption. The exposure scenario then may be based on the model outputs from the first 70 years of the modeling duration.

- **Last years of simulation.** In this case, the exposure being assessed is that which occurs during the ending years of the simulation, with the number of years involved equal to the exposure duration selected for assessment.
  - **30 -year Exposure Duration.** For this ED, the ECs would vary reflecting the predicted concentrations from the last 30 years of the model simulation.
  - **70-year Exposure Duration.** In this case, the analyst is using a lifetime exposure assumption. The exposure scenario may then employ varying ECs reflecting the predicted concentrations from the last 70 years of the model simulation.

Note: When using varying exposure concentrations for the exposure scenario, other variables included in the calculation of ingestion exposure estimates (pollutant intake, mg/kg-day) for the population(s) of interest may also vary. For example, if the exposure scenario includes exposure for cohorts aging from birth - 30 years, other exposure factors (e.g., body weight, consumption rate) will also vary over time.

20.4 Calculating Intake Variable Values

Each intake variable in Equation 20-1 (e.g., consumption rate, body weight) has a range of potential values. Intake variable values for a given pathway may be selected so that the combination of all intake variables results in an estimate for an individual at the "high-end" of potential exposure levels. Alternatively, the intake variables may be selected to represent a "central tendency" individual expected to receive an average exposure. In doing this, the assessor needs to avoid combinations of parameter values that are inconsistent (e.g., low body weight used in combination with high dietary intake rates), and must keep in mind the ultimate objective of being within the distribution of actual expected exposures and doses, and not beyond it. Commonly, both the central tendency and high end intakes are quantified. In some cases, the distribution of intake rates in the population may be described using probabilistic risk assessment methods (discussed in Part VI).

EPA recommends values for intake variables for the U.S. population in the *Exposure Factors Handbook*,[7] the *Child-Specific Exposure Factors Handbook*,[8] and the *Consolidated Human Activity Database*.[9][a] EPA also recently published draft guidance on selecting the appropriate age groups for assessing childhood exposures.[10] Note, however, that there are likely to be differences between recommended default, and regional and site-specific, exposure parameter values. This may be especially true for consumption rate (see below).

For **central tendency** estimates, risk assessors commonly set all of the exposure factors in the Equation 20-1 at central tendency values. If only limited information on the distribution of the exposure or dose factors is available, risk assessors commonly approach the **high-end** estimates by identifying the most sensitive variables and using high-end values for a subset of these variables, leaving others at their central values. As mentioned earlier, the assessor needs to avoid combinations of parameter values that are inconsistent (e.g., low body weight with high dietary intake rates) and must keep in mind the ultimate objective of being within the distribution of actual expected exposures and doses.

Maximizing all variables will in virtually all cases result in an estimate that is above the actual values seen in the population. When the principal parameters of the dose equation (e.g., concentration [appropriately integrated over time], intake rate, and duration) are broken out into sub-components, it may be necessary to use maximum values for more than two of these sub-component parameters, depending on a sensitivity analysis.

For **probabilistic analyses**, values for exposure factors are commonly allowed to vary according to specific assumed distributions of potential values.

Note that the high-end intake estimate is a plausible estimate of intake for those persons at the upper end of the exposure distribution. This descriptor is intended to estimate the exposures that are expected to occur in small but definable high-end segments of the subject population

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[a]NCEA recently published a new compilation of consumption data from the 1994-1996 CSFII. This data updates CSFII data in the 1997 Exposure Factors Handbook.
See: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=56610.

(but not higher than the highest person in the population), but may not be appropriate for estimating exposure for the population as a whole.[1]

20.4.1 Consumption Rate

Consumption rate is the amount of contaminated food or medium consumed per event or unit of time (e.g., amount of fish consumed per meal or per day). The consumption rate is multiplied by a fraction of the total dietary intake for this type of food or medium, representing the amount consumed from the study area. The specific fraction applied depends on the analysis.

- For screening-level analyses, it is common to assume that the person obtains 100 percent of the food type from the study area (e.g., farm, water body) being evaluated. This assumption also might be used for a subsistence-type receptor (e.g., a local fish consumer who only eats fish caught from the study area).

- For higher tiers of analyses, it is common to assume that the person obtains some of the food type from the study area (i.e., the contaminated fraction) and some of the food type from other sources (e.g., at the grocery store). This latter fraction generally is assumed to be uncontaminated by the source(s) under assessment. Thus, if a person is assumed to eat ½ pound of fish per day, but only 25 percent is caught within the study area, the assumed consumption of contaminated fish would be 1/8 pound per day.

The following pathway-specific considerations are important for estimating consumption rate.

- **Food Ingestion**. Plants and animals may accumulate COPCs that were deposited onto soil or water. Humans may be exposed to these compounds via the food chain when they consume these plants (and animals that consume these plants) as a food source. Human intake of COPCs is quantified on the basis of the concentration of COPC in the food (Section 20.3) and:
  - The types of foods consumed, which vary with age (e.g., children and adults often eat different things), geographical region, and sociocultural factors (e.g., ethnicity, cultural factors);
  - The amount of food consumed per day, which can vary with age, sex, and geographic region, and also within these categories;
  - The fraction of the diet contaminated by COPCs (which can vary by food type); and
  - The effect of food preparation techniques on concentrations of COPCs in the food itself.

- **Soil Ingestion**. Children and adults may receive direct exposure to COPCs in soil when they consume soil that has adhered to their hands (called incidental soil ingestion). Factors that influence exposure by soil ingestion include concentration of the COPC in soil, the rate of soil ingestion during the time of exposure, and the length of time spent in the vicinity of contaminated soil. Soil ingestion rates in children are based on studies that measure the quantities of nonabsorbable tracer minerals in the feces of young children. Ingestion rates for adults are based on assumptions about exposed surface area and frequency of hand-to-mouth transfer. Indoor dust and outdoor soil may both contribute to the total daily incidental ingestion of soil (indoor dust is partially made up of outdoor soil that has been tracked inside).

In addition, some young children – referred to as "pica" children – may intentionally eat soil. The typical medical and scientific use of the term "pica" refers to the ingestion of nonfood items, such as soil, chalk, and crayons.[10] Such behavior is considered a temporary part of a child's development. For risk assessment purposes, pica is typically defined as "an abnormally high soil ingestion rate" and is believed to be uncommon in the general population. If available information indicates that there are children exhibiting pica behavior in the assessment area, it may be appropriate to include these children as a separate group in the exposure assessment. EPA's *Exposure Factors Handbook* provides quantitative data on soil ingestion rates related to pica.[11]

Inhalation of soil resulting from dust resuspension by wind erosion generally is not a significant pathway of concern for air toxics.[5] However, it may be an issue for locations at which there is little vegetative cover. Methodologies have been developed to assess the exposure to pollutants resuspended by wind erosion for landfills and Superfund sites.[12] The exposure estimate from resuspended soil would depend on moisture content of the soil, fraction of vegetation cover, wind velocity, soil particle size, COPC concentration in the soil, and size of the contaminated area.

Depth of Contaminated Soils: A Key Variable

When exposures to COPCs in soils are modeled for human health risk assessment, an important factor affecting the exposure estimate is the depth of contaminated soils used to calculate soil concentrations. The same deposition rate will result in different soil concentrations depending on how deeply the COPCs are assumed to mix or migrate into the soil. Mixing depth also may affect exposure estimates via specific pathways. For example, in calculations of exposures resulting from uptake through plant roots, the average concentration of COPCs over the depth of the plant root determines plant uptake. However, calculations that assess soil ingestion through hand-to-mouth activity commonly focus on only the top few centimeters of soil.

COPCs deposited onto undisturbed soils generally are assumed to remain in the shallow, upper soil layer. However, COPCs deposited onto soil surfaces may be moved into lower soil profiles by tilling, whether manually in a garden or mechanically in a large field. Other factors such as soil disturbance by domestic animals (e.g., cattle in an enclosure) also may need to be considered. Some chemicals are also highly soluble in water and may be carried deeper into soil along with infiltrating rainwater. The key questions to ask therefore include:

- Are soils tilled, or is it reasonable to assume they are undisturbed?
- If soils are tilled, what mixing depth is reasonable to assume?
- What other factors might affect how deeply COPCs will be moved into soils?

EPA guidance and other references[5][13] provide a more detailed discussion of depth of contaminated soils, along with recommended values.

- **Ingestion of Drinking Water**. In air toxics assessments, assessors only evaluate the ingestion of drinking water when an affected surface water body or collected precipitation (e.g., a cistern) is used as a drinking water source.[b] Important factors affecting the concentration of COPCs in a surface water body include the location of the surface water body or precipitation collection apparatus relative to emissions sources; concentrations of COPCs in and characteristics of the soils (which affects runoff and leachate concentrations); and the size and location of the watershed. For drinking water, the exposure estimate is affected by:
  - The concentration of the COPC in the water;
  - The daily amount of drinkable water ingested; and
  - The fraction of time that the individual spends in the area serviced by that water supply system. (Note that for screening level analyses, 100% of drinking water may be presumed to come from the contaminated source.)

  Note that in estimated exposures associated with drinking water supplies, risk assessors commonly assume that the drinking water undergoes at least a minimum level of treatment to remove solids (i.e., particles in the water which are PB-HAPs or onto which PB-HAPs may be absorbed). Therefore, the risk assessment commonly focuses on the dissolved concentrations of PB-HAPs in drinking water sources.

Groundwater as a Source of Drinking Water

If site-specific circumstances suggest that groundwater may represent a potential concern (e.g., the presence of extremely shallow aquifers used for drinking water purposes or a karst environment in which the local surface water significantly affects the quality of ground water used as a drinking water source), the TRIM.FaTE library includes a groundwater compartment that can be used to assess the groundwater pathway. EPA's *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*[14] and *Draft Technical Background Document for Soil Screening Guidance*[15] discuss the methods for evaluating the groundwater pathway.

- **Ingestion of Fish**. Factors that affect human exposure by ingestion of fish from a surface water body include:
  - Sediment and water COPC concentrations;
  - The types of fish and shellfish consumed;
  - The portion of fish eaten (e.g., fillet only, fillet plus skin, whole body);
  - The effect of food preparation techniques on concentrations of COPCs in the fish;
  - Ingestion rates for the various fish and shellfish groups; and
  - The fraction of dietary fish caught in the surface water body or bodies being evaluated. (Note that for screening level analyses, 100 percent of fish/shellfish is presumed to come from the contaminated water body.)

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[b] Note that ingestion of contaminated groundwater generally is not a significant pathway of concern for air toxics risk assessments because most air toxics that persist and may bioaccumulate tend to get bound up in soil and, therefore, tend not to move readily into groundwater. However, if the groundwater pathway were a concern for a specific study, it would be evaluated in generally the same way as the ingestion of surface water pathway (i.e., as a drinking water source; however, depending on the circumstances, groundwater may or may not be treated to remove particles prior to consumption).

The types of fish consumed will affect exposure because different types of fish and shellfish accumulate COPCs at different rates. For example, fatty fish tend to accumulate lipophilic organic compounds more readily than lean fish. The amount of fish consumed also affects exposure because people who eat large amounts of fish will tend to have higher exposures. Fish consumption rates and the parts of the fish that are consumed can vary greatly, depending on geographic region and social or cultural factors. Also, because all of a person's dietary fish may not originate from the surface water body near the source of the PB-HAP, the fraction of locally caught fish is also a variable for exposure.

20.4.2 Exposure Frequency

The specific exposure frequency will depend on how the exposure analysis is set up. For example, a scenario-based analysis would specify one or more exposure frequencies for each defined scenario. A typical screening-level exposure frequency is 350 days per year; this number is based on the assumption that all people spend a minimum of two weeks at a location other than the exposure scenario location selected for analysis (e.g., on vacation).[(1) (5)] However, many activities vary on a weekly and/or seasonal basis. For example, recreational fishing is more likely to occur on weekends than on weekdays, and most areas in the U.S. have limited fishing and hunting seasons.

20.4.3 Exposure Duration

Exposure duration is the length of time over which exposure occurs (e.g., a lifetime or a particular residence time). As noted in Section 20.3 above, choice of ED will depend on many factors, including the purpose of the assessment or risk management decision, the tier of analysis, and the particular effect(s) of concern. There are no universally established ED values for risk assessments because different EDs may be appropriate in different situations. Some commonly used EDs include:

- Lifetime (70 years) – generally used for screening-level analyses;
- High-end number of years a person resides in a single location (about 30 years);
- Median number of years a person resides in a single location (about 9-10 years); and
- Seven years (ten percent of an assumed lifetime) – sometimes used for noncancer effects.

Although a source may remain in the same location for more than 70 years, and a person may have a lifetime of exposure to emissions from that source, U.S. Bureau of the Census data on population mobility indicate that many Americans do not always remain in the same area for their assumed 70-year lifetime.[(16)] An estimate of the number of years that a person is likely to spend in one area can be derived from information about mobility rate and median time in a residence.

Analysts may use long EDs when conducting simple screening analyses performed to determine if more complex analyses are necessary. The rationale for use of such EDs is that if risks are not of concern when the exposure duration is long, then they would not be of concern given other, shorter, exposure durations. (Typically analysts also make other conservative or "health-protective" assumptions when conducting this type of screening analysis.) Analysts may use specific EDs particular to the legal framework for the assessment. For example, the residual risk section of the Clean Air Act (CAA) references an Agency rulemaking for which one prominent

risk metric considered a 70-year exposure duration (see CAA section 112(f)(2) and 54 *Federal Register* 38044).

The type of risk metric being derived also influences the consideration of exposure duration. For example, when the analyst wants to describe central tendency risk based on a deterministic analysis, s/he typically will use mean or median exposure assumptions to calculate risk.[c] Similarly, when the analyst wants to describe high-end risk based on a deterministic analysis, s/he may use high-end exposure assumptions or a combination of central tendency and high-end exposure assumptions that provide a reasonable estimate of the individual risk for those persons at the upper end of the risk distribution. As explained in EPA's *Policy on Risk Characterization*:[17] "Conceptually, high-end exposure means exposure above about the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest exposure."[d] When the analyst wants to conduct a probabilistic analysis of risk, s/he typically will use or develop a distribution of exposure durations from the available data (e.g., see EPA's *Exposure Factors Handbook, Part III*; Tables 15-164, 15-166, 15-167, and 15-168).[10]

The areal extent of the impacted area(s) may also be a consideration. If a source of concern occurs in the majority of communities, then it is possible that individuals may be exposed to the source for a longer period of time than one might predict using standard estimates of exposure duration. In this case, the analyst might assume that even though an individual changes residence, the individual still would be exposed to the source of concern, and thus the individual's exposure duration would be greater than typically anticipated. Such an analysis must consider whether the concentration of the pollutant at the multiple locations of exposure would be equivalent. Because location-specific parameters such as meteorological conditions, distance from the source, and the presence of certain pathways of exposure (e.g., surface water, home-grown produce) may vary considerably by geographic area, the analyst likely will have to estimate exposure concentrations for each geographic location or community of interest. Similarly, if a single source impacts a large geographic area, then it is possible that national estimates of population mobility will not adequately capture an individual's potential duration of exposure. That is, an individual may move from one point of exposure associated with a particular source to another point of exposure associated with that same source. For example, data indicate 29 percent of home buyers move less than five miles to a new home (Table 15-171 in EPA's *Exposure Factors Handbook, Part III*[10]). Similar to the caution expressed above, the concentrations of pollutants within an area impacted by a single source may vary considerably. The analysis should reasonably account for such situations.

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[c]The central tendency estimate of adult exposure duration commonly used in risk assessments is 9 years (Section 15.4.3 and Table 15-174 in EPA's *Exposure Factors Handbook, Part III*).[10] This estimate is a median value based on national residential occupancy data for the general population. This estimate may not be appropriate in certain situations, such as when population-specific data exist or when the analyst is evaluating a specific sub-population that is expected to differ from the general population (e.g., farm families).

[d]As described in Section 20.4, estimation of high-end exposure will sometimes involve setting exposure duration at its high-end value. The high-end estimate of adult exposure duration typically used in risk assessments is 30 years (Section 15.4.3 and Table 15-174 in EPA's *Exposure Factors Handbook, Part III*),[10] although this may vary for specific sub-populations.

The persistence of the source-associated contamination may also be an important consideration in the exposure duration for ingestion pathway exposure assessment. For example, the analyst should not automatically assume that the exposure duration can be no greater than the operating life of the source. Persistent pollutants may remain in the environment (e.g., soils and sediments) for years after the primary source is discontinued. Nevertheless, in certain cases, once the source of exposure stops, the pollutant concentrations in the affected media may diminish. Particularly in more refined assessments, the exposure concentration may reflect any expected variations in media or food concentrations over time.

When evaluating the risk of noncancer health effects from ingestion exposures (i.e., calculating hazard quotients for ingestion exposures), we do not average pollutant dose over the lifetime of an individual as we do when calculating carcinogenic risk. Rather, when calculating hazard quotients for ingestion exposures, we average the dose over an averaging time equivalent to only the period of exposure (i.e., we calculate an average daily dose rather than a lifetime average daily dose). Consequently, the values for exposure duration and averaging time are the same, and mathematically cancel each other out. Nevertheless, when calculating average daily dose, the analyst must still consider exposure duration when selecting and computing food and media intakes for use in the dose equation. EPA typically considers exposures of seven years or greater as chronic exposures. Food and media intakes that represent time-weighted averages over a seven-year period are reasonable for evaluating chronic non-cancer health effects. **Durations as short as one year are also commonly used, particularly in screening assessments, and for childhood evaluations where intake on a per body weight basis may rapidly change from year to year**.

20.4.4 Body Weight

The choice of body weight for use in the exposure assessment depends on the definition of the population group at potential risk. Because children have lower body weights, typical ingestion exposures per unit of body weight, such as for soil, milk, and fruits, tend to be higher for children. If a lifetime exposure duration (or an exposure duration over the childhood and adult years) is being evaluated, it needs to be based on differing values for the different age groups. If a less than a lifetime exposure estimate is being evaluated, it is important to include the children's age group in the specific scenarios or cohorts used. EPA's *Exposure Factors Handbook*[6] and *Child-Specific Exposure Factors Handbook*[7] provide age-specific values for body weight and consumption rate per unit body weight.

20.5 Calculating Averaging Time Value

When evaluating exposure for the purposes of assessing hazard (vs. predicting cancer risk), **intakes** are calculated by averaging intakes over the period of exposure (i.e., subchronic or chronic durations) and result in average daily doses or ADDs for the duration of interest. For evaluation of cancer risks, potential dose is calculated as the average daily dose over a lifetime (i.e., chronic daily intakes, also called lifetime average daily doses or LADDs). The approach for carcinogens is based on the premise that risk is proportional to total lifetime dose (i.e., a high dose received over a short period of time is equivalent to a corresponding low dose spread over a lifetime).[18] The basis for this approach becomes less strong as the exposures in question become more intense but less frequent, especially when there is evidence that the agent has shown age-related variations in carcinogenic potency, or a nonlinear dose-response relationship.

In some cases, therefore, it may be necessary to consult a toxicologist to assess the level of uncertainty associated with the exposure assessment for carcinogens.

Note that, even when the exposure of interest is a full lifetime, chronic hazards are generally calculated separately for chronic exposures to age groups that differ substantially with regard to pertinent exposure factors (e.g., ingestion rate or body weight) and are not combined (i.e., usually the oral route hazards calculated for children are not added to the hazards posed to adults to represent a "lifetime hazard"). Rather, both hazard quotients/indices are presented as chronic hazard metrics relevant to the two groups. When assessing carcinogenic risks for a lifetime exposure, on the other hand, cancer risk estimates are usually added across different age groups, since the risk received over discrete periods of time (e.g., as a child, as a young adult, as an older adult) are each considered to be fractions of the risk associated with a full lifetime of exposure. Note that in calculating LADDs, it is essential to account for differences in the values of different intake variables (e.g., body weight, consumption rate) at different ages.

20.6 Combining Exposure Estimates Across Pathways

A given population may receive exposure to an individual chemical from several different exposure pathways. For example, individuals may receive exposure via inhalation of the chemical in the air and via ingestion of surface water and fish that have become contaminated through deposition. The specific exposure scenarios or cohorts defined for the analysis may include more than one pathway. The corresponding intake variables used in the analysis may need to account for the number of pathways over which exposure will be combined. For example, to develop a high-end estimate for a scenario that includes inhalation, ingestion of soil, and ingestion of fish, it may be necessary to combine high-end exposure assumptions for all pathways. In other cases, it may be more appropriate combine high-end exposure assumptions for particular pathways with more central-tendency assumptions for others. Otherwise, the estimate may represent an extreme situation in which the simulated behavior is assumed to result in high exposures via all pathways.

Two steps are required to determine whether intake estimates should be combined for a single scenario:

- **Identify reasonable exposure pathway combinations**. Identify exposure pathways that have the potential to expose the *same* individual, cohort, or subpopulation at the key exposure areas evaluated in the exposure assessment, making sure to consider *areas of highest exposure* for each pathway. For each pathway, the intake estimates have been developed for a particular exposure area and time period; they do not necessarily apply to other locations or time periods. Hence, if two pathways do not affect the same individual, cohort, or subpopulation, neither pathway's exposure estimate affects the other, and exposures should not be combined.

- **Examine whether it is likely that the *same* individuals would consistently face a reasonable central tendency or high-end exposure by more than one pathway**. Once reasonable exposure pathway combinations have been identified, it is necessary to examine whether it is likely that the *same individuals* would *consistently* face central tendency or high-end exposure conditions. As noted in Section 20.4 above, the exposure estimate for each exposure pathway includes many conservative estimates. Also, some of the exposure

parameters are not completely predictable in space and/or time (e.g., the maximum downwind concentration may shift compass direction). For real-world situations in which contaminant concentrations vary over time and space, the same individual or cohort may or may not experience central-tendency or high-end exposure conditions for more than one pathway over the same period of time. Thus, it is important to clearly explain why the key assumptions chosen for more than one pathway for an individual, subpopulation, or cohort are set at central tendency and/or high-end exposure estimates. (Note that an important goal in the analysis of high-end receptors is to identify exposures that are in the high-end of the range - usually higher than the 90th percentile exposure - but not higher than the highest exposure in the population.)

20.7 Exposure Models

Exposure models have been developed that automate the calculation of chemical intake. They may simply calculate exposure for a set of individual scenarios, or they may draw upon activity pattern and/or dietary survey databases to characterize cohort exposure within a population. Three exposure models are described below.

California Total Exposure Model for Hazardous Waste Sites (CalTOX)

As described previously in Part II, Chapter 9, the California Environmental Protection Agency funded the development of the CalTOX program.[19] CalTOX has been developed as a set of spreadsheet models and spreadsheet data sets to assist in assessing human exposures and defining soil clean-up levels at uncontrolled hazardous wastes sites. CalTOX addresses contaminated soils and the contamination of adjacent air, surface water, sediments, and ground water. The modeling components of CalTOX include exposure scenario models. The exposure models encompass twenty-three exposure pathways. The exposure assessment process consists of relating pollutant concentrations in the multimedia model compartments to pollutant concentrations in the media with which a human population has contact (e.g., personal air, tap water, foods, household dusts, soils). The temporal resolution is either daily for inhalation and dermal exposure or annual for ingestion. The aggregation period is variable, depending on the duration of residence at a single location. The spatial resolution and modeling domain are user-specified, but generally encompass some vicinity around the waste site of interest. Activity data, such as inhalation, ingestion, and dermal contact rates, are derived from EPA's *Exposure Factors Handbook.*[6]

TRIM.Expo

As discussed in Chapter 18, TRIM.Expo is the exposure component of the TRIM modeling system. The ingestion component of TRIM.Expo ($TRIM.Expo_{Ingestion}$) is designed to take input values from TRIM.FaTE, but may also be operated independently with inputs from measurement studies or alternative models. $TRIM.Expo_{Ingestion}$ will employ a scenario-based approach, based on that used in the 3MRA modeling system, in its initial version. Information about the ingestion component of TRIM.Expo is available on EPA's Fate, Exposure and Risk Analysis (FERA) web site: http://www.epa.gov/ttn/fera.

Stochastic Human Exposure and Dose Simulation Model (SHEDS)

The Stochastic Human Exposure and Dose Simulation (SHEDS) Model[20] is a probabilistic, physically-based model that simulates aggregate exposure and dose for population cohorts and multimedia pollutants of interest. It is being developed by EPA's National Exposure Research Laboratory (http://www.epa.gov/nerlpage/). At present the model is applied to assess children's exposures to pesticides (SHEDS-Pesticides) and population exposures to particulate matter (SHEDS-PM).

SHEDS-Pesticides focuses on children's aggregate population exposure to pesticides. Activity data are selected from daily sequential time/location/activity diaries from surveys contained in EPA's Consolidated Human Activity Database (CHAD).[8] For each individual, SHEDS-Pesticides constructs daily exposure and dose time profiles for the inhalation, dietary and non-dietary ingestion, and dermal contact exposure routes, and then aggregates the dose profiles across routes. A pharmacokinetic component has been incorporated to predict pollutant or metabolite concentrations in the blood compartment or eliminated urine. Exposure and dose metrics of interest (e.g., peak, time-averaged, time-integrated) are extracted from the individual's profiles. Two-stage Monte-Carlo sampling is applied to predict the range and distribution of aggregate doses within the specified population and identify the uncertainties associated with percentiles of interest.

SHEDS-Pesticides is currently being refined to characterize both aggregate and cumulative dose associated with human exposure (i.e., for both adults and children) to a variety of environmental pollutants in addition to pesticides. SHEDS-Pesticides will eventually be expanded to include source-to-concentration (i.e., fate and transport) models and more complete exposure-to-dose models (i.e., pharmacokinetic or dosimetric models).

SHEDS-PM estimates the population distribution of particulate matter (PM) exposure by sampling from distributions of ambient PM concentrations, distributions of emission strengths for indoor sources of PM (e.g., cigarette smoking and cooking), and distributions of mass-balance parameters (e.g., air exchange rate, penetration rate, deposition rate). A steady-state mass balance equation is used to calculate PM concentrations for the residential and other microenvironments. Additional model inputs include demographic and human activity pattern data from the National Human Activity Pattern Survey (NHAPS). Output from the SHEDS-PM model includes distributions of PM exposures in various microenvironments (e.g., in the home, in vehicles, outdoors) and the relative contributions of these various microenvironments to the total exposure.

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Chapter 21 Ingestion Toxicity Assessment

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21.1 Introduction

As described previously in Chapter 12, the purpose of the toxicity assessment is to weigh available evidence regarding the potential for toxicity in exposed individuals (**hazard identification**) and to quantify the toxicity by deriving an appropriate dose-response value (**dose-response assessment**). Toxicity assessment is the second part of the general risk equation. The toxicity assessment is accomplished in two steps: **hazard identification** and **dose-response assessment**. Although the toxicity assessment is an integral and important part of the overall air toxics risk assessment, this is usually accomplished prior to the risk assessment. EPA has completed the toxicity assessment for all HAPs and has made available the resulting toxicity information and dose-response values, which have undergone extensive peer review (see Appendix C).[a]

Risk = *f* (metric of exposure, measure of toxicity)
Toxicity Assessment is a Two-Step Process:

1. **Hazard Identification** –What types of effects does the chemical cause? Under what circumstances?
2. **Dose-response Assessment** – How potent is the chemical as a carcinogen and/or for noncancer effects?

This chapter focuses on toxicity assessment for the ingestion (oral) pathway. Dermal toxicity assessment is described in detail in several EPA guidance documents.[1] The ingestion pathway uses the same general types of studies, hazard and dose-response information, and dose-response methods to assess toxicity as those used for the inhalation pathway (see Chapter 12). The discussion in this chapter focuses on the unique features of toxicity assessment for the oral pathway.

Ingestion Dose-Response Values[a]

Oral Cancer Slope Factor (CSF): An upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime exposure to an agent. For ingestion, this estimate is usually expressed in units of amount of risk per amount of intake and is written as risk per mg/kg-day or simply $(mg/kg\text{-}d)^{-1}$.

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive sub-populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Generally used in EPA's noncancer health assessments. RfDs are usually given in units of intake per day on a body weight basis (written as mg/kg-d).

[a]The phrase "dose-response" is used generally here and elsewhere in the document. EPA's values for ingestion, however, are related to oral intake rather than dose. Consideration of the relationship between exposure concentration, dose, and dosimetry (what happens to a chemical in the body once it is ingested) may be considered, depending on data availability in the derivation of these values.

[a]See http://www.epa.gov/ttn/atw/toxsource/summary.html for an up-to-date list of dose-response values.

21.2 Hazard Identification

The hazard identification process for the ingestion pathway is identical to that for the inhalation pathway, although the specific toxic effects of concern and details of the toxicity studies are derived from feeding a chemical to animals (either in food or drinking water) rather than on having the animals inhale the chemical. As with inhalation, the hazard identification step includes consideration of various types of studies (e.g., feeding, in vitro, etc.) and the resulting weight of evidence with regard to potential for carcinogenicity and identification of critical effects. See Part II, Chapter 12, for information on the hazard identification step.

21.3 Predictive Approach for Cancer Effects

The approach to dose-response assessment for cancer effects is identical to that for the inhalation pathway discussed in Chapter 12, including:

- Determination of the **point of departure** (**POD**);
- **Duration adjustment** of the POD to a continuous exposure;
- Extrapolation of an animal study POD into its corresponding **Human Equivalent Dose** (**POD_{HED}**); and
- **Low-dose extrapolation** from the POD_{HED} to lower doses for the purposes of deriving the oral cancer risk estimate.

As with inhalation, the first three steps are also performed in the derivation of reference values for ingestion, such as the oral RfD. In addition to the steps shown above, the derivation of RfDs are followed by the application of uncertainty factors (see Section 21.4). Additionally, the use of tools such as pharmacokinetic modeling, which go beyond these default approaches, may facilitate the accomplishment of several of these steps.

21.3.1 Determining the Point of Departure (POD)

The process for determining the POD for ingestion exposures is identical to that for inhalation exposures. The POD may be the no-observed-adverse-effect level (NOAEL) or lowest-observed-adverse-effect level (LOAEL), or it may be a **benchmark dose** (**BMD**) for noncancer effects.[b]

21.3.2 Deriving the Human Equivalent Dose

The optimal approach for extrapolating from an animal study to a human dose-response relationship is to use Physiologically Based Pharmacokinetic (PBPK)[c] modeling. When such a model us used, the duration adjustment step is incorporated into that model. Otherwise, any duration adjustment, if necessary (e.g., when the exposure is not via daily feed), would be accomplished by deriving an average daily dose for the exposure period (e.g., two years in an animal cancer bioassay).

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[b]Note that the corresponding value for inhalation exposures is the benchmark concentration (BMC).

[c]A model that estimates the dose to a target tissue or organ by taking into account the rate of absorption into the body, distribution among target organs and tissues, metabolism, and excretion.

For purposes of cancer assessment, an animal to human body weight-based scaling factor is applied to the oral study POD (duration-adjusted if applicable) to extrapolate to a human equivalent oral exposure.[2] The default scaling factor is based on the body mass raised to the 3/4 power of the test animals relative to humans. This step stems from the consideration of various studies of the species differences in toxicity of certain compounds, including data collected on chemotherapeutic agents.[3] These data served as the principal basis for the use of a body surface area or metabolic rate scaling as the default method in cancer risk assessments. Empirically, the best estimate of surface area scaling is $BW^{2/3}$ and for metabolic rate scaling is $BW^{3/4}$.[4] These findings reflect general expectations of more rapid distribution, clearance, and metabolism by smaller animals.

In the case of the RfD, a scaling factor is not currently applied. Instead, the interspecies uncertainty factor is intended to account for potential differences in sensitivity of humans compared to the test animal, including this consideration.[d]

A PBPK model can accommodate adjustments for metabolic rate as well as other species-related dosimetric variables such as liver perfusion rates. The model therefore provides a more accurate estimate of steady-state target site concentrations than use of default methods. EPA's preferred approach for calculating a HED for oral exposures is to use a chemical-specific PBPK model parameterized for the animal species and body regions (e.g., of the gastrointestinal tract) involved in the toxicity.

21.3.3 Extrapolating from POD to Derive the Oral Cancer Slope Factor

As with inhalation, extrapolation from the POD_{HED} to lower doses is usually necessary and, in the absence of a data set rich enough to support a biologically based model (e.g., a PBPK model), is conducted using linear extrapolation or a nonlinear extrapolation using a Reference Dose approach.

The **Cancer Slope Factor** (**CSF**) for oral exposures is derived in a similar way as the unit risk estimate for inhalation (URE) (see Chapter 12). The CSF is derived using the upper bound estimate of risk. In other words, the true risk to humans, while not identifiable, is not likely to exceed the upper-bound estimate (the CSF). The CSF is presented as the risk of cancer per mg of intake of the substance per kg body weight per day ($[mg/kg\text{-}day]^{(-1)}$).

21.4 Dose-response Assessment for Derivation of a Reference Dose

The oral **reference dose** is expressed as a chronic dietary intake level (in units of mg of the substance per kilogram body weight per day, or mg/kg-day) for the human population (including sensitive sub-populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime. In other words, exposures at or below the RfD will probably not cause adverse health effects, even to sensitive sub-populations. While the RfD is routinely employed for

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[d] At the time of publication, an Agency activity is underway to "harmonize" the cancer assessment and RfD development methods with regard to the method employed for interspecies scaling, which may result in the use of body weight scaling in the development of the RfD.

noncancer effects, it may be inclusive of cancer for those pollutants for which a nonlinear (e.g., threshold) mode of action has been demonstrated consistent with the Cancer Guidelines.

As with the derivation of an inhalation reference concentration, the reference dose is derived by dividing the POD by one or more **uncertainty factors** (**UFs**). EPA includes with each RfD a statement of high, medium, or low confidence based on the completeness of the database for that substance. High confidence RfDs are considered less likely to change substantially with the collection of additional information, while low confidence RfDs may be especially vulnerable to change.[5]

The UFs are applied to account for recognized uncertainties in the extrapolations from the experimental data conditions to an estimate appropriate to the assumed human scenario. As with the derivation of RfCs, a UF of 10, 3, or 1 is applied for each of the following extrapolations:

- Animal to human;
- Human to exposed sensitive human populations;
- Subchronic to chronic;
- LOAEL to NOAEL; and
- Incomplete to complete database.

The UFs are generally an order of magnitude (10), although consideration of available information on the chemical may result in the use of reduced UFs for RfDs (3 or 1). It is noted that as there is currently no default dosimetric adjustment for the oral route. The uncertainty factor for extrapolation from animal to human data is usually the full 10, as compared to the reduced factor of 3, routinely used for RfCs which employs an interspecies dosimetric adjustment. Additional discussion on the application of uncertainty factors is provided in Section 12.4.3.

21.5 Sources of Human Health Reference Values for Risk Assessment

Appendix C provides a current listing of chronic oral dose-response values (i.e., RfDs and CSFs) for HAPs. Chapter 12 describes additional sources of human health reference values for risk assessment for the ingestion route.

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Chapter 22 Multipathway Risk Characterization

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22.1 Introduction

The last component of risk assessment, Risk Characterization, integrates the information from the exposure assessment (Chapter 20) and toxicity assessment (Chapter 21), using a combination of qualitative information, quantitative information, and a discussion of uncertainty.[1] Risk assessors should present the risk characterization and its components so that they are transparent, clear, and consistent with EPA guidance and policy, and thus components should support the conclusion that the analysis is reasonably conservative enough for its intended purpose. The risk summary and risk conclusions must be complete, informative, and useful for decision-makers. Major uncertainties associated with determining the nature and extent of the risk should be identified and discussed.

Risk characterization for the multipathway risk assessment is performed using the same approach as described for the inhalation pathway (Chapter 13), except that risks for both inhalation and ingestion are considered. As for inhalation-only analyses, most multipathway risk assessments for air toxics will focus on estimating individual risk and hazard. This chapter focuses on the unique features of risk characterization for multipathway analyses. ***This chapter also assumes that the inhalation risk characterization has been completed, as described in Chapter 13.***

Steps in a Multipathway Risk Characterization

1. Organize outputs of the ingestion exposure and toxicity assessments.
2. Derive cancer risk estimates and noncancer hazard quotients for each pollutant in each pathway.
3. Derive multiple pollutant cancer risk estimates and noncancer hazard indices for each pathway.
4. In consideration of target organ, develop target organ specific hazard indices, if appropriate.
5. As appropriate, combine information on cancer risk and noncancer hazard from the ingestion analysis with appropriate risk information from the inhalation analysis to derive a total estimate of cancer risk and noncancer hazard.
6. Identify key features and assumptions of exposure and toxicity assessments.
7. Assess and characterize key uncertainties associated with the assessment.
8. Consider additional relevant information (e.g., related studies).

The risk characterization should be written consistent with EPA guidance and policy, including a risk summary and risk conclusions that are complete, informative, and useful for decision-makers, and which clearly identify and discuss the major uncertainties associated with determining the nature and extent of the risk.

The general process for characterizing cancer risks and noncancer hazards for multipathway analyses can be thought of as developing information to fill in a matrix similar to that shown in Exhibit 22-1 (which presents cancer risks for a group of chemicals; a similar matrix can be developed to present noncancer hazards [see Exhibit 22-2]). A table like this would be developed for each of the types of receptors being evaluated in the study area (e.g., adult farmer – high-end exposure; adult farmer – central tendency exposures; child resident – high-end exposure). This type of presentation format shows the total risk by chemical, pathway, and across all pathways. In addition, this format allows one to quickly identify both the individual chemicals and pathways that contribute most to the total risk estimate. The following sections describe how to develop the numbers to fill in such a table for both multipathway cancer risk estimates (Section 22.2) and multipathway noncancer hazards (Section 22.3). The focus of this

chapter is on developing risks and hazards for the ingestion pathways; procedures for developing inhalation risk estimates have previously been provided in Chapter 13.

Exhibit 22-1. Example Matrix for Estimating Excess Cancer Risks for Multiple Chemical Exposure through Multiple Ingestion Pathways for a Particular Exposure Scenario

	Pathway 1 (Vegetable Ingestion Risk Estimate)[a]	Pathway 2 (Fish Ingestion Risk Estimate)[a]	Pathway 3 (Egg Ingestion Risk Estimate)[a]	Pathway 4 (Beef Ingestion Risk Estimate)[a]	Aggregate Chemical Ingestion Risk Estimate [a]
Chemical 1	1×10^{-6}	3×10^{-4}	9×10^{-8}	8×10^{-5}	4×10^{-4}
Chemical 2	4×10^{-7}	4×10^{-6}	4×10^{-8}	4×10^{-7}	5×10^{-6}
Chemical 3	4×10^{-9}	7×10^{-7}	3×10^{-8}	9×10^{-9}	8×10^{-7}
Chemical 4	9×10^{-7}	1×10^{-6}	6×10^{-7}	6×10^{-7}	3×10^{-6}
Cumulative Ingestion Pathway Risk Estimate [a]	3×10^{-6}	3×10^{-4}	7×10^{-7}	8×10^{-5}	4×10^{-4}

[a] Standard rules for rounding apply which will commonly lead to an answer of one significant figure in both risk and hazard estimates. For presentation purposes, hazard quotients (and hazard indices) and cancer risk estimates are usually reported as one significant figure.

22.2 Cancer Risk Estimates

As discussed in detail in Chapter 13, estimated individual cancer risk is expressed as the probability that a person will develop cancer as a result of the estimated exposure over a lifetime. This predicted risk is the **incremental risk** of cancer from the exposure being analyzed, which are in addition to other risks due to any other factors (e.g., smoking). Due to default assumptions in their derivation, cancer slope factors (CSFs) are generally considered to be "plausible upper-bound" estimates, regardless of whether they are based on statistical upper bounds or best fits. As noted in Chapter 13, risks may be estimated for both the central tendency (average exposure) case and for the high-end (exposure that is expected to occur in the upper range of the distribution) case, or probabilistic techniques can be used to develop a distribution of estimated risks.

22.2.1 Characterizing Individual Pollutant Ingestion Risk - Scenario Approach

The first step in characterizing individual pollutant risk for an exposure scenario (e.g., a recreational fisher) is to quantify risk for each ingestion exposure pathway being evaluated. In this step, cancer risks for individual pollutants are estimated by multiplying the estimate of the lifetime average daily dose (LADD) for each ingestion exposure pathway by the appropriate CSF to estimate the potential incremental cancer risk:

$$\text{Risk} = \text{LADD} \times \text{CSF} \qquad \text{(Equation 22-1)}$$

where:

Risk	=	Individual cancer risk (expressed as an upper-bound risk of contracting cancer over a lifetime) for each pollutant via the ingestion pathway being evaluated (unitless);
LADD	=	Lifetime Average Daily Dose for the pollutant via the ingestion pathway being evaluated (mg/kg-d); and
CSF	=	Cancer Slope Factor for the pollutant via the ingestion pathway being evaluated [$(mg/kg\text{-}d)^{-1}$]

Estimates of cancer risk are usually expressed as a probability represented in scientific notation as a negative exponent of 10. For example, an additional risk of contracting cancer of 1 chance in 10,000 (or one additional person in 10,000) is written as $1x10^{-4}$. Because CSFs are typically upper-bound estimates, actual risks may be lower than predicted (see Chapter 12) – note that the true value of the risk is unknown and may be as low as zero.[2] These statistical projections of hypothetical risk are intended as screening tools for risk managers and cannot be used to make realistic predictions of biological effects.

Risks are generally evaluated initially for **individuals** within the potentially exposed population. **Population risks** for the exposed population may also be estimated, which may be useful in estimating potential economic costs and benefits from risk reduction. Sensitive subpopulations should also be considered, when possible. Estimates of **incidence** also are possible, although there are some caveats associated with these measures (see Chapter 13).

For carcinogens being assessed based on the assumption of nonlinear dose-response, for which a reference dose (RfD) was derived that considers cancer as well as other effects, the hazard quotient approach will be appropriate for risk characterization (see Section 22.3).

22.2.2 Characterizing Risk from Exposure to Multiple Pollutants - Scenario Approach

For each exposure pathway of a scenario, exposure may be to multiple chemicals at the same time rather than a single chemical; however, CSFs are usually available only for individual compounds within a mixture. Consequently, a component-by-component approach is usually employed.[3] The following equation estimates the predicted cumulative incremental individual cancer risk from multiple substances for a single exposure pathway, assuming additive effects from simultaneous exposures to several carcinogens:

$$Risk_T = Risk_1 + Risk_2 + \ldots + Risk_i \qquad \text{(Equation 22-2)}$$

where:

$Risk_T$	=	Cumulative individual ingestion cancer risk (expressed as an upper-bound risk of contracting cancer over a lifetime); and
$Risk_i$	=	Individual ingestion risk estimate for the ith substance.

In screening-level assessments of carcinogens for which there is an assumption of a linear dose-response relationship, the cancer risks predicted for individual chemicals may be added to estimate cumulative cancer risk for each pathway. This approach is based on an assumption that

the risks associated with individual chemicals in the mixture are additive. In more refined assessments, the chemicals being assessed may be evaluated to determine whether effects from multiple chemicals are synergistic (greater than additive) or antagonistic (less than additive), although sufficient data for this evaluation are usually lacking. In those cases where CSFs are available for a chemical mixture of concern, risk characterization can be conducted on the mixture using the same procedures used for a single compound.

For carcinogens being assessed based on the assumption of nonlinear dose-response, for which an RfD considering cancer as well as other effects has been derived, the hazard quotient approach will be appropriate (see Section 22.3).

Aggregate vs. Cumulative Risk

Aggregate risk refers to risk attributed to a single chemical across multiple pathways/routes

Cumulative risk refers to risk attributed to simultaneous exposure to multiple chemicals via a single or multiple pathways/routes

22.2.3 Combining Risk Estimates across Multiple Ingestion Pathways - Scenario Approach

To evaluate risks associated with the aggregate exposure across multiple pathways of a given scenario, the individual pollutant cancer risk estimates may be summed for each chemical across the multiple ingestion pathways assessed. Additionally, a cumulative multi-pathway risk estimate may be derived by summing cumulative (multiple pollutant) cancer risk estimates across the multiple ingestion pathways.

22.2.4 Evaluating Risk Estimates from Inhalation and Ingestion Exposures

Depending on the ingestion scenario, the inhalation pathway will also have been assessed. In such cases, the inhalation exposures must be presented along with the ingestion exposures to provide an overall estimate of risk across the multiple pathways. When there is a compatibility in the exposure scenarios, inhalation and ingestion risk estimates can be combined. Essentially, an additional column for inhalation can be added to Exhibit 22-1 to achieve this result. Regardless, when both routes are assessed, risk estimates for both routes of exposure should be presented, along with descriptions regarding the populations assessed for all pathways and routes, thereby clarifying any differences in populations.

It is important to note, however, that the methods and assumptions used to derive the inhalation and ingestion risks may not always yield compatible exposure scenarios. This is particularly important when population-level (versus individual) risk estimates are being developed. For example, a scenario-based ingestion exposure assessment will not be easily amenable to producing estimates of numbers of people at different risk levels, while a population-based inhalation assessment may be more appropriate. In addition, it would generally not be appropriate to add an inhalation risk that presumes a 70-year exposure duration with an ingestion pathway that presumes a 30-year exposure duration. Any matching of exposure durations among pathways in a multipathway assessment should be carefully considered.

22.3 Noncancer Hazard

For noncancer effects (as well as carcinogens being assessed based on the assumption of nonlinear dose-response), ingestion exposure concentrations are compared to RfDs, which are estimates (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to

the human population (including sensitive sub-populations) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime (see Chapter 21).

As with carcinogens, the development of hazard quotients (HQs) for ingestion typically is performed first for individual air toxics. Then, hazard indices (HIs) may be developed for multiple pollutant exposures and summed across pathways to develop multiple pathway cumulative hazard estimates. An additional step in the multipathway analysis is to evaluate combining both ingestion and inhalation hazard estimates. These steps are described in separate subsections below.

22.3.1 Characterizing Individual Pollutant Hazard - Scenario Approach

The first step in characterizing individual pollutant hazard for an exposure scenario (e.g., a recreational fisher) is to quantify hazard for each pollutant being evaluated. For ingestion exposures, noncancer hazards are estimated by dividing the estimate of the Average Daily Dose (ADD) by the chronic oral RfD to yield an HQ for individual chemicals:

$$HQ = ADD \div RfD \qquad \text{(Equation 22-3)}$$

where:

HQ	=	Hazard Quotient for the pollutant via each ingestion pathway being evaluated (unitless);
ADD	=	Estimate of the Average Daily Dose for the pollutant via the ingestion pathway being evaluated (mg/kg-d); and
RfD	=	Corresponding reference dose for the pollutant via the ingestion pathway being evaluated (mg/kg-d).

In screening assessments, the chronic exposure estimate is commonly based on a simplifying assumption of continued similar conditions for a long-term period (for example, that the maximum annual average modeled concentration remains constant during the full course of the exposure duration). A more refined assessment might consider how concentration changes with time over the exposure duration. In both cases, it is important to match the type of RfD value to the specific exposure scenario. For example, for childhood scenarios (e.g., ages 0-6), risk assessors commonly use chronic RfDs (rather than subchronic). Subchronic RfDs[(a)] are more commonly used to evaluate exposure scenarios that last a year or less (e.g., a construction worker who is exposed for 6 months). For exposure durations of a few years, both chronic and subchronic values may be considered, with chronic values commonly being used, particularly in screening assessments, with explicit recognition of the decision and its basis. Acute toxicity values are for exposures that are much shorter in duration (usually 24 hours or less); however, such exposures generally are not evaluated in a multipathway air toxics risk assessment.

Based on the definition of the RfD, an HQ less than or equal to one indicates that adverse noncancer effects are **not likely to occur**. With exposures increasingly greater than the RfD (i.e.,

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[a]Although subchronic RfDs are not routinely developed by EPA, ATSDR develops MRLs for "intermediate" exposures and describes them as being relevant to exposure durations on the order of weeks to months (i.e., >14 days to 364 days).

HQs increasingly greater than one), the **potential for adverse effects increases**, but we do not know by how much. An HQ of 100 does not mean that the hazard is 10 times greater than an HQ of 10. Also an HQ of 10 for one substance may not have the same meaning (in terms of hazard) as another substance resulting in the same HQ.

22.3.2 Multiple Pollutant Hazard

Noncancer health effects data are usually available only for individual compounds within a mixture. In these cases, the individual HQs can be summed together to calculate a multi-pollutant HI:

$$HI = HQ_1 + HQ_2 + ...+ HQ_i \qquad \text{(Equation 22-4)}$$

where

HI = Hazard index; and
HQ_i = Hazard quotient for the ith air toxic.

For screening-level assessments, a simple HI may first be calculated for all chemicals of potential concern (COPCs) (Exhibit 22-2). This approach is based on the assumption that even when individual pollutant levels are lower than the corresponding reference levels, some pollutants may work together such that their potential for harm is additive and the combined exposure to the group of chemicals poses greater likelihood of harm. Some groups of chemicals can also behave antagonistically, such that combined exposure poses less likelihood of harm, or synergistically, such that combined exposure poses harm in a greater than additive manner, although information needed to perform such an analysis is generally not available. Where this type of HI exceeds the criterion of interest, a more refined analysis is warranted.

The assumption of dose additivity is most appropriate to compounds that induce the same effect by similar modes of action. Thus, EPA guidance for chemical mixtures[3] suggests subgrouping pollutant-specific HQs by toxicological similarity of the pollutants for subsequent calculations; that is, calculating a **target-organ-specific-hazard index (TOSHI)** for each subgrouping of pollutants. This calculation allows for a more appropriate estimate of overall hazard.

The HI approach encompassing all chemicals in a mixture may be appropriate for a screening-level study. However, it is important to note that applying the HI equation to compounds that may produce different effects, or that act by different mechanisms, could overestimate the potential for effects. Consequently, in a refined assessment, it is more appropriate to calculate a separate HI for each noncancer endpoint of concern when target organs or modes of action are known to be similar. Refined assessments also may employ techniques more complex than the HI derived using RfDs.[4]

22.3.3 Evaluating Hazard Estimates From Inhalation and Ingestion Exposures

As with carcinogenic assessments, inhalation hazards must be combined with ingestion hazards to provide total hazard across all exposure pathways for a receptor. Similar to Exhibit 22-1, inhalation and ingestion risk estimates can be combined either by chemical across pathways or across chemicals within a pathway. Essentially, an additional column for inhalation can be added to Exhibit 22-2 to achieve this result.

Exhibit 22-2. Example Matrix for Characterizing Hazard for Multiple Chemical Exposure through Multiple Ingestion Pathways for a Particular Exposure Scenario					
	Pathway 1 (Vegetable Ingestion HQ Estimate)[(a)]	Pathway 2 (Fish Ingestion HQ Estimate)[(a)]	Pathway 3 (Egg Ingestion HQ Estimate)[(a)]	Pathway 4 (Beef Ingestion HQ Estimate)[(a)]	Aggregate Chemical Ingestion HQ Estimate[(a)]
Chemical 1	2×10^{-1}	2×10^{-1}	4×10^{-2}	2×10^{-1}	7×10^{-1}
Chemical 2	3×10^{-1}	7×10^{-1}	3×10^{-2}	2×10^{-1}	1
Chemical 3	1×10^{-1}	4×10^{-1}	2×10^{-1}	4×10^{-1}	1
Chemical 4	9×10^{-2}	1×10^{-2}	1×10^{-1}	2×10^{-2}	3×10^{-1}
Cumulative Ingestion Pathway HI [(a)]	7×10^{-1}	1	4×10^{-1}	9×10^{-1}	3

[(a)] Standard rules for rounding apply which will commonly lead to an answer of one significant figure in both risk and hazard estimates. For presentation purposes, hazard quotients (and hazard indices) and cancer risk estimates are usually reported as one significant figure.

22.4 Interpretation and Presentation of Risks/Hazards

In the final part of the risk characterization, estimates of cancer risk and noncancer hazard should be presented in the context of uncertainties and limitations in the data and methodology. Exposure estimates and assumptions, toxicity estimates and assumptions, and the assessment of uncertainty should be discussed. Chapter 13 provides more detailed information and examples. Part VI of this reference manual discusses risk communication and other elements of the risk-based decision-making process.

Estimating Risk for Drinking Water Sources

In evaluating potential risks associated with drinking water supplies, risk assessors commonly assume that the drinking water undergoes at least a minimum level of treatment to remove solids (i.e., particles in the water which are persistent bioaccumulative hazardous air pollutants [PB-HAPs] or onto which PB-HAPs may be absorbed). Therefore, the risk assessment commonly focuses on the dissolved concentrations of PB-HAPs in drinking water sources. In addition, if the drinking water source is part of a public drinking water system, the risk assessment may also assume that the water is treated to meet applicable drinking water standards (i.e., treated to maximum contaminant levels or MCLs, unless study-specific information indicates otherwise) for chemicals regulated under the drinking water program. National Primary Drinking Water Regulations are enforceable standards that apply to public water systems. The MCLs are the highest level of a specific list of contaminants allowed in drinking water (see http://www.epa.gov/safewater/mcl.html).

Note that multipathway air toxics risk assessments are subject to additional sources of uncertainty as compared to inhalation risk assessments. The multimedia modeling effort is both more complex and less certain due to many factors. For example: (1) there are many more chemical-dependent and chemical-independent variables involved as input values to the models;

(2) the models involve analysis of the transfer of air toxics from the air to other media (e.g., soil, sediment, water), the subsequent movement of the air toxics between these media (e.g., soil runoff to surface water), and uptake and metabolism by biota; and (3) many variables affect the ingestion of food, water, and other media by humans and wildlife, and the exposure and risk estimates may differ considerably as a consequence of the assumptions used to derive intake estimates. Sampling of biota and abiotic media also may be more complex. Additional uncertainties are incorporated in the risk assessment when exposure estimates to multiple substances across multiple pathways are summed.

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PART IV

ECOLOGICAL RISK ASSESSMENT

Chapter 23 Overview and Getting Started: Problem Formulation

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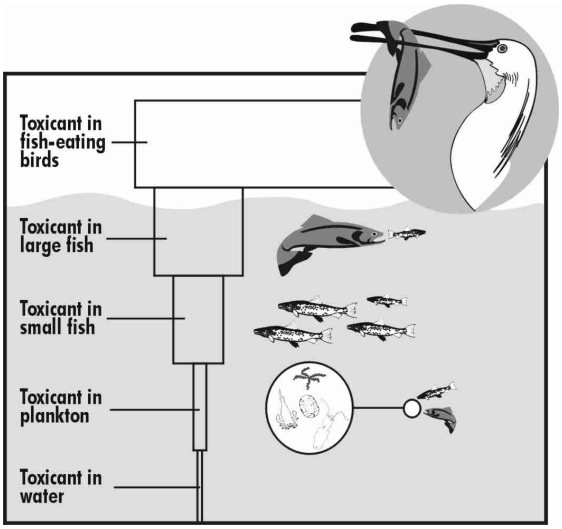
23.1 Introduction

Part IV constitutes a snapshot of EPA's current thinking and approach to the adaptation of the evolving methods of ecological risk assessment to the context of Federal and state control of air toxics. While inhalation risk assessment has been increasingly used in regulatory contexts over the last several years, ecological risk assessment tools are less well developed and field tested in a regulatory context. Part IV should be considered a living document for review and input. By publishing Part IV in its current state of development, EPA is soliciting the involvement of persons with experience in this field to help improve these assessment methods for use in a regulatory context. EPA anticipates revisions to this draft section of Part IV on the basis of this input.

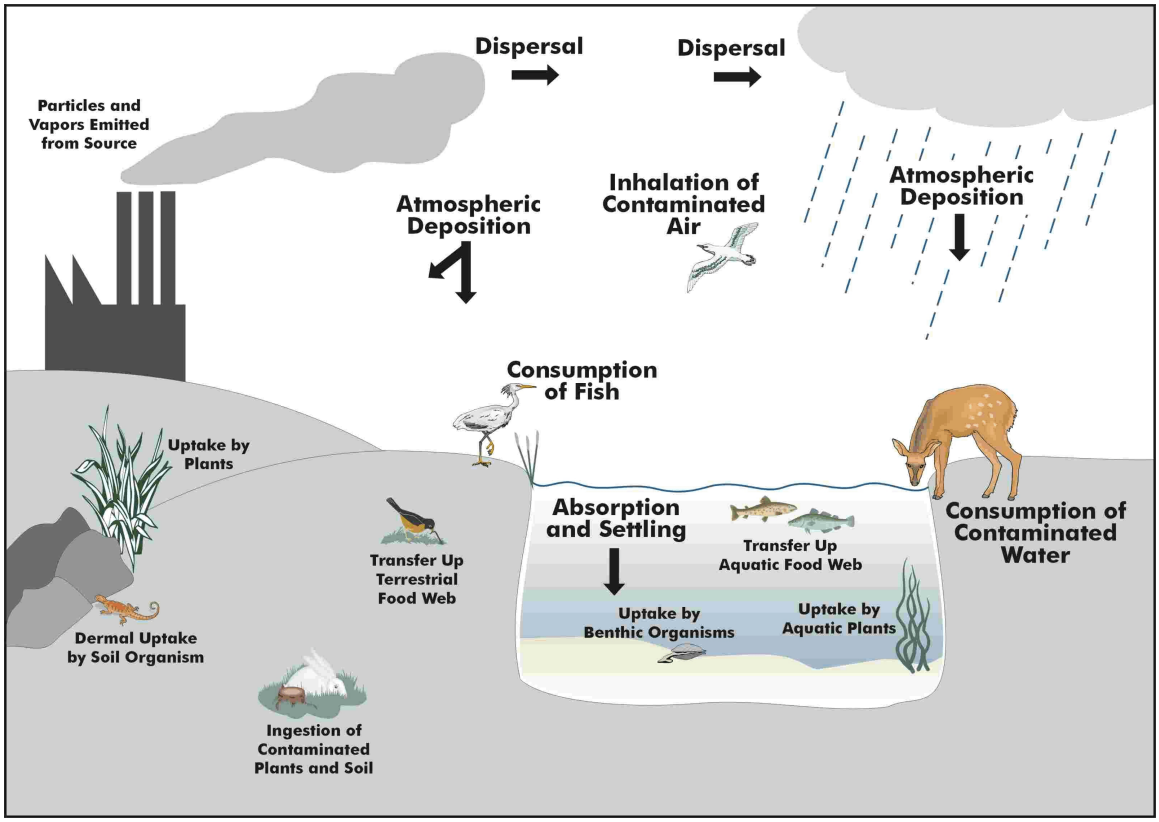
Part III of this Reference Manual discusses how to plan for and conduct a multipathway human health risk assessment when air toxics that persist and may also bioaccumulate (e.g., the persistent bioaccumulative hazardous air pollutant compounds, or PB-HAPs) in media other than air and/or biomagnify in food chains are present in releases. For these compounds, the risk assessment generally will need to include consideration of exposure pathways that involve deposition of air toxics onto soil and plants and into water, subsequent uptake by biota, and potential human exposures via consumption of contaminated soils, sediments, surface waters, and foods. These substances may also pose risks to ecological receptors from direct exposure to contaminated media or through indirect exposure via aquatic and terrestrial food chains (see Exhibit 23-1). The preliminary list of PB-HAPs was derived primarily on the basis of exposure and risk/hazard once HAPs are deposited onto soils, into surface waters, etc. Its derivation did not consider direct exposures of ecological receptors to air toxics while they are in the air (e.g., phytotoxic effects on plants; inhalation by animals). Additional HAPs of potential concern for ecological risk may be identified as EPA gains more familiarity with ecological risk assessments for air toxics. Appendix D describes the process by which EPA identified the PB-HAP compounds.



Trophic Levels and Biomagnification

The trophic level is a way to describe where an organism may be located within an aquatic or terrestrial food web. The lowest trophic level consists of primary producers, the green plants that convert sunlight into carbohydrates via photosynthesis. The next trophic level generally consists of primary consumers, or the organisms that feed directly on green plants. The next level up, often termed secondary consumers, represents animals that feed on primary consumers. The highest trophic level consists of the top predators in the food web. For some chemicals, the concentration in biological tissue can increase as it moves up the food chain, a process called **biomagnification**.

Exhibit 23-1. Air Toxics Exposure Pathways of Potential Concern for Ecological Receptors



This graphic illustrates some of the potential multimedia pathways of concern for air toxics exposure to ecological receptors. Air toxics released from a source disperse through the air and eventually fall to the earth (atmospheric deposition) via settling and/or precipitation. Air toxics deposited to soil may be absorbed or ingested by plants and soil invertebrates (uptake). Terrestrial animals may be exposed to air toxics via ingestion of contaminated plants and soil, or by consuming contaminated terrestrial animals (for those air toxics that bioaccumulate and transfer up the terrestrial food web). Air toxics deposited to water may be dissolved in the water column and/or may settle and be absorbed into aquatic sediments. Air toxics in sediments may be absorbed or ingested by benthic organisms (uptake); those in sediments and the water column may be absorbed by aquatic plants (uptake). Aquatic organisms (e.g., fish) may be exposed directly to air toxics in the water column and/or by consuming contaminated aquatic organisms (for those air toxics that bioaccumulate and transfer up the aquatic food web). Terrestrial animals may be exposed to air toxics by eating contaminated fish or shellfish and/or by drinking contaminated water. Note also that, while in the atmosphere, air toxics may also have direct impacts on plants (direct exposure) and terrestrial animals (inhalation).

This part (Part IV) of this reference manual introduces the basic concepts of ecological risk assessment and describes their application to air toxics. Several differences of particular importance are highlighted in a text box on page 23-3. The discussion of ecological risk assessment follows the same general framework as that presented in Part III since the overall concept is the same; namely that certain air toxics may move from the air into other media where exposures to organisms (in this case, non-human organisms) can occur with potentially adverse outcomes. Readers are strongly encouraged to become familiar with the information provided in Part III before reading this Part. ***However, although there are many similarities between***

multimedia human health risk assessment and ecological risk assessment (e.g., they may use the same multimedia monitoring and modeling tools), professional expertise will always be required to apply the ecological risk assessment principles and tools identified in this document to specific assessment areas or problems. This document is not a substitute for a working familiarity with ecological principles, their application, and the field of ecological risk assessment.

Air toxics may have adverse effects on ecological receptors through direct exposures (e.g., inhalation by animals; direct deposition onto plants). However, EPA does not have sufficient experience with multipathway air toxics risk assessments to identify the circumstances for which these exposures would represent a potential concern. This reference manual therefore does not address these additional exposure pathways. The methods for conducting such an analysis are described in greater detail in EPA's Guidelines for Ecological Risk Assessment.[1]

This chapter presents an overview of ecological risk assessment and discusses the initial planning and scoping activities. The remaining chapters of this part focus on Characterization of Exposure (Chapter 24), Characterization of Ecological Effects (Chapter 25), and Risk Characterization (Chapter 26). The discussion presented here is based largely on EPA's *Guidelines for Ecological Risk Assessment*[1] and the *Residual Risk Report to Congress.*[2] The *Guidelines for Ecological Risk Assessment* were developed especially for evaluating ecological risk. Readers are also strongly encouraged to become familiar with that document for a more complete understanding of EPA's recommended approach to ecological risk assessment. Interested readers are also referred to *EPA's Ecological Risk and Decision Making Workshop* materials which provide detailed information on the definition of ecological risk assessment, how it relates to human health assessment, the ecosystem protection place-based approach, and the bases for ecological protection and risk assessment at EPA.[3]

Key Ecological Risk Assessment Resources

- NCEA's Ecological Risk Assessment webpage http://cfpub.epa.gov/ncea/cfm/ecologic.cfm
- The Oak Ridge National Laboratory Ecological Risk Assessment webpage on tools, guidance, and applications http://www.esd.ornl.gov/programs/ecorisk/ecorisk.html
- The Superfund Ecological Risk Assessment Program http://epa.gov/superfund/programs/risk/ecolgc.htm
- Navy Guidance for Conducting Ecological Risk Assessments http://web.ead.anl.gov/ecorisk/
- EPA's Watershed Ecological Risk Assessment program http://cfpub.epa.gov/ncea/cfm/weracs.cfm?ActType=default

Some Important Differences Between Ecological Risk Assessment and Multipathway Human Health Risk Assessment

- **Planning and scoping**. The ecological risk assessment requires more preliminary analysis and deliberation regarding endpoints to be assessed and toxicity reference values to be used because ecological systems are more complex and are not as well understood biologically as human health systems. The planning and scoping team should include individuals with specific expertise in ecological risk assessment.

- **Assessment area**. It may be necessary to evaluate additional portions of the assessment area that are not of concern from a human health perspective.

- **Potentially exposed populations**. The focus shifts from potentially exposed individual humans to potentially exposed populations and species of ecological receptors of concern. In many cases, the exposure assessment may need to address multiple species and life-stages, many of which have physiological and biochemical processes that differ significantly from humans. (When threatened or endangered species are present, the assessment may also include an evaluation of those organisms as individuals).

- **Exposure pathways and exposure routes**. It may be necessary to assess different exposure pathways and routes that are not of concern for human health.

- **Ecological effects assessment**. Ecological systems have traits and properties that are different from humans and, thus, the ecological effects assessment (comparable to hazard assessment for human health) may consider a wider range of potential causal relationships.

- **Risk characterization**. While risks may be assessed at multiple levels of ecological organization (i.e., organism, population, community, and ecosystem), they generally are assessed at the population level in air toxics assessments. (Nevertheless, when appropriate, consideration should be given to assessments at high levels of ecological organization, such as at the landscape level).

23.2 Overview of Air Toxics Ecological Risk Assessment

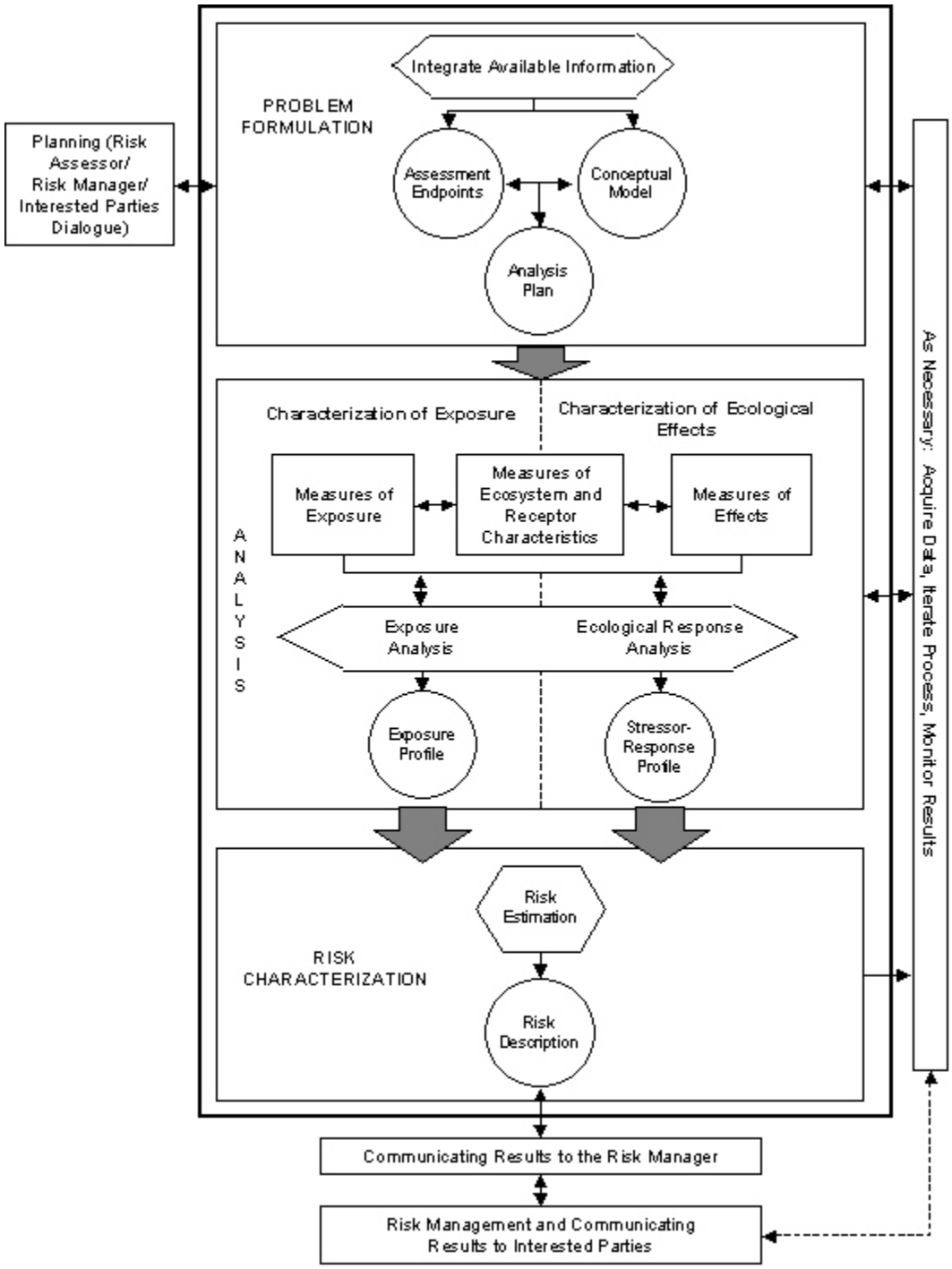
The ecological risk assessment process has three main steps that broadly correspond to the four basic steps in human health risk assessment methodology (Exhibit 23-2):[1]

- **Problem formulation**, which corresponds to the problem formulation step of the human health risk assessment methodology (planning and scoping activities similar to human health risk assessment are also integrated with this step; however, they are discussed separately below to maintain the operational structure of the ecological risk assessment as described in EPA's ecological risk assessment guidelines);

- **Analysis**, which corresponds to the exposure assessment and toxicity assessment steps of the human health risk assessment methodology; and

- **Risk characterization**, which corresponds to the risk characterization step of the human health risk assessment methodology.

Exhibit 23-2. Ecological Risk Assessment Framework



Source: EPA Guidelines for Ecological Risk Assessment[1]

23.2.1 Problem Formulation

Problem formulation provides the foundation for the entire ecological risk assessment. This step includes:

- Identifying risk management goals from an ecological perspective, ecological receptors of concern (e.g., wetlands, fish populations, keystone species that impact the overall ecosystem), and assessment endpoints (explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes);

- Developing the ecological risk part of the conceptual model as necessary to account for ecological exposure pathways and receptors; and

- If necessary, developing the Sampling and Analysis Plan and associated Quality Assurance Project Plan to collect data on exposures and measures of effects that are needed to support the ecological risk assessment.

As with human health risk assessments, problem formulation is often an iterative process, in which substantial re-evaluation may occur as new information and data become available. Data collection in subsequent iterations often is triggered by identification of major data gaps and uncertainties in the risk characterization that prevent confident decision-making by risk managers.

The problem formulation process for ecological risk assessment for air toxics focuses on developing a common understanding of what needs to be done to assess *ecological* risks associated with pathways involving deposition; the transfer of compounds to soil, water, sediment, and biota, and subsequent exposure. While the ecological risk assessment may build on the foundation of the human health multipathway assessment (e.g., using the same emissions data and multimedia models), the problem formulation step is particularly critical for the ecological risk assessment because of the effort needed to understand and identify ecological receptors, exposure pathways, endpoints, and management goals. The ecological risk assessment is not simply an "add-on" to the human health multipathway risk assessment. The problem formulation effort will need to consider a wide variety of possible ecological receptors that are not similar to humans. For example:

- Different species (and life stages) may have very different responses to the same exposure. Therefore, knowledge of the exposure-response of many species, including those that may be particularly sensitive to the air toxic, is needed.

- Ecosystems may show adverse effects at lower exposures than most individual species do because species that are important in terms of ecosystem function (e.g., energy flow, nutrient recycling) may also be sensitive to toxic effects. Ecosystem-level metrics such as species diversity indices may be more sensitive indicators of adverse effects than are toxicological studies.

- There may be many different types of ecosystems present in the assessment area, and sensitivity likely varies among them. Therefore, the particular features of the ecosystem(s) that occur in areas where high exposures are predicted may be particularly important.

An Ecological Risk Assessment Case Study: Ozone Risks To Agroecosystems

The case study summarized here provides an example of how EPA has assessed environmental risks from an air pollutant (ozone) as part of EPA's effort to promulgate National Ambient Air Quality Standards (NAAQS) for criteria air pollutants (see Chapter 2). Note that this example is for ozone, a criteria air pollutant; however, the concepts presented here are relevant to air toxics risk assessment. In addition, an agroecosystem, such as the system discussed here, is more of a human construct than a natural ecosystem and is provided here only for illustration of general principles. An actual air toxics ecological risk assessment of a natural system would have to consider site-specific characteristics of the system in question.

Problem Formulation. Pursuant to the Clean Air Act (CAA), EPA is required to set NAAQS for "any pollutant which, if present in the air, may reasonably be anticipated to endanger public health or welfare and whose presence in the air results from numerous or diverse mobile and/or stationary sources." EPA develops public health (primary) and welfare (secondary) NAAQS. According to section 302 of the CAA, the term welfare "includes ... effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values ...." A secondary standard, as defined in section 109(b)(2) of the CAA, must "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air."

This case study focuses on an assessment endpoint for agricultural crops (e.g., the prevention of an economically adverse reduction in crop yields). Yield loss is defined as an impairment of, or decrease in, the value of the intended use of the plant. This concept includes a decrease in the weight of the marketable plant organ, reduction in aesthetic values, changes in crop quality, and/or occurrence of foliar injury when foliage is the marketable part of the plant. These types of yield loss can be directly measured as changes in crop growth, foliar injury, or productivity, so they also serve as the measures of effect for the assessment.

Exposure Analysis. EPA used ambient ozone monitoring data across the U.S. and a Geographic Information System (GIS) model to project national cumulative, seasonal ozone for the maximum three month period during the summer ozone season. This allowed EPA to project ozone concentrations for some rural parts of the country where no monitoring data were available but where crops were grown, and to estimate the attainment of alternative NAAQS scenarios. The U.S. Department of Agriculture's (USDA's) national crop inventory data were used to identify where ozone-sensitive crop species were being grown and in what quantities. This information allowed the Agency to estimate the extent of exposure of ozone-sensitive species under the different scenarios.

Ecological Effects Analysis. Stressor-response profiles describing the relationship between ozone and growth and productivity for 15 crop species representative of major production crops in the U.S. (e.g., crops that are economically valuable to the U.S., of regional importance, and representative of a number of crop types) had already been developed from field studies conducted from 1980 to 1986 under the National Crop Loss Assessment Network (NCLAN) program. The NCLAN studies also included secondary stressors (e.g., low soil moisture and co-exposure with other pollutants like sulfur dioxide), which helped EPA interpret the environmental effects data for ozone.

Risk Characterization. Under the different NAAQS scenarios, the Agency estimated the increased protection from ozone-related effects on vegetation associated with attainment of the different NAAQS scenarios. Monetized estimates of increased protection associated with several alternative standards for economically important crops were also developed. This analysis focused on ozone effects on vegetation since these public welfare effects are of most concern at ozone concentrations typically occurring in the U.S. By affecting commercial crops and natural vegetation, ozone may also indirectly affect natural ecosystem components such as soils, water, animals, and wildlife.

Source: U.S. Environmental Protection Agency. 1999. *Residual Risk Report to Congress*. Office of Air Quality Planning and Standards, Research Triangle, NC, March 1999. EPA-453/R-99-011.

23.2.2 Analysis

Analysis includes two principal steps. **Characterization of exposures** includes identifying the **contaminants of potential ecological concern** (COPECs) that may affect ecological receptors, characterizing the spatial and/or temporal pattern of stressor concentrations in environmental media (including certain body burden levels), and analyzing the level of contact or co-occurrence (exposure) between the stressors and the ecological receptors. This often is done using the multimedia models identified in Chapter 18; however, different models or approaches may be appropriate. **Characterization of ecological effects** includes identifying the types of effects that different stressors may have on ecological receptors, along with characterizing the **stressor-response relationship** (the relationship between the level of exposure to the stressor and the expected biological or ecological response). A common result is the identification of **ecological toxicity reference values (TRVs)**, which are concentrations of chemicals in environmental media (including biota such as fish tissues) below which no significant ecological effects are anticipated. TRVs are similar, in concept, to RfDs (reference doses) and RfCs (reference concentrations) for human health noncancer evaluations. TRVs may be screening level (i.e., conservative, generic values) or more refined values for use in higher levels of analysis. They may be point values, ranges, or developed using more advanced probabilistic methods (such as Monte Carlo techniques). The ecological exposure characterization also is likely to differ significantly from the corresponding multipathway exposure assessment for human health. For example:

- In addition to food chain (ingestion) exposures, many ecological receptors can be exposed to air toxics via direct contact with contaminated soils (e.g., earthworms) or sediments (e.g., sediment-dwelling invertebrates, bottom-feeding fish); direct exposure to surface water (e.g., free-swimming invertebrates and fish); or direct exposure to contaminated air via inhalation (e.g., birds), dermal contact (e.g., amphibians), deposition to plant surfaces, etc.

- Particular geographic areas of concern may differ because ecological receptors may occur in areas rarely used by human populations (e.g., large wetland areas, ponds where people rarely fish).

- Sampling and analysis may involve a wider range of media (e.g., sediment) and different types of biota (e.g., earthworms, aquatic invertebrates). Each type of sampling and analysis has its own methods, protocols, and Quality Assurance/Quality Control (QA/QC) procedures.

- Quantitative metrics of exposure may include both direct and indirect exposures for ecological receptors. Quantification of direct exposure is similar to human health inhalation analyses, in which ambient concentrations of COPECs in soil, water, and/or sediment are compared to corresponding TRVs. Quantification of indirect exposure via ingestion is similar to that for human health ingestion analyses, except that different food items may be involved, and the appropriate ecological **exposure factors** (e.g., diet, body weight) will be different. As with human health analyses, many exposure factors can be treated either as constants or as distributions in the exposure assessment. Ecological exposure assessments for ingestion pathways frequently use bioenergetic models to more explicitly relate intake to adverse effects.[4]

23.2.3 Evaluation of Ecological Effects

The characterization of ecological effects is similar to a toxicity assessment for human health. It considers the types of adverse effects associated with chemical exposures, stressor-response relationships, and related uncertainties. There are two primary differences:

- Adverse effects of concern generally focus at the population, community, or ecosystem level. With rare exceptions (e.g., threatened or endangered species), effects to individual organisms are not the primary concern. Note, however, that ecological risk assessments often use estimates of impacts to individual organisms (e.g., mortality, reproductive effects) to infer impacts at higher levels of organization because exposure-response data for populations, communities, or ecosystems often are lacking. Some approaches are available, however, for incorporating population-level analysis in ecological risk assessments.[5]

- A distinction is made between **assessment endpoints**, which are the environmental values to be protected, and **measures of effects**, which are the specific measures used to evaluate risk to the assessment endpoints (assessment endpoints and measures of effects are defined in Section 23.3.4.2).

23.2.4 Ecological Risk Characterization

Similar to human health risk characterization, ecological risk characterization combines information concerning exposure to chemicals with information regarding effects of chemicals to estimate risks. Human health risk assessments consider health effects in the bodies of individual people. Ecological risk assessments consider various "health" issues that can range from actual health effects in the bodies of individual ecological receptors to something more attuned to the "health" of the ecosystem as measured by species richness and diversity.

23.3 Planning and Scoping

To ensure that the ecological risk assessment will provide information useful to the risk managers who will be making the risk management decisions, EPA's *Guidelines for Ecological Risk Assessment* recommends a planning and scoping dialogue occur between the risk assessors, risk managers, and where appropriate, interested stakeholders at the very start of the risk assessment process. The outcome of the planning and scoping phase is an agreement on the basic goals, scope, and timing of the risk assessment. Important goals of the dialogue are the identification of the risk management goals and risk management options that the risk assessment will be designed to inform (see accompanying text box). This 'kick-off' dialogue sets the stage for the problem formulation phase, when the plans for the ecological risk assessment are finalized.

Planning and Scoping the Ecological Risk Assessment

The planning phase is complete when agreements are reached on:

- The management goals for ecological values;
- The range of management options the risk assessment is to support;
- Objectives for the risk assessment, including criteria for success; and
- The focus and scope of the assessment, and resource availability.

When actually performing the problem formulation phase of an ecological risk assessment, the five-step planning and scoping process identified for human health risk assessments is a helpful tool to get the right people involved and the risk questions, expectations, and plans in place to make the overall assessment go smoothly and in a scientifically responsible manner. Similar to the human health evaluation process, the risk assessment and management team should be assembled to start identifying the concern, identifying who needs to be involved in the risk assessment process, determining the scope of the risk assessment, describing why there may be a problem, and determining how the concern will be evaluated.

23.3.1 What is the Concern?

In human health risk assessment and risk management, the assessors are dealing with a single organism (human beings) and the precedent and rationale for specific risk management goals (such as the $1x10^{-6}$ to $1x10^{-4}$ cancer risk range) are generally well established. The parallel process for ecosystems, however, is not as easy to study or as straightforward to manage. To begin with, it can be difficult to choose which of many organisms in a study area to evaluate. Moreover, there is little agreement on which (if any) organisms or ecosystems are important enough to single out for protection. These factors make planning, evaluation, and management of ecological risks more complicated and time-consuming (and often, more controversial).

EPA's Risk Assessment Forum developed draft guidance[6] to help decision-makers work with risk assessors, stakeholders, and other analysts to plan for ecological risk assessments that will effectively inform the decisions they need to make. Planning for ecological risk assessment includes three primary steps:

1. **Defining the risk management decision to be made, the context in which it will be made, and its purpose**. This includes articulating the decision or problem that the risk manager faces, understanding the social and legal context for the decision, placing preliminary boundaries on the scope of the risk assessment, and identifying who needs to be involved. Appropriately framing the context will help ensure that management objectives are relevant to the risk manager's decision and increase the likelihood that the information generated by the risk assessment will be useful.

2. **Developing objectives**. This starts with a clear statement of the problem, issue, or opportunity identified in the first step and ends with a set of specific objectives which will guide all of the remaining steps. An important determination is the "what to protect" (i.e., the assessment endpoint) question for ecological issues and to describe what is at stake. Key questions include:
   - What should be protected? Define the entities, ecological processes, and geographic areas to be considered.
   - How is "protection" defined? Define the ecological objectives.
   - What are the most important objectives and how can they be achieved? Review and structure objectives.

   In some cases, there is a strong consensus on "what to protect" (e.g., if a commercially important resource such as a fishery is potentially exposed). In many other cases, it is not always obvious to a risk manager or the public what features of an ecosystem are of potential concern or what the broader consequences would be from adverse effects to those features.

Developing a consensus on the specific risk management objectives may be a difficult and time-consuming part of the planning and scoping process.

3. **Identifying what information is needed to inform the decision**. When identifying information needs, planners are encouraged to think ahead about everything that will be needed to decide what to do about identified risks. Ecological risk is part of the picture, but issues such as feasibility, practicability, cost, and acceptability also need to be factored into the decision. They should also consider who and what resources are available to perform the ecological risk assessment. The aim of this step is to narrow down which questions the risk assessment should address and identify those that will be addressed elsewhere.

The questions identified at this step will be examined during the remainder of the problem formulation process. Management objectives are by definition closely related to the assessment endpoints evaluated in ecological risk assessment, and it should be possible to characterize them using the measures described below.

Assessment Endpoints

According to EPA's *Guidelines for Ecological Risk Assessment*,[1] an assessment endpoint is an explicit expression of the environmental value that is to be protected, and is operationally defined by an ecological entity and its attributes. For example, a particular area has air toxics releases that may be affecting area salmon populations that are important for location recreation and commercial fishermen as well as an important resource for a local Native American tribe. In the study area, the salmon population is the valued ecological entity; reproduction and age class structure of a salmon population are some of their most important attributes. An appropriate assessment endpoint for this study area might be stated as *salmon reproduction and age class structure*. The ecological risk assessment for this study area would be structured to evaluate whether this specific salmon population is at risk from air toxics with regard to healthy reproductive ability and age class structure.

Given the diversity of species and other ecological attributes in almost any study area, the assessors generally establish at least one assessment endpoint that will, together, provide an assessment of air toxics impacts on the ecosystem as a whole. More than one assessment endpoint may be necessary at the ecosystem level.

23.3.2 Identifying The Participants

The participants for the ecological risk assessment may include some of the same people as those for the human health multipathway risk assessment (e.g., multimedia modelers that understand how to model for both human and ecological receptors). However,

- Additional risk managers may be involved, including natural resource management agencies such as the U.S. Fish and Wildlife Service; state, local, or tribal (S/L/T) fish and game departments; and/or private-sector risk managers.

- The risk assessment technical team will need significantly different experts (e.g., aquatic ecologists, experienced ecological risk assessors).

- The specific set of interested or affected parties may change or be expanded (e.g., different environmental groups may be more concerned/involved; local fishermen may become interested).

EPA's Public Involvement Policy may be helpful in performing this task (see http://www.epa.gov/stakeholders/policy2003/index.htm). Part V of this document provides additional information on community involvement.

23.3.3 Determining the Scope of the Risk Assessment

The scope of the human health multipathway risk assessment may expand to include additional exposure pathways and exposure routes, and to address ecological receptors of concern.

- The specific chemicals that will be the focus of the ecological risk assessment will generally be those that persist, bioaccumulate, and biomagnify (the PB-HAP compounds); however, a different set of PB-HAP compounds may be of more concern for the ecological risk assessment than for human health risk assessment. As with human health risk assessment, additional compounds may need to be added to the analysis, depending on study-area specific considerations.

- The specific sources included in the analysis may be focused on the subset that releases most or all of the identified COPECs.

- The physical boundaries of the study area may need to expand to include geographic areas where COPECs may be transported after deposition (e.g., the COPECs may have the potential to be deposited in a watershed and be carried out of the geographic area defined for the human health multipathway modeling).

23.3.4 Study-Specific Conceptual Model

A study-specific conceptual model for the ecological risk assessment is developed using the fundamental elements of the conceptual model developed for the human health multipathway assessment as a starting point. Steps to develop the study-specific ecological risk conceptual model include the following:

- Determine whether the set of potential sources and chemicals that were identified in the human health multimedia risk assessment are appropriate for the ecological risk assessment.

- Consider expanding the set of potential sources, chemicals, and exposure pathways to include those identified below (potential exposure pathways are listed in Exhibit 23-3).

- Identify ecological receptors of concern (see Section 23.3.4.1).

- Formulate a **risk hypothesis** that describes possible relationships between emissions of a chemical, exposure, and assessment endpoint response, including the information that sets the problem in perspective, as well as an identification of the proposed relationships that need evaluation.

- Identify assessment endpoints and measures of effects (See Section 23.3.4.2).

Exhibit 23-3. Common Exposure Pathways Considered for Ecological Air Toxics Risk Assessments
Direct exposure pathways: air → soil → soil-dwelling biota air → soil → water → aquatic biota air → water → aquatic biota air → water → sediment → aquatic biota air → soil → water → sediment → aquatic biota air → vegetation **Indirect exposure pathways:** air → vegetation → bird/mammal air → soil → vegetation → bird/mammal air → soil → water → aquatic biota → fish air → soil → water → aquatic biota → fish → bird/mammal air → water → aquatic biota → fish air → water → aquatic biota → fish → bird/mammal air → soil → water → sediment → aquatic biota → fish air → soil → water → sediment → aquatic biota → fish → bird/mammal

Conceptual model diagrams, such as the example illustrated in Exhibit 23-4, are used (along with the risk hypothesis) to select the pathways to be evaluated in the analysis phase of the ecological risk assessment, as well as to assist in communication with risk managers.

As with human health risk assessments, the conceptual model for an ecological risk assessment must provide both a graphical representation of the important exposure pathways that are presumed to be occurring along with a written description that outlines each element of the conceptual model. Taken together, these two parts of the conceptual model clearly identify the sources of concern, the COPECs that will be evaluated, the exposure pathways, and the assessment endpoints. Similar to conceptual models for human health analysis, the conceptual model may be modified (perhaps a number of times) as more is learned about the study area.

23.3.4.1 Identifying Receptors of Concern

Ecological receptors of concern are an important part of the conceptual model. These may be plants, animals, habitats, communities, or larger ecosystem elements. Specific receptors may be of concern for a variety of reasons, including:

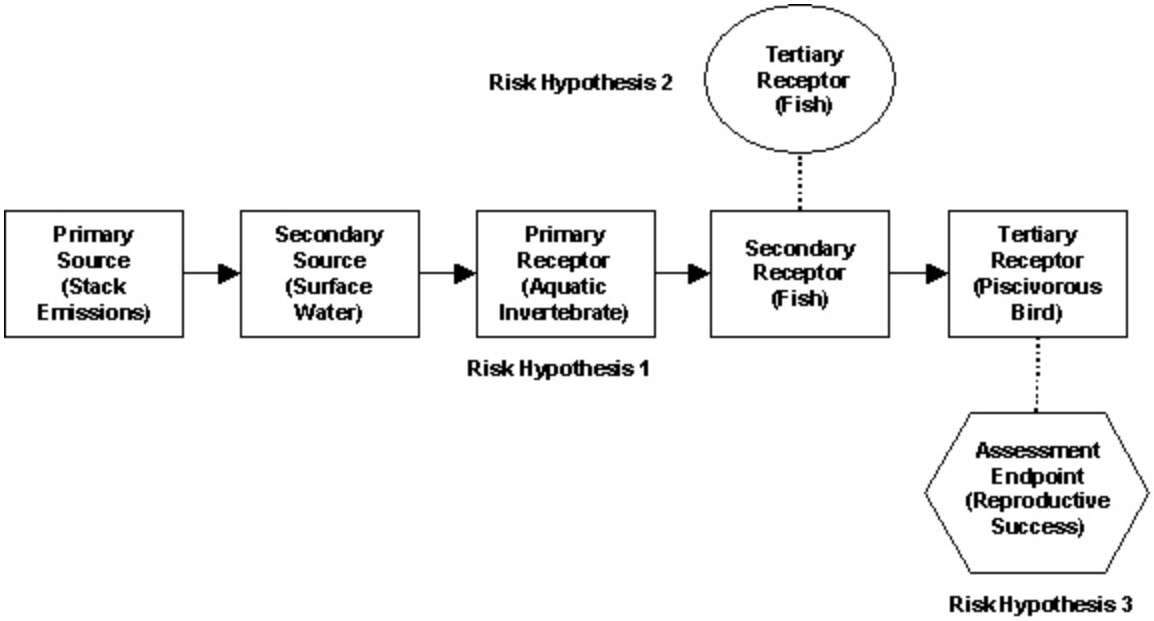
- The receptor (or one of it's life stages) is particularly vulnerable or sensitive to one or more COPECs;

- The receptor (usually a species or a community such as a wetland) is listed as endangered or threatened or is otherwise given special legal protection by the state or federal government;

- The receptor plays an important part in the overall structure or function of the ecological community or ecosystem;

- The receptor is of particular economic or cultural value to stakeholders.

Exhibit 23-4. Conceptual Model Diagram for Exposure of Piscivorous Birds to Air Toxics



Conceptual model diagrams are used, along with the risk hypothesis, to select the pathways to be evaluated in the analysis phase of the ecological risk assessment, as well as to assist in communication with risk managers. The three risk hypotheses in this hypothetical example are:

- **Risk Hypothesis 1**: Concentrations of chemical X in the surface water column are less than a level known to cause adverse effects on survival and reproduction in *Daphnia*
  - Mechanism: Chemical X causes mortality and inhibits larval development

- **Risk Hypothesis 2**: Dietary intake levels of chemical X in lake trout are less than a level known to cause adverse effects on reproductive ability
  - Mechanism: Due to a lack of enzyme A in lake trout, chemical X rapidly accumulates in lipid tissues and damages reproductive organs

- **Risk Hypothesis 3**: Dietary intake levels of chemical X in kingfisher chicks (passed to them by their parents) is less than a level known to adversely affect their survival
  - Mechanism: Chemical X accumulating in egg lipids is a metabolic toxin to the developing embryo

For taxonomic, physiological, and exposure reasons, it is important to consider a broad range of potential ecological receptors during problem formulation. For example, the types of adverse effects that may occur to terrestrial plant communities (e.g., impacts to photosynthesis, nitrogen fixation, nutrient uptake; foliar damage) are very different than the types of adverse effects that may occur to terrestrial mammals. Many ecological receptors (e.g., molds, lichens, many invertebrates) have unique physiological and biochemical features that may make them particularly sensitive to air toxics. Sensitive life stages often are a particular concern. In surface waters and sediments, early life stages (e.g., eggs, larvae) may be particularly sensitive to contaminants due to their small size (e.g., contaminants may readily penetrate cell membranes) and developmental processes (e.g., major metamorphosis from one life stage to another). Many terrestrial organisms (e.g., amphibians, dragonflies) have aquatic-dwelling early life stages. In addition, many invertebrates that can bioaccumulate PB-HAPs (e.g., aquatic dwelling dragonfly larvae) may be sources of food for sensitive life stages of other species (e.g., nestling birds). Often it is important to understand the aquatic and terrestrial food webs in the habitats of concern because these can be important parts of ecological exposure pathways. Top predators are often of special concern for exposure to PB-HAP compounds.

Ecological receptors for each habitat potentially impacted should be identified to ensure (1) plant and animal communities representative of the habitat are represented by the habitat-specific food web, and (2) potentially complete exposure pathways are identified. Screening-level ecological assessments often focus on the most sensitive organisms within an ecosystem or on the most sensitive life stages within a species, if these are known. Ecological receptor identification may need to include species both known and expected to be present in a specific habitat being evaluated, and include resident and migratory populations. Consultation with ecological experts is recommended. Potential sources of information include:

- **Government Organizations**. The U.S. Fish and Wildlife Service has biologists and other ecological experts and also maintains National Wetland Inventory maps.[7] State Natural Heritage Programs provide maps or lists of species based on geographic location, and are very helpful in identifying threatened or endangered species or areas of special concern.

- **Private or Local Organizations**. Private or professional organizations that are examples of sources of information include: National Audubon Society, the Nature Conservancy, local wildlife clubs, and universities.

- **General Literature**. Monographs, field guides, and other literature describing the flora and fauna of America and/or a particular region or state may be useful sources of information.

23.3.4.2 Identifying Assessment Endpoints and Measures of Effects

As previously noted, an **assessment endpoint** is an explicit expression of the environmental value that is to be protected or is of concern. It includes the identification of the ecological entity for the analysis (e.g., a species, ecological resource, habitat type, or community) as well as the attribute of that entity that is potentially at risk and important to protect (e.g., reproductive success, production per unit area, surface area coverage, biodiversity). The **measures of effects** are the measures used to assess these endpoints.[8]

Generally, a manageable subset of the most important assessment endpoints is selected for the risk assessment, and specific measures of effects that address each assessment endpoint are identified. EPA guidance documents discuss additional issues that are important in the identification of assessment endpoints.[9]

Appropriate selection of relevant assessment endpoints is critical so that the risk assessment provides valuable information for the associated risk management decisions. Assessment endpoints that can be measured directly are most effective, although assessment endpoints that cannot be measured directly, but can be represented by measures that are easily monitored or modeled, may also be used. Additional uncertainty is introduced depending on the relationship between the measurement and the assessment endpoints. Exhibit 23-5 provides examples of assessment endpoints, measures of effect, and other elements of the problem formulation phase.

EPA has recently released guidance that describes a set of endpoints, known as Generic Ecological Assessment Endpoints (GEAE), that can be considered and adapted for specific ecological risk assessments.[9] The entities and properties comprising the initial set of GEAEs is presented in Exhibit 23-6. The EPA Guidance defines GEAE further and provides the basis for the terms *assessment community* and *assessment population*, which are used in the definitions. In addition, EPA's Science Advisory Board recently published a *Framework for Assessing and Reporting on Ecological Condition*,[10] which includes a checklist of ecological attributes that should be considered when conducting ecological risk assessments and developing ecological management objectives (Exhibit 23-7). Note that many of these GEAEs and attributes focus at levels of ecological organization higher than organisms (e.g., species richness) or on ecological processes (e.g., nutrient cycling) rather than attributes of organisms (e.g., growth, reproduction).

It often is useful to summarize the results of the problem formulation process in a **problem formulation summary** that lists management objectives, assessment endpoints, and the structure of the risk assessment from exposure scenarios through risk characterization. Exhibit 23-8 provides an example problem formulation summary.

23.3.5 Analysis Plan and Quality Assurance Program Plan (QAPP)

As noted in Parts II and III of this reference manual, the Analysis Plan and QAPP are formulated by considering both the the conceptual model and the data quality required for the risk management decision. The Analysis Plan and QAPP, including data quality objectives, are just as important for the ecological risk assessment as they are for the human health risk assessment, and in some cases may be more complex. The analysis plan for the ecological risk assessment will need to match each of the elements of the conceptual model with the analytical approach that will be used to develop data about the element, including: sources; exposed populations and exposure pathways; exposure concentrations of COPEC; exposure conditions; toxicity of COPECs; risk characterization; QA/QC; documentation; roles and responsibilities; resources; and schedule.

Because the focus is on ecological receptors, additional types of monitoring (sampling and analysis) may need to be conducted. For example, it may be important to measure concentrations of COPECs in the sediments of surface water bodies as part of the analysis of direct exposures for sediment-dwelling invertebrates as well as bioaccumulation from these invertebrates to predatory fish through the aquatic food web.

Exhibit 23-5. Example of Ecological Risk Assessment Problem Formulation: EPA's Water Quality Criteria

A specific example of elements of the problem formulation step in a national-level ecological risk assessment can be found in the development of Ambient Water Quality Criteria by EPA's Office of Water pursuant to the Clean Water Act (CWA).[11] Water quality criteria have been developed for the protection of aquatic life from chemical stressors. The following elements of problem formulation support subsequent analyses in the risk assessments used to establish specific criteria.

Regulatory Goal

- CWA Section 101: Protect the chemical, physical, and biological integrity of the Nation's water.

Program Management Decisions

- Protect 99 percent of individuals in 95 percent of the species in aquatic communities from acute and chronic effects resulting from exposure to a chemical stressor.

Assessment Endpoints

- Survival of fish, aquatic invertebrates, and algal species under acute exposure
- Survival, growth, and reproduction of fish, aquatic invertebrates, and algal species under chronic exposure

Measures of Effect

- Laboratory LC_{50}s for at least eight species meeting certain requirements
- Chronic no-observed-adverse-effect-levels (NOAELs) for at least three species meeting certain requirements

Measures of Ecosystem and Receptor Characteristics

- Water hardness (for some metals)
- pH

The water quality criterion is a TRV derived from a distributional analysis of single-species toxicity data. It is assumed that the species tested (which represent a range of taxonomic groups) adequately represent the composition and sensitivities of species in a natural community.

Exhibit 23-6. Generic Ecological Assessment Endpoints[a]		
Entity	**Attribute**	**Identified EPA Precedents**
Organism-level endpoints		
Organisms (in an assessment population or community)	Kills (mass mortality, conspicuous mortality)	Vertebrates
	Gross anomalies	Vertebrates, shellfish, plants
	Survival, fecundity, growth	**Endangered species, migratory birds, marine mammals, bald and golden eagles**, vertebrates, invertebrates, plants
Population-level endpoints		
Assessment population	Extirpation	Vertebrates
	Abundance	Vertebrates, shellfish
	Production	Vertebrates (game/resource species), harvested plants
Community and ecosystem-level endpoints		
Assessment communities, assemblages, and ecosystems	Taxa richness	Aquatic communities, **coral reefs**
	Abundance	Aquatic communities
	Production	Plant assemblages
	Area	**Wetlands, coral reefs**, endangered/rare ecosystems
	Function	**Wetlands**
	Physical structure	Aquatic ecosystems
Officially designated endpoints		
Critical habitat for endangered or threatened species	Area Quality	
Special places	Ecological properties that relate to the special or legally protected properties	e.g., **National Parks, National Wildlife Refuges, Great Lakes**

[a]Generic ecological assessment endpoints for which EPA has identified existing policies and precedents (in particular, the specific entities listed in the third column). Bold indicates protection by federal statute.
Source: EPA's *Generic Ecological Assessment Endpoints (GEAE) for Ecological Risk Assessment*[9]

Exhibit 23-7. Essential Ecological Attributes and Reporting Categories	
Landscape Condition • Extent of ecological system/habitat types • Landscape composition • Landscape pattern and structure **Biotic Condition** • Ecosystems and communities – Community extent – Community composition – Trophic structure – Community dynamics – Physical structure • Species and populations – Population size – Genetic diversity – Population structure – Population dynamics – Habitat suitability • Organism condition – Physiological status – Symptoms of disease or trauma – Signs of disease **Chemical and Physical Characteristics (Water, Air, Soil, and Sediment)** • Nutrient concentrations – Nitrogen – Phosphorus – Other nutrients • Trace inorganic and organic chemicals – Metals – Other trace elements – Organic compounds • Other chemical parameters – pH – Dissolved oxygen – Salinity – Organic matter – Other • Physical parameters	**Ecological Processes** • Energy flow – Primary production – Net ecosystem production – Growth efficiency • Material flow – Organic carbon cycling – Nitrogen and phosphorus cycling – Other nutrient cycling **Hydrology and Geomporphology** • Surface and groundwater flows – Pattern of surface flows – Hydrodynamics – Pattern of groundwater flow – Salinity patterns – Water storage • Dynamic structural characteristics – Channel/shoreline morphology, complexity – Distribution/extent of connected floodplain – Aquatic physical habitat complexity • Sediment and material transport – Sediment supply/movement – Particle size distribution patterns – Other material flux **Natural Disturbance Regimes** • Frequency • Intensity • Extent • Duration
Source: U.S. EPA. 2002. *A Framework for Assessing and Reporting on Ecological Condition*[10]	

Exhibit 23-8. Example Problem Formulation Summary

1. **Management Objective**
   - Bald eagle (entity), local population size (attribute), should be stable (desired state)

2. **Assessment Endpoints**
   - Bald eagle (entity), reproduction (measurable attribute)
   - Bald eagle (entity), chick survival (measurable attribute)

3. **Exposure Scenario**
   - Sediment –> pore water –> benthic invertebtrates –> forage fish –> bald eagle

4. **Risk Hypothesis**
   - Dose of chemical X to adult bald eagles from consumption of fish is less than a level known to cause adverse effects on reproductive ability
     - Mechanism: Chemical X damages reproductive organs (or interferes with egg shell development)
   - Dose of chemical X to bald eagle chicks (passed to them by their parents) is less than a level known to adversely affect their survival
     - Mechanism: Chemical X accumulating in egg lipids is a metabolic toxin to the developing embryo

5. **Metrics of Exposure**
   - Concentration of chemical X in fish
   - Dose of chemical X received through consumption of fish

6. **Measure of Effect**
   - TRV for chemical X (NOAEL or LOAEL) where adult reproduction was an endpoint
   - TRV for chemical X (NOAEL or LOAEL) where chick survival (mortality) was and endpoint

7. **Measure of Characteristics**
   - Proximity of bald eagle nest site to potentially contaminated foraging areas
   - Proximity of alternative (non-contaminated) foraging areas to the nest site

8. **Risk Characterization**
   - HQ = Oral Intake of chemical X/TRV (separate calculations for adults and chicks)

23.4 Tiered Ecological Risk Assessments

One of the key elements in the ecological risk assessment process is deciding if and when further analysis is warranted. As with human health risk assessment, EPA recommends a tiered approach to ecological risk assessment.[1] Each of these tiers follows the basic three steps (problem formulation, analysis, and risk characterization) but with varying levels of complexity in the assessment and with varying requirements for resources. Examples of the three tiers of ecological risk assessment approaches are described briefly below.

- **Screening-Level** ecological risk assessments provide a general indication of the *potential* for ecological risk (or lack thereof) and may be conducted for several purposes including: (1) to prioritize COPECs based on their relative environmental behavior (e.g., relative potential for bioaccumulation or to exhibit chronic toxicity) or determine their relative contribution to the overall risk estimate; (2) to estimate the likelihood that a particular ecological risk exists; (3) to identify the need for additional data collection efforts; or (4) to focus more detailed ecological risk assessments where warranted. Screening assessments often use simplified conservative assumptions in place of detailed modeling. For example, concentrations in aquatic invertebrates or fish might be estimated from the modeled or measured water concentrations (obtained as part of a multipathway human health risk assessment) and available bioconcentration factors (BCFs) or bioaccumulation factors (BAFs). Another example is the comparison of maximum sediment and water concentrations to screening level TRVs. A screening level assessment, while abbreviated, is nonetheless a complete risk assessment. Therefore, each assessment should include documentation supporting the risk characterization and uncertainty analysis. Some examples of screening level TRVs used in screening level ecological risk assessments are available from EPA's draft Ecological Soil Screening Level Guidance (http://www.epa.gov/superfund/programs/risk/ecorisk/guidance.pdf) and EPA Region 4 (http://www.epa.gov/region4/waste/ots/ecolbul.htm).

- **More Refined** assessments are generally used to: (1) identify and characterize the current and potential threats to the environment from an air toxics release; (2) evaluate the ecological impacts of alternative emissions control or abatement policies; and (3) establish emissions levels that will protect those natural resources at risk. A more refined assessment may contain a more intensive evaluation than a screening level assessment, and usually employs multipathway analysis to estimate if, and to what extent, ecological receptors (e.g., an oyster fishery, a wild duck population, or a unique wetland community) may be exposed. The exposure and potential impact are characterized and evaluated against predetermined assessment endpoints (i.e., edibility of oysters, sustainability of the duck population, maintenance of the integrity of the wetland community). This tier may be iterative. For example, a multipathway analysis using conservative assumptions may first be performed to identify whether any of the COPECs emitted from the sources in an area pose a potentially significant concern to one or more ecological receptors. If so, a more detailed multipathway risk assessment, using more site-specific data, may be performed. From this last stage a detailed characterization of the environmental risks is developed.

- **Probabilistic** assessments are used to increase the strength of the *predictive* evaluation of ecological risks, as well as help better evaluate distributions of observational data for an ecological risk assessment. Screening-level and more refined assessments usually utilize simplified point estimates in the development of a risk characterization, while the

probabilistic tier of assessment uses probability distributions as inputs. Therefore, this tier generally can yield risk estimates that allow for a more complete characterization of variability and uncertainty. Although probabilistic assessments generally are resource-intensive, they may be especially valuable in situations when the risks are close to a policy threshold or if the management decisions, if implemented, would require significant expenditures.

Additional Reference Materials

EPA has developed extensive technical and policy guidance on how ecological risk assessments should be planned and performed. These are available at EPA's "Tools for Ecological Risk Assessment" website http://www.epa.gov/superfund/programs/risk/tooleco.htm.

- EPA's *Guidelines for Ecological Risk Assessment*, April 1998. This document expands upon and replaces the earlier 1992 *Framework for Ecological Risk Assessment.*

- EPA's *Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments, Interim Final*, June 1997. This document includes processes and steps for use in ecological risk assessments at Superfund sites. This document supersedes the 1989 *RAGS, Volume II, Environmental Evaluation Manual, Interim Final*. Supplements to ERAGS include the *Eco Updates* (Intermittent Bulletin Series, 1991 to present), which provide brief recommendations on common issues for Superfund ecological risk assessments. The approaches and methods outlined in the *Guidelines* and in *ERAGS* are generally consistent with each other.

- *Risk Assessment Guidance for Superfund (RAGS): Volume 1–Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments)*, June 2001. This guidance specifies formats that are required to present data and results in baseline risk assessments at Superfund sites; many of these formats are useful for air toxics ecological risk assessments.

- Policy Memorandum: *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, F. Henry Habicht, Deputy Administrator, Feb. 26, 1992. This policy requires baseline risk assessments to present ranges of risks based on "central tendency" and "high-end" exposures with corresponding risk estimates.

- Policy Memorandum: *Role of the Ecological Risk Assessment in the Baseline Risk Assessment*, Elliott Laws, Assistant Administrator, August 12, 1994. This policy requires the same high level of effort and quality for ecological risk assessments as commonly performed for human health risk assessments at Superfund sites.

- Policy Memorandum: *EPA Risk Characterization Program*, Carol Browner, Administrator, March 21, 1995. This policy clarifies the presentation of hazards and uncertainty in human health and ecological risk assessments, calling for clarity, transparency, reasonableness, and consistency.

- *Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites*. Stephen D. Luftig for Larry D. Reed, October 7, 1999. This document presents six key principles in ecological risk management and decision-making at Superfund sites; these principles are also useful for air toxics ecological risk assessments.

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Chapter 24 Analysis: Characterization of Ecological Exposure

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24.1 Introduction

As noted in the previous chapter, the analysis step of ecological risk assessment includes both characterization of exposures and characterization of ecological effects. This chapter describes the approaches and methods used for exposure characterization. Chapter 25 discusses the approaches and measures used for characterization of ecological effects. The discussion in this chapter is based largely on EPA's *Guidelines for Ecological Risk Assessment*.[1] Readers are referred to that document for a more complete discussion of available approaches and methods.

24.2 Characterization of Exposure

Ecological exposure refers to the contact of an ecological receptor with an air toxic through direct or indirect exposure pathways. As with human health risk assessment, characterization of ecological exposure should initially evaluate (in the problem formulation phase) all exposure pathways that are potentially complete. Unlike human health exposure, ecological risk assessments will generally identify a limited number of specific metrics of exposure to actually quantify since it is not usually possible to evaluate all exposure pathways for all the species or other ecosystem attributes present in any given study area. Initially the assessors will generally consider all exposure pathways broadly, but then identify the assessment endpoints which will lead to a specific and narrowly defined set of exposure pathways to actually study in depth.

Ecological exposure pathways that are generally important for air toxics include all pathways where contaminants are taken up directly from environmental media (e.g., air, soil, sediment, and surface or rain water) for lower trophic level organisms (including plants) and ingestion of contaminated plant or animal food items for higher trophic level receptors. Pathways that may be important in specific cases include foliar and root uptake by plants, deposition and dermal exposure pathways, and ingestion via grooming, preening, and food consumption.

Once the specific set of exposure pathways to be studied are determined (and the matching assessment endpoints that are to be assessed are determined), characterization of ecological exposure is based initially on information derived from modeling and/or existing monitoring data. Later, additional modeling and/or site-specific empirical information may be obtained. The objective of the exposure characterization is to produce a summary exposure profile that identifies the exposed ecological entity, describes the course a stressor takes from the source to that entity (i.e., the exposure pathway), and describes the intensity and spatial and temporal extent of co-occurrence or contact (see Section 24.2.4.3). The exposure profile also describes the influence of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur. Exhibit 24-1 provides a list of questions that can help define the specific information needed to characterize exposure.

Exposure characterization includes the following steps, each of which is discussed in a separate subsection below:[1]

- Quantifying releases of contaminants of potential ecological concern (COPEC);
- Estimating chemical fate and transport via modeling and/or monitoring;
- Quantifying exposure (e.g., exposure concentrations and dietary intakes);
- Evaluating uncertainty; and
- Preparing documentation.

Exhibit 24-1. Questions to Ask Concerning Source, Stressor, Exposure, and Ecosystem Characteristics

Source and Stressor Characteristics

- What is the nature of the source(s) (e.g., point vs. nonpoint vs. mobile sources)?
- What is the intensity of the stressor (e.g., the dose or concentration of a chemical)?
- What is the chemical form of the stressor and its lability as a function of local physical-chemical conditions?
- What is the mode of action? How does the stressor impact organisms or ecosystem functions?
- How does the stressor come into contact with a receptor (transport)?

Exposure Characteristics

- With what frequency does a stressor release occur (e.g., is it episodic or continuous; is it subject to daily, seasonal, or annual periodicity)?
- What is the duration of release and exposure? How long does the stressor persist in the environment (e.g., what is its half-life)?
- What is the timing of exposure? When does it occur in relation to critical organism life cycles or ecosystem events (e.g., reproduction, lake overturn)?
- What is the spatial scale of exposure? Is the extent or influence of the stressor local, regional, global, habitat-specific, or ecosystem-wide?
- What is the distribution? How does the stressor move through the environment (e.g., fate and transport)?

Ecosystems Potentially at Risk

- What are the geographic boundaries of the study area? How do they relate to functional characteristics of the ecosystem?
- What are the key abiotic factors influencing the ecosystem (e.g., climatic factors, geology, hydrology, soil type, water quality)?
- Where and how are functional characteristics driving the ecosystem (e.g., energy source and processing, nutrient cycling)?
- What are the structural characteristics of the ecosystem (e.g., species number and abundance, trophic relationships)?
- What habitat types are present?
- How do these characteristics influence the susceptibility (sensitivity and likelihood of exposure) of the ecosystem to the stressor(s)? For example, what portion of the receptor's home range is in the area of impact?
- Are there unique features that are particularly valued (e.g., the last representative of an ecosystem type)?
- What is the landscape context within which the ecosystem occurs?

Source: EPA Guidelines for Ecological Risk Assessment[1]

24.2.1 Quantifying Releases

The process used to quantify releases of air toxics for purposes of ecological risk assessment is identical to that for the human health analyses (see Chapter 7).

24.2.2 Estimating Chemical Fate and Transport

The process and methods used to estimate chemical fate and transport generally are similar to those used for multipathway human health risk assessments. Key differences and special considerations are highlighted in the subsections that follow.

24.2.2.1 Physical and Chemical Parameters

The same physical and chemical parameters identified in Chapter 17 affect the persistence of air toxics in the environment and their potential to accumulate in ecological food webs. Additional considerations are specific to ecological risk assessment.

- The bioconcentration factors (BCFs) and bioaccumulation factors (BAFs) used to characterize ecological exposure may be different than corresponding factors used for the human health exposure assessment. For example, wildlife may eat different species of fish/shellfish than humans; these may have different BCFs or BAFs. Also, whole-fish BCFs or BAFs are used for ecological exposure rather than those specific to the parts of the fish people normally eat (e.g., fillets).

- Chemical speciation (e.g., for metals such as mercury) may be an important determinant of exposure and bioavailablity.[(a)]

- Fate and transport analysis may need to examine a wider range of lower-trophic level organisms to assess impacts to the communities and ecosystems of interest as well as to develop exposure estimates for ecological food webs.

24.2.2.2 Multimedia Modeling

As with human health exposure assessment, some combination of multimedia modeling and monitoring is generally used for ecological exposure assessment. The appropriate mix of modeling and monitoring will depend on the level of assessment and the risk management goals.

Modeling is relatively easy and inexpensive to implement and can be used to evaluate not only risks from current levels of contamination, but also how risks might change over time (e.g., concentrations of persistent bioaccumulative hazardous air pollutant [PB-HAP] compounds in fish may slowly increase over time in the presence of a continuous release) or as a result of

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[a]EPA's Science Policy Council is embarking on the development of an assessment framework for metals. The first step in the process is formulation of an Action Plan that will identify key scientific issues specific to metals and metal compounds that need to be addressed by the framework, potential approaches to consider for inclusion in the framework (including models and methods), an outline of the framework, and the necessary steps to complete the framework.

potential changes in land use (a change in land use might alter a number of habitat factors that influence the number and identity of ecological receptors). The modeling approach, however, has inherent uncertainties, which may lead to either over- or underestimates of exposure.

Model choices range from simple, screening-level procedures that require a minimum of data to more sophisticated methods that describe processes in more detail, but require a considerable amount of data. The same multimedia models used for the multipathway human health exposure assessment generally can be used for at least part of the ecological exposure assessment (e.g., the same models can be used to estimate concentrations in abiotic media at specific locations, whether for human health or ecological exposure assessment). However, choice of specific exposure points or areas may differ due to the focus on ecological receptors, as will the specific food webs being evaluated. Specific models may also be configured in ways that facilitate ecological exposure assessments. For example, TRIM (Total Risk Integrated Methodology) includes a fate, transport, and ecological exposure model (TRIM.FaTE) which simulates multimedia pollutant transfers and ecological receptor exposures in an ecosystem of interest (see Part III).[2] However, other approaches (e.g., Multiple Pathways of Exposure) are not specifically designed for ecological exposure assessment).

24.2.2.3 Multimedia Monitoring

The term monitoring in ecological risk assessment can also be more broadly used to mean collection of any type of empirical field data for the assessment (e.g., plant counts and spatial distribution in an assessment area). The use of monitoring in ecological risk assessment can serve a number of purposes. For example, if there is a need to reduce uncertainties in the predictive modeling approach, monitoring can be performed in various media and biota in the study area. As with human health exposure assessment, monitoring can be used to confirm or calibrate predictive modeling estimates of contaminant concentrations in media or biota.

For higher-tier risk assessments, monitoring for ecological exposures also may include site-specific toxicity or bioaccumulation studies, in which test organisms are exposed to the actual mixtures of contaminants from within the study area to develop site-specific and chemical-specific toxicological and/or bioaccumulation relationships (See Chapter 25). However, poorly designed sampling or toxicological evaluations of environmental media from the site may not allow a definitive identification of the cause of adverse response. For example, receptor abundance and diversity as demographic data reflect many factors (e.g., habitat suitability, availability of food, and predator-prey relationships). If these factors are not properly controlled in the experimental design of the study (e.g., through use of a comparison site or a gradient design that examines effects along a two-dimensional gradient downwind of sources), conclusions regarding chemical stressors can be confounded. In addition, monitoring may not provide sufficient information to develop estimates of potential risks should land use or exposure change in the future.

Monitoring techniques for ecological exposure characterization may differ from those used for multipathway human health exposure assessment. In particular, different species or components of the food web may be of concern. For example, large invertebrates such as dragonfly larvae often are a focus for ecological exposure assessments because they are important components of surface water ecosystems as well as key prey items for both aquatic (e.g., fish) and terrestrial (e.g., birds) predators.

Example Consideration in Monitoring: Soil Sampling for Ecological Risk Assessments

The depth over which surface soils are sampled should reflect the type of exposure expected in the study area, the type of receptors expected in the study area, the depth of biological activity, and the depth of potential contamination. For example, if exposures to epigeic (surface dwelling) earthworms are a concern, concentrations in the first few inches of soil are most relevant. On the other hand, if a burrowing mammal is of concern, concentrations at a depth of two or more feet may need to be estimated. Careful consideration of the size, shape, and orientation of sampling volume is important since they have an effect on the reported measured contaminant concentration values.[3] Selection of sampling design and methods can be accomplished by use of the Data Quality Objectives (DQO) process discussed in Chapter 7. Additional soil sampling guidance that may be consulted includes EPA's *Preparation of Soil Sampling Protocols: Sampling Techniques and Strategies* [4] and *Guidance for Data Usability in Risk Assessment*.[5]

24.2.3 Quantifying Exposure

Three elements are important components of quantifying exposure: the specific metrics of exposures that are to be used, the dimensions of exposure, and the exposure profile. Each is described in a separate subsection below. These estimates can be produced by some models such as TRIM.FaTE.[6]

24.2.3.1 Metrics of Exposure

Depending on the specific receptors and pathways of concern, ecological exposure is quantified generally in one of three ways.[1]

- Exposures to abiotic media may be evaluated using contaminant media concentrations as the **exposure concentrations** – that is, concentrations of air toxics in soil, sediment, and/or surface water at the exposure points. This is because the ecological toxicity reference levels (TRVs) used to characterize risk are based on laboratory studies that directly relate environmental concentrations in these media to adverse ecological impacts (e.g., a laboratory study that dissolves known concentrations of a chemical in water and measures adverse responses in the invertebrates or fish living in that water - the resulting concentration in water that shows no effect is then compared to modeled or monitored concentrations of the chemical in study area surface water).

- Exposures via the ingestion route of exposure may be evaluated using the **average daily dose (ADD)**, generally expressed as mg of chemical per kg of body weight per day (mg/kg-d). The general formula[b] for calculating ADD for ecological receptors is similar to that used for human health ingestion exposure:[1]

$$ADD_{pot} = \sum_{k=1}^{m} (C_k \times FR_k \times NIR_k) \qquad \text{(Equation 24-1)}$$

[b]The TRIM.FATE model[6] can output estimates of ingestion intake at user-designated time points in a dynamic simulation, and as an average over a user-designated period, as well as estimates for steady-state simulation.

where

ADD_{pot} = Potential average daily dose, expressed in units of mg/kg-day.

Chemical-related variable:

C_k = Average contaminant concentration in the kth type of food, expressed in units of mg/kg (wet weight)

Variables that describe the exposed ecological receptor population (also termed "wildlife exposure factors"):

FR_k = Fraction of intake of the kth food type that is from the contaminated area (unitless).
NIR_k = Normalized ingestion rate of the kth food type of a wet-weight basis, expressed in kg food/kg body-weight-day.
m = Number of contaminated food types

Exposure factors can be found in the EPA *Wildlife Exposure Factors Handbook*.[7]

Contaminant concentration (C_k) is commonly estimated with the use of multimedia models. In some situations (e.g., a higher tier of analysis), C_k in food has been measured directly at the point of contact where exposure occurs. An example is the use of food collected from the mouths of nestling birds to evaluate exposure to pesticides through contaminated food. Although such measurements can be difficult to obtain, they reduce the need for assumptions about the frequency and magnitude of contact.

- Exposures to some stressors are evaluated using **uptake**. Some stressors must be internally absorbed to exhibit adverse effects. For example, a contaminant that causes liver tumors in fish must be absorbed and reach the target organ to cause the effect. Uptake is evaluated by considering the amount of stressor internally absorbed by an organism and is a function of the following:
  - Chemical form of the contaminant (speciation);
  - Medium (sorptive properties or presence of solvents);
  - Biological membrane (e.g., integrity, permeability); and
  - Organism (e.g., sickness, active uptake).

Because of interactions among these factors, uptake will vary on a study-specific basis. Uptake is usually assessed by modifying an estimate of the exposure concentration indicating the **bioavailable fraction** (i.e., the proportion of the stressor that is available for uptake) actually absorbed (e.g., monomeric aluminum is generally bioavailable to certain aquatic receptors while polymeric aluminum generally is not). Absorption factors and bioavailability measured for the chemical, ecosystem, and organism of interest are preferred. Internal dose can also be evaluated using a physiologically-based pharmacokinetic (PBPK) model or by measuring biomarkers or residues in receptors.

When using a tiered approach, conservative assumptions generally are used at the screening level. Exhibit 24-2 presents examples of conservative assumptions; these are described in more detail in EPA's *Guidelines for Ecological Risk Assessment*.[1]

Exhibit 24-2. Examples of Conservative Assumptions for Ecological Exposure Estimation	
Exposure Factor	**Assumed Value**
Area-use factor (factor related to home range and population density)	100 percent (organism lives completely within area of highest exposure concentrations)
Bioavailability	100 percent
Life stage	most sensitive life stage
Body weight	minimum possible
Food ingestion rate	maximum possible
Dietary composition	100 percent of diet consists of the most contaminated dietary component
The use of conservative assumptions should be informed by study-specific information. For example, assuming 100 percent for area-use factor and diet would not be appropriate if study-specific information indicates otherwise (e.g., the receptor is only present in the assessment area part of the year). Similarly, use of the most sensitive life stage would only be appropriate if that life stage were reasonably expected to be exposed to the chemical.	

24.2.3.2 Dimensions of Exposure

Three dimensions are considered when quantifying exposure: intensity, time, and space.

- **Intensity**. Intensity is generally expressed as the amount of chemical contacted per day. Intensity may be affected by a number of factors, including the concentration of the chemical in various media and biota and chemical form (e.g., speciation), which may affect toxicity, bioavailabilty, and/or bioconcentration.

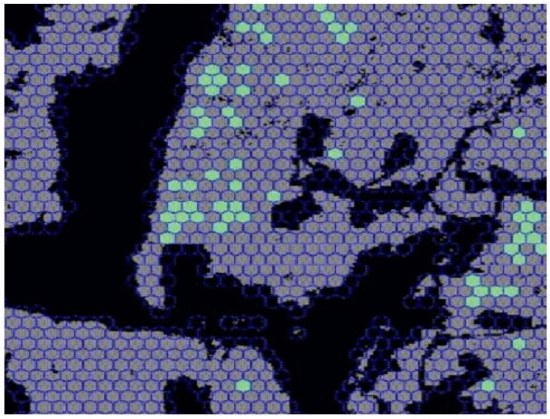
- **Time**. The temporal dimension has aspects of duration, frequency, and timing. For air toxics assessments, intensity and time may sometimes be combined by averaging intensity over time. Due to the emphasis on persistence and bioaccumulation, the focus of the ecological exposure characterization for air toxics is generally on chronic (long-term) exposures. In using predictive modeling to estimate exposure concentrations, an average annual concentration generally is sufficient, at least for screening-level analyses. An exception would include situations where the release and the presence of ecological receptors are both periodic (e.g., releases are much higher in the spring and summer, when ecological receptors are more abundant and active). If using predictive modeling to develop estimates of the average daily dose (ADD), the duration of time modeled generally should be sufficient for concentrations of air toxics in the media and biota of concern to reach equilibrium. If the models indicate that equilibrium is not reached, the duration of time modeled generally should be at least as long as the period of time over which releases are likely to occur (e.g., the design life of a specific facility). Timing is particularly important if the exposure coincides with a sensitive life stage of the receptor organism.

- **Space**. Space is important because ecological risk assessments generally focus at the population level or higher (e.g., community, ecosystem). Therefore, space is a measure of the total fraction of the population, community, or ecosystem that is potentially exposed – a factor that will impact the overall risk characterization. Space is generally expressed in terms of areas (e.g., hectares, acres, square meters) that exceed a particular chemical threshold level. However, another important spatial consideration is the **fraction** of the overall habitat type that is potentially affected. At larger spatial scales, the shape or arrangement of exposure may be an important issue, and area alone may not be the appropriate descriptor. Geographic Information Systems (GIS) have greatly expanded the options for analyzing and presenting the spatial dimension of exposure (see Part VII of this reference manual for more information about GIS). Several recent papers discuss ways to incorporate spatial considerations in ecological risk assessments.[8]

Sometimes, temporal and spacial considerations must both be considered together. For example, in the case of acidic deposition, the andromous fish species in Maryland and other middle-Atlantic states have a special risk scenario. Specifically, their spawning run occurs at the same time when the weather pattern changes in the late winter and early spring from a coastal to a continental pattern. This increases acidic deposition to the headwaters where the spawning occurs and the eggs and hatchlings are at the most vulnerable part of their life cycle.

Using Spatial Information in Ecological Exposure Assessment

Many terrestrial organisms that might be evaluated in an ecological risk assessment are mobile. Where these populations spend their time depends on the locations of habitats necessary to provide food, breeding sites, and protection from predators. Behaviors such as migration also affect locations of receptor populations. Screening-level assessments usually assume that the ecological receptors of interest reside at the locations of the highest exposures modeled. In subsequent tiers of analysis, the assessor may spatially refine the exposure estimate by considering the habitat use and foraging areas of the receptor(s) of interest. GIS land cover and land use information can be used to estimate where an ecological receptor is likely to reside or breed. For example, EPA's Western Ecology Division of the National Health and Environmental Effects Laboratory developed a model called Program to Assist in Tracking Critical Habitat (PATCH), which can be used to generate "patch-by-patch" descriptions of landscapes, assessments of the number, quality, and spatial orientation of breeding sites, and map-based estimates of the occupancy rate. In the example output shown here, the medium grey areas denote significant/acceptable habitat and the lighter gray (or light green) areas denote areas suitable for breeding. This information can be used to identify where the ecological receptors are likely to reside or breed, and the modeled exposure concentrations at those locations can be used in the risk characterization calculations. The PATCH software and user's guides are available at: http://www.epa.gov/wed/pages/models/patch/patchmain.htm.



Example PATCH Output.

24.2.3.3 Exposure Profile

The final product of the ecological exposure assessment is an exposure profile. Exposure is generally described in terms of intensity, space, and time, and in units that can be combined with the ecological effects assessment (see Chapter 25). The exposure profile identifies the receptor and describes each exposure pathway as well as the intensity, spatial extent, and temporal extent of exposure. The exposure profile also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur. Depending on the risk assessment, the exposure profile may be a written stand alone document or a module of a larger document. In either case, the objective is to ensure that the information needed for risk characterization has been collected, evaluated, and presented in a clear, concise, and transparent way. The exposure profile also provides an opportunity to verify that all of the important exposure pathways identified in the conceptual model (i.e., those that support an evaluation of the assessment endpoints) were evaluated.

Questions Addressed by the Exposure Profile

- How may exposure occur?
- What may be exposed?
- How much exposure may occur?
- When and where may exposure occur?
- How may exposure vary?
- How uncertain are the exposure estimates?
- What is the likelihood that exposure will occur?

24.2.3.4 Evaluating Variability and Uncertainty

The exposure profile described in the previous section should aid understanding of how exposure can vary depending on receptor attributes (exposure factors) or stressor levels. Variability can be described qualitatively, by using a distribution or by describing where a point estimate is likely to fall on a distribution. EPA policy recommends the use of both central tendency and high-end exposure estimates.[9]

The exposure profile also should summarize important uncertainties (e.g., lack of knowledge), including:

- Identification of key assumptions and how they were addressed;
- Discussion (and quantification, if possible) of the magnitude of modeling, sampling, and/or measurement error;
- Identification of the most sensitive variables influencing the exposure estimate; and
- Identification of which uncertainties can be reduced through additional data collection, modeling, or analysis (e.g., in a subsequent tier of analysis).

Professional judgment often is needed to determine the uncertainty associated with information taken from the literature and any extrapolations used in developing a parameter to estimate exposures. All assumptions used to estimate exposures should be stated, including some description of the degree of bias possible in each. Where literature values are used, an indication of the range of values that could be considered appropriate also should be indicated. The uncertainty and variability associated with ecological effects criteria must also be taken into

consideration. A more thorough description of how to deal with variability and uncertainty in the risk assessment process is provided in Chapter 31.

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Chapter 25 Analysis: Characterization of Ecological Effects

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25.1 Introduction

As noted in the previous chapter, the analysis step of ecological risk assessment includes characterization of exposures and characterization of ecological effects. Chapter 24 described the approaches and methods used for exposure characterization. This chapter describes the approaches and measures used for characterization of ecological effects. The discussion in this chapter is based largely on EPA's *Ecological Risk Assessment Guidelines*.[1] Readers are referred to that document for a more complete discussion of available approaches and methods.

The methodology used to characterize ecological effects is generally similar to that used for human health toxicity assessment. One of the distinctive features of ecological effects characterization relates to the more general management goal of protecting a receptor population or community rather than a single individual. This has led to the development of water, sediment, and soil quality criteria that are designed to protect the communities of organisms that inhabit surface waters and soils. It also provides the option of using a distribution or range of values to characterize chemical toxicity (an option not generally available in human health risk assessment).

Characterization of ecological effects involves describing the potential effects resulting from exposure to a stressor, linking these effect to the assessment endpoints identified during problem formulation, and evaluating the **stressor-response relationship** (i.e., how the effects will change with varying stressor levels). The characterization begins by evaluating effects information to specify the resulting effects, verifying that these effects are consistent with the assessment endpoints, and confirming that the conditions under which the effects occur are consistent with the conceptual model. Once this has been done, the effects characterization involves two additional steps: (1) performing an ecological response analysis, and (2) developing a **stressor-response profile** which also contains an analysis of uncertainty and variability. Each of these additional steps is discussed in a separate section below.

25.2 Ecological Response Analysis

Ecological response analysis examines three primary elements: identifying stressor-response relationships, establishing causality, and determining the linkages between measurable ecological effects and assessment endpoints. Each is described in a separate subsection below.

25.2.1 Stressor-Response Analysis

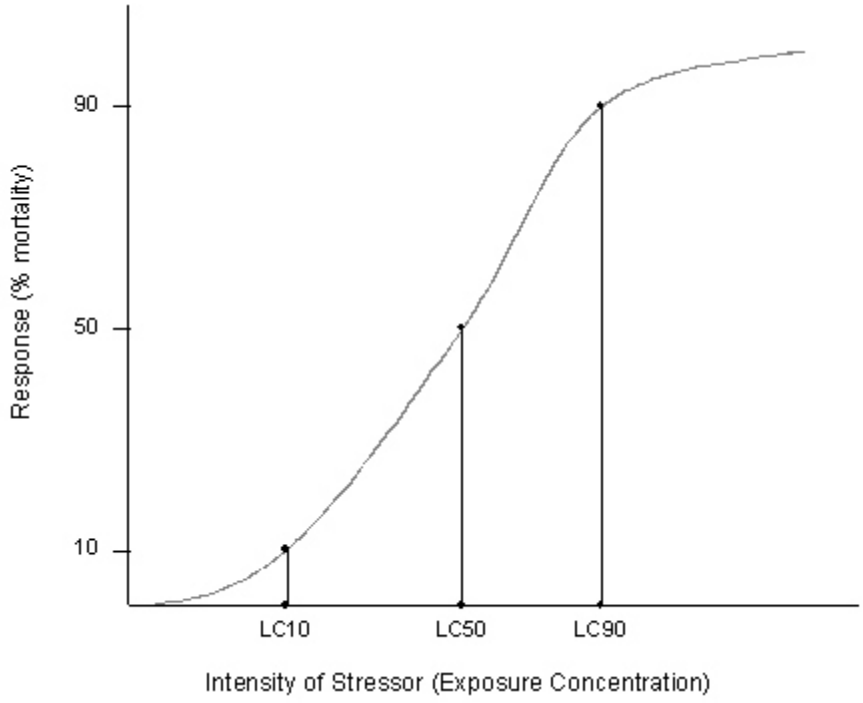
Stressor-response analysis for ecological effects is functionally similar to dose-response analysis for human health effects (e.g., see Chapter 12). The specific stressor-response relationship(s) used in a given risk assessment depend on the scope and nature of the assessment as defined in the problem formulation and reflected in the analysis plan. Three types of stressor-response relationships are commonly used: point estimates, stressor-response curves, and cumulative distribution functions. Each of these is discussed in a separate subsection below.

25.2.1.1 Ecological Effect Levels

Ecological effect levels are point estimates of an exposure associated with a given effect (e.g., a concentration that results in 50 percent mortality in the exposed population, or LC_{50}) used to

compare with an environmental exposure concentration. Data on the toxicity of a chemical is usually obtained from laboratory studies in which groups of organisms (e.g., invertebrates, benthic organisms, plants, earthworms, laboratory mammals, fish) are exposed to varying levels of the chemical, and one or more responses (endpoints such as survival, growth, reproduction) are measured. Various statistical methods are used to establish thresholds for adverse ecological effects associated with acute or chronic exposures. Risk assessors often choose no-effect or low-effect levels as screening values. Stressor-response relationships may be relatively simple (as illustrated in Exhibit 25-1) or may be very complex.

Exhibit 25-1. Hypothetical Simple Stressor-Response Relationship



Hypothetical relationship between intensity of stressor (in this example, concentration of a chemical in water) and ecological response (in this example, percent mortality of an exposed population of minnows). Different points on the curve represent, respectively, the concentration resulting in 10 percent mortality (LC10), 50 percent mortality (LC50), and 90 percent mortality (LC90).

Several specific point estimates are commonly used to characterize ecological effects (Exhibit 25-2):

- **Median effect concentrations or doses** are those levels that result in effects that occur in 50 percent of the test organisms exposed to a stressor. The median effect level is always associated with a time parameter (e.g., 24 hours, 48 hours). Because the tests used to derive median effects levels seldom exceed 96 hours, these values are used primarily to assess acute (short-term) exposures.

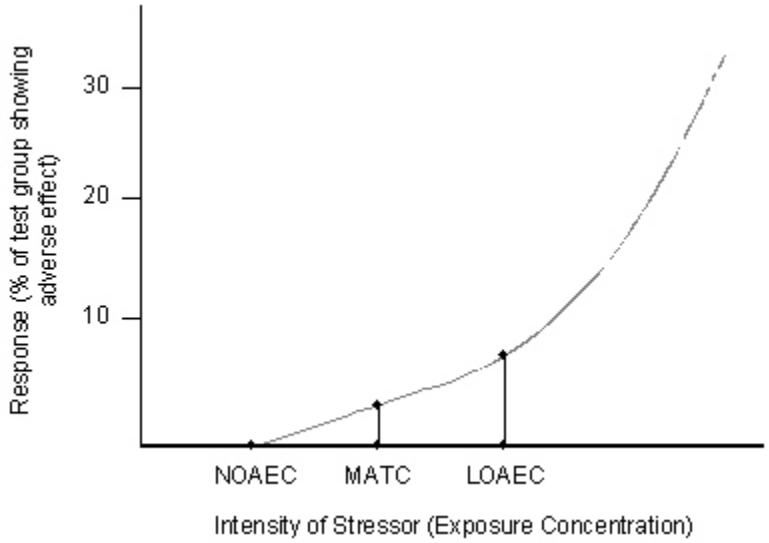
Exhibit 25-2. Commonly Used Point Estimates

Median effect concentrations or doses (acute exposures)

LC_{50} Concentration (food or water) resulting in mortality in 50 percent of the exposed organisms
LD_{50} Dose (usually in dietary studies) resulting in mortality in 50 percent of the exposed organisms
EC_{50} Concentration resulting in a non-lethal effect (e.g., growth, reproduction) in 50 percent of the exposed organisms
ED_{50} Dose resulting in a non-lethal effect (e.g., growth, reproduction) in 50 percent of the exposed organisms

Low- or no-effect concentrations or doses (chronic exposures)

NOAEL no-observed-adverse-effect-level, the highest dose for which adverse effects are not statistically different from controls
LOAEL lowest-observed-adverse-effect level, the lowest dose at which adverse effects are statistically different from controls
NOEC no-observed-effect-concentration, the highest ambient concentration for which adverse effects are not statistically different from controls
LOEC lowest-observed-effect concentration, the lowest ambient concentration at which adverse effects are statistically different from controls
MATC maximum acceptable toxicant concentration, the range of concentrations between the LOEC and NOEC
GMATC geometric mean of the MATC, the geometric mean of the LOEC and NOEC



- **Low- or no-effect concentrations or doses** are derived from experimental data using statistical estimates. The no-effect level is determined by experimental conditions as well as the variability inherent in the experimental data. Thus, depending on experimental conditions (e.g., the range of concentrations tested), two separate tests using the same chemical and the same organism could result in different no-effect levels. Low- or no-effect levels are used primarily to assess chronic (longer-term) exposures.

A variety of different types of studies can be used to develop ecological stressor-response relationships, including field studies, laboratory studies, and microcosm studies (Exhibit 25-3).

For air toxics, stress-response analysis can include both primary and secondary effects.

Point Estimates, TRVs, and Benchmarks

The terms **Toxicity Reference Values (TRVs)** and **Ecological Benchmarks** are used to describe those **Point Estimates** identified or derived for use in ecological risk assessments. These particular point estimates may be derived from a single study (e.g., an NOEC or EC_{50}) or from the integration of multiple studies (e.g., water quality criteria). When TRVs or benchmarks are drawn from a single study, they are usually set in consideration of multiple studies (e.g., from the study most relevant to the purposes and specifics of the assessment has been selected, or the most sensitive result among the relevant studies)

- **Primary effects** (e.g., lethality, reduced growth, neurological/behavioral deficits, impaired reproduction) result from exposure of aquatic and terrestrial organisms to air toxics. An example of a chronic effect would be reduced reproduction in a fish species exposed to air toxics in a surface water body or in a terrestrial bird eating contaminated fish from a small pond. An extreme example of an acute primary effect might be deaths of birds caused by inhalation of a particular toxin. Toxic effects on survival, growth, development, and reproduction might have population-level consequences for a species (e.g., result in local population extinction over time) and are widely accepted as endpoints for characterizing ecological risks. In recent years, more subtle effects have been investigated, including those pertaining to clinical signs of poisoning, immunotoxicity, and even behavioral changes that might influence survival, growth, development, or reproduction.

- **Secondary effects** (e.g., loss of prey species in the community) result from the action of air toxics on supporting components of the ecosystem. These secondary effects occur through biological interaction of one or more species' populations with individuals or populations that have been primarily affected. For example, exposure to an air toxic may adversely affect one or more species of microscopic algae, bacteria, or fungus, which can adversely affect an ecosystem's nutrient cycling and primary production. This can lead to an alteration in the abundance, distribution, and age structure of a species or population dependent on these microscopic organisms, which can then lead to changes in competition and food web interactions in other species. These ecosystem effects can be propagated to still other populations, affecting their presence or representation within the ecosystem. A relatively simple example of secondary effects involves the aerial application of pesticides that dramatically reduced the population of an aquatic insect. This impact to the insect population indirectly affects wild ducklings in the ecosystem, which depend on the insects as a food supply.[2] Although it often is possible to identify the potential for secondary effects, developing stressor-response functions for secondary effects (e.g., in a manner analogous to that illustrated in Exhibit 25-2) is not an easy task. A recent paper provides one example of the evaluation of secondary effects in ecological risk assessment.[3]

The use of the point estimate approach has some potential limitations. The most important is that the point estimate established by a given study depends on both the range of doses tested and the statistical power of the study (e.g., the ability to detect an effect if it occurs). For example, studies with low power (e.g., those with only a few test animals per dose group) tend to yield NOAEL or NOEC values that are higher than studies with good power (those with many animals

per dose group). In addition, the choice of some point estimates (e.g., NOEC and LOEC) is restricted to concentrations that were tested, which may or may not be close to the environmentally relevant concentrations, and this uncertainty increases as the interval between doses increases. Finally, it is not always easy to interpret the significance of an exposure that exceeds some particular point estimate, since the severity and incidence of response depends on the shape and slope of the exposure response curve (information that is not captured in a point estimate).

Exhibit 25-3. Types of Ecological Stressor-Response Studies
• **Laboratory Studies**. Most information on ecological stressor-response comes from laboratory ecotoxicology studies using a generic set of species to represent different components of terrestrial or aquatic ecosystems. For example, the freshwater crustacean *Daphnia,* is often used as a surrogate for all small invertebrates that inhabit surface waters, and various species of minnows are used as surrogates for fish. Laboratory studies are relatively easy and inexpensive to conduct, and effects can be directly linked to exposure to a single air toxic. There is uncertainty, however, in extrapolating the results from standard laboratory species to the wide array of species in the environment or from the controlled laboratory conditions to the complex conditions that occur in nature. Additionally, in most cases, laboratory studies are not designed to assess effects on populations, communities, and ecosystems. • **Field Studies**. Studies of wildlife, populations, communities, and ecosystems exposed to air toxics in natural settings can provide valuable information on stressor-response effects. Field data can be valuable in demonstrating the presence or absence of a cause-effect relationship that can provide a basis for prioritization or for recognizing the efficacy of a risk reduction action. These studies also can be used to assess stressor-response relationships for the site-specific mixtures of concern. However, the study organisms may be exposed to numerous types of stressors (chemical and non-chemical), and the effects of individual air toxics (and sometimes site-specific mixtures) may be difficult to isolate. In addition, field studies are conducted infrequently due to the significant time and resources required. Comparison of the study area to a control area is necessary to evaluate the potential impact of the chemical release. • **Microcosm Studies**. Microcosm studies use assemblages of several different taxa and environmental media in an enclosed experimental system as a surrogate for natural ecosystems. Such studies can control for some of the uncertainty associated with multiple stressor exposure in field studies. These studies also may provide information about food web dynamics and the interactions of populations or organisms. As with field studies, microcosm studies are time and resource intensive and, therefore, may be relatively uncommon for air toxic studies.

A variety of point estimates are used in ecological risk assessments. Some are developed from acute (short-term) exposures; others are developed from chronic (long-term) exposures. Three general types of point estimates are available for use in ecological risk assessments:

- **Community-level criteria**. EPA has developed ambient water quality criteria (AWQC) and sediment quality criteria for the protection of aquatic communities. These values are based on consideration of a cumulative distribution function (see Section 25.2.1.4). For example, AWQC are designed to protect 95 percent of all aquatic species in freshwater or marine environments. Criteria have been developed for both acute and chronic exposures, although for a limited number of chemicals.

- **Effect levels from laboratory toxicity tests**. A variety of aquatic species are routinely used in ecological toxicity tests, including fathead minnows (a small fish species) and *Daphnia* (a tiny freshwater crustacean). Effects of concern can include acute effects such as mortality (e.g., LD_{50}) as well as chronic effects such as reproduction. Toxicity tests also are available for terrestrial organisms (e.g., earthworms) and occasionally involve vertebrate species of wildlife (e.g., the effects of polychlorinated biphenyls (PCBs) have been studied extensively in mink).

- **Effect levels from field bioassays**. In some cases, ecological effects are evaluated directly by exposing test organisms to ambient conditions. This most often is done where complex mixtures of chemicals are present (e.g., in soils or sediments).

The point estimates employed in ecological risk assessments may be generally termed toxicity reference values (TRVs).[a] They may be values taken from individual toxicity studies (e.g., NOECs or EC_{50}s)or the result of integration of multiple studies (e.g., water quality criteria). TRVs may be developed for site-specific ecological receptors, depending on the importance of those receptors to the local ecosystem, or for an endpoint not previously evaluated. For example, while some TRVs may be based on survival, growth, and reproductive success of a population, TRVs protective of a threatened or endangered species, a valuable game species (e.g., trout), or an ecologically key species (e.g., wolf) might be based on an endpoint that is relevant to individual organism health (e.g., a neurological deficit) rather than to population maintenance. On the other hand, TRVs based on higher effect levels (e.g., 20 to 50 percent or higher of the population is affected) might be appropriate for species for which great functional redundancy exists in the ecosystem (e.g., different herbaceous plants).[4]

Derivation of TRVs for pathways involving wildlife ingestion would require information on food ingestion rates for sensitive and highly exposed animal species and information on the degree of bioaccumulation in appropriate trophic components. Examples of these derivations for aquatic systems can be found in the Great Lakes Water Quality Initiative (GLWQI) for mercury, dichlorodiphenyltrichloroethane (DDT), PCBs, and dioxin (2,3,7,8-TCDD)[5] and for terrestrial systems in the EPA methods of assessing exposures to combustor emissions.[6] EPA's *Wildlife Exposure Factors Handbook* [7] also provides data, references, and guidance for conducting exposure assessments for wildlife species exposed to toxic chemicals in their environment.

EPA and other organizations have developed a number of types of TRVs based on data for a chemical's toxicity to freshwater or saltwater organisms (see Exhibit 25-4). Toxicity data for longer term or chronic exposures generally will be more useful for an air toxics risk assessment; however, short term or acute toxicity data may be used for chemicals that lack or have incomplete chronic data. EPA has in the past used acute values in conjunction with conversion factors (i.e., acute-to-chronic ratios) to estimate chronic toxicity values, specifically for the derivation of chronic Ambient Water Quality Criteria and Great Lakes Water Quality Initiative criteria for aquatic life.

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[a]Note that some ecological risk assessment guidance refers to the point estimates of ecological effects selected for a given assessment as Toxicity Reference Values (TRVs), while others use the term ecological benchmarks.

25.2.1.2 Selection of TRVs for a Particular Assessment

In reviewing toxicity studies for potential use in identifying or developing specific TRVs to use in a given assessment, the following questions should be considered:

- What taxa are used in the study?
- Did the study present any significant methodological difficulties?
- Did the study identify a LOAEL?
- Were the adverse effects seen possibly related to growth and survival, or reproduction and development?
- Did the study identify a NOAEL?
- Was the study duration appropriate to assess potential effects of chronic exposure?

If the test species are not within the taxonomic group of the ecological receptors of concern, the study may need to be rejected because the test species are too distantly related to assume similar physiological responses to a toxic agent.

Many studies may be of limited use in selection of TRVs. Potential deficiencies include:

- No control group was analyzed, or there was a high incidence of effects in the control group (applies to laboratory studies);
- No reference area was analyzed, or there was a high incidence of effects in the reference area (applies to field studies);
- No statistical analysis of results was conducted;
- In the case of fish/shellfish, body burdens were estimated, not measured;
- In the case of fish/shellfish, only fillet, carcass (guts, gills, and scales removed), or other body part concentrations were measured, not the whole body;
- In the case of wildlife, insufficient data were provided to calculate the dose to the animal; and
- Multiple contaminants were present in the experimental studies.

Most environmental contamination concerns for air toxics that persist and bioaccumulate will tend to be long-term and relatively low-level. As such, the most appropriate toxicity studies are those evaluating chronic (long-term) toxicity or, if chronic studies are not available, subchronic (medium-term) exposure durations. Although no one definition of "chronic" is accepted by human or ecological toxicologists, the general concept is that the duration encompasses a significant portion of the species life span (e.g., ten weeks for birds and one year for mammals). "Subchronic" is commonly defined as a 90-day or longer study for mammals and 10 weeks or fewer for birds. For aquatic bioassays, chronic tests may span multiple generations and assess sensitive growth or reproductive endpoints. In mammalian and avian tests, the term average daily dietary dose (e.g., expressed as mg/kg-day) generally implies chronic or subchronic exposure.[8]

In order to develop TRVs (sometimes termed benchmarks) for avian and mammalian receptors, Oak Ridge National Laboratory's Toxicological Benchmarks for Wildlife,[11] and some information from EPA's Integrated Risk Information System[9] can be used (in a more limited fashion). Information provided in these sources has to be modified using allometric information available in EPA's *Wildlife Exposure Factors Handbook*[7] to better represent potential wildlife species sensitivity.

Exhibit 25-4. Sources of Ecological TRVs or Benchmarks		
Data Source	**Available Toxicity Reference Value(s)**	**Overview of Data Source and Values**
EPA Office of Water Ambient Water Quality Criteria (AWQC)	• AWQC Chronic Criteria • AWQC Acute Criteria Note: many state water quality standards are based on AWQC	EPA has developed national recommended water quality criteria for the protection of aquatic life for approximately 150 pollutants. These criteria are published pursuant to Section 304(a) of the Clean Water Act (CWA) and provide guidance for States and Tribes to use in adopting water quality standards under Section 303(c) of the CWA. Source: http://www.epa.gov/waterscience/criteria/aqlife.html
Great Lakes Water Quality Initiative (GLWQI) Criteria Documents	• GLWQI Tier I Criteria • Final Chronic Values (FCVs)	GLWQI Tier I criteria and final chronic values (FCVs) are calculated under the same guidelines as the Sediment Quality Criteria (SQC). Draft GLWQI criteria documents were released for public review and were revised as necessary before they were published as "final." • Tier I Criteria are designed to be protective of aquatic communities • FCVs are designed to measure chronic toxicity to aquatic organisms Source: *Final Water Quality Guidance for the Great Lakes System.* Federal Register, Mar. 23, 1995, vol. 60, no. 56, p. 15365-15424
EPA Soil Screening Levels	• Soil screening levels	EPA has developed a methodology and initial soil screening levels protective of ecological receptors. Source: U.S. Environmental Protection Agency. 2000. *Ecological Soil Screening Guidance (Draft)*. Office of Emergency and Remedial Response, Washington, D.C., July 2000. http://www.epa.gov/superfund/programs/risk/ecorisk/ecossl.htm.
EPA Region 4 Soil Screening Levels	• Soil screening levels	Source: U.S. Environmental Protection Agency. 1995. Supplemental Guidance to RAGS: Region 4 Bulletins No. 2. Ecological Risk Assessment. Region IV, Waste Management Division. http://www.epa.gov/region04/waste/ots/ecolbul.htm

Exhibit 25-4. Sources of Ecological TRVs or Benchmarks		
Data Source	**Available Toxicity Reference Value(s)**	**Overview of Data Source and Values**
Ecotox Thresholds ECO Update and EPA's Hazardous Waste Identification Rule (HWIR) documents	• GLWQI Tier II Criteria • Secondary Chronic Values (SCVs)	The GLWQI Tier II criteria and SCVs have received some peer review prior to publication, and 12 of them are included in the HWIR, which underwent public comment before promulgation. The GLWQI Tier II methodology calculates SCVs in a similar way to FCVs, but uses statistically derived "adjustment factors" and has less rigorous data requirements. • Tier II Criteria are designed to be protective of aquatic communities • SCVs are designed to measure chronic toxicity to aquatic organisms Source: *Ecotox Thresholds ECO Update* (volume 3, No. 2, January 1996, EPA/540/F-95/038).
ECOTOXicology database (ECOTOX)	• Point Estimates from Chronic Tests (e.g., EC_{50}, EC_{10}, LC_{50}, or GMATC) • Point Estimates from Acute Tests (e.g., LC_{50})	ECOTOX is a source for locating single chemical toxicity data for aquatic life, terrestrial plants, and wildlife. ECOTOX was created and is maintained by EPA's Office of Research and Development and the National Health and Environmental Effects Research Laboratory's Mid-Continent Ecology Division. ECOTOX is a source for locating single chemical toxicity data from three EPA ecological effects databases: AQUIRE, TERRETOX, and PHYTOTOX. AQUIRE and TERRETOX contain information on lethal, sublethal, and residue effects. AQUIRE includes toxic effects data on all aquatic species including plants and animals and freshwater and saltwater species. TERRETOX is the terrestrial animal database. It primarily focuses on wildlife species but the database does include information on domestic species. PHYTOTOX is a terrestrial plant database that includes lethal and sublethal toxic effects data. Source: http://www.epa.gov/ecotox.
Sediment Quality Criteria	• Varies	EPA and other agencies have developed sediment quality criteria for the protection of benthic communities. These criteria are highly specific to regions and bodies of water in the U.S. Regional experts are the recommended source for appropriate site-specific criteria.

Exhibit 25-4. Sources of Ecological TRVs or Benchmarks		
Data Source	**Available Toxicity Reference Value(s)**	**Overview of Data Source and Values**
Ecological Structure Activity Relationships (ECOSAR)	• Estimated Chronic GMATC • Estimated Acute Data (LC_{50} or EC_{50})	ECOSAR is a computer program that uses structure-activity relationships (based on available data) to predict the acute and chronic toxicity of organic chemicals to aquatic organisms. ECOSAR provides quantitative estimates of chronic values (e.g., GMATC), acute LC_{50} values, and acute EC_{50} values for industrial chemicals for several aquatic species (e.g., fish, daphnia, green algae, mysids). When the estimated aquatic toxicity value exceeds the water solubility of the compound, the estimated value is flagged; this situation generally is interpreted to mean that the chemical has no toxic effects in a saturated solution. Source: http://www.epa.gov/oppt/newchems/21ecosar.htm
Exposure-Related Effects Database (ERED)	Tissue-based effects values for fish and benthic invertebrates	The U.S. Army Corps of Engineers Exposure-Related Effects Database (ERED) lists toxicity information for a large number and wide taxonomic range of fish and shellfish. ERED is constantly being updated. Source: http://www.wes.army.mil/el/ered/
Jarvinen and Ankley database	Fish and shellfish exposure and effects information	The authors assembled a database of fish and shellfish exposure and effect information. Source: Jarvinen and Ankley (1999)[9]
Oak Ridge National Laboratory (ORNL) Soil Invertebrate toxicity database	Acute and chronic TRVs for soil invertebrates and microbial processes	This report focuses on chemicals found at U.S. Department of Energy (DOE) sites; however there are overlaps with air toxics (metals and organics). Source: Efroymson et al. (1997);[8] http://www.esd.ornl.gov/programs/ecorisk/documents/tm126r21.pdf
ORNL Plant toxicity database	Acute and chronic TRVs for terrestrial plants	This report presents a standard method for deriving TRVs, a set of data concerning effects of chemicals in soil or soil solution on plants, and a set of phytotoxicity TRVs for 38 chemicals potentially associated with DOE sites. Source: Efroymson et al. (1997)[8]
ORNL Wildlife toxicity database	Wildlife NOAEL and LOAELs	This report presents both NOAEL- and LOAEL-based TRVs for assessment of effects of 85 chemicals on 9 representative mammalian wildlife species and 11 avian wildlife species. Source: Sample et al. (1996)[10]

25.2.1.3 Stressor-Response Curves

One way to resolve some of the limitations in the TRV approach is to fit a mathematical equation to the available exposure-response data and describe the entire **stressor-response curve**. Data from individual experiments may be used to develop curves and point estimates both with and without associated uncertainty estimates. The advantages of curve-fitting approaches include using all of the available experimental data, the ability to interpolate to values other than the data points measured, and an improved ability to extrapolate to values outside the range of experimental data (e.g., for a low- or no-effect level). Curve-fitting often is used to extrapolate from observed effects levels to develop estimates of NOAELs, NOECs, and/or GMATCs. Stressor-response curves can be developed using any convenient data fitting software, but EPA has developed a software package specifically designed for this type of effort. This software is referred to as the Benchmark Dose Software (BMDS). More information on this software can be found on the National Center for Environmental Assessment's webpage.[11] A disadvantage of curve fitting is that the number of data points required may not always be available (e.g., especially for toxicity tests with wildlife species)

25.2.1.4 Species Sensitivity Distribution

In some cases, risk management decisions may also consider community-level effects as well as population-level or sub-population effects (one example is the Ambient Water Quality Criteria for the protection of aquatic life discussed in Section 25.2.1.1). That is, a stressor might be considered to be below a level of concern for the sustainability of a community if only a small fraction of the total number of exposed species are affected. In this case, toxicological responses may be best characterized by the distribution of toxicity values across species. This is called a **Species Sensitivity Distribution (SSD)**. The SSD approach is generally used for communities of aquatic receptors, since all of the different species that make up the community (e.g., all fish, benthic invertebrates, aquatic plants, and amphibians that reside in a stream) will be exposed to approximately the same concentration of contaminant in the water.

The process for generating an SSD consists of the following steps:

(1) Select an appropriate type of endpoint (e.g., lethality, growth, reproduction), and select an appropriate type of point estimate from the exposure-response curve for each species. For example, the TRV might be the LC_{50} for lethality or the EC_{20} for growth. The key requirement is that the SSD be composed of TRVs that are all of the same type, not a mixture.

(2) Collect all reliable values for that type of TRV from the literature for as many relevant species as possible. When more than one value is available for a particular species, either select the value that is judged to be of highest quality and/or highest relevance, or combine the values across studies to derive a single composite value for each species. It is important to have only one value per species to maintain equal weighting across species.

(3) Characterize the distribution of values across species with an appropriate SSD. Note that there is no *a priori* reason to expect that an SSD will be well characterized by a parametric distribution, so both parametric and empirical distributions should be considered.

Once an SSD has been developed, the fraction of species in the exposed community that may be affected at some specified concentration may be determined either from the empirical distribution or from the fitted distribution. These distributions can help identify stressor levels that affect a minority or majority of species.

A limiting factor in the use of SSDs is the amount of data needed as inputs. SSDs also can be derived from models that use Monte Carlo or other methods to generate distributions based on measured or estimated variation in input parameters for the models.

25.2.2 Linking Measures of Effects to Assessment Endpoints

As noted in Chapter 23, assessment endpoints express the environmental values of concern for the risk assessment; however they cannot always be measured directly. For example, the assessment endpoint may be maintaining a healthy population of trout in a lake, but measures of effect (e.g., toxicity tests) were conducted on different species (e.g., fathead minnows). Where there is a lack of time, monetary resources, or practical means to acquire more data, extrapolations may be the only way to bridge the gap in available data. Two general approaches are used for such extrapolations:

Examples of Extrapolations

- Between taxa (e.g., minnow to rainbow trout)
- Between responses (e.g., mortality to growth or reproduction)
- From laboratory to field
- Between geographic areas
- Between spatial scales
- From data collected over a short time frame to longer-term effects

- **Empirical extrapolations or process models**. Empirical extrapolations use experimental or observational data; process-based approaches rely on some level of understanding of the underlying operations of the system of interest.

- **Professional judgment**. This is not as desirable as empirical or process-based approaches, but it is the only option when data are lacking. However, professional judgment can be credible, provided it has a sound scientific basis.

One of the most common types of extrapolations is that of effects observed in the laboratory (e.g., toxicity tests) to those observed in the field. Exhibit 25-5 highlights the general questions to consider when performing such an extrapolation.

When conducting field sampling or other monitoring studies, it sometimes is difficult to identify exposure-response relationships. However, there are a number of reasons why a relationship between a chemical and a toxic response in a natural system may not be apparent (Exhibit 25-6). Therefore, the lack of an observed exposure-response relationship does not disprove that one or more air toxics caused an apparent toxic effect. These sources of variation should be considered during planning and scoping, but may not become apparent until field studies have begun.

Exhibit 25-5. Questions to Consider When Extrapolating from Effects Observed in the Laboratory to Potential Effects in Natural Systems
Exposure Factors • How will environmental fate and transformation of the air toxic affect exposure in the field? • How comparable are exposure conditions and the timing of exposure? • How comparable are the routes of exposure? • How do abiotic factors influence bioavailability and exposure? • How likely are preference and avoidance behaviors in the receptors of concern? • How does life-stage affect exposure? **Effects factors** • What is known about the biotic and abiotic factors controlling populations of the receptors of concern? • To what degree are critical life-stage data available? • How may exposure to the same or other stressors in the field have altered organism sensitivity?

Empirical approaches are derived from experimental data or observations. They commonly are used when adequate effects data are available, but the understanding of the underlying mechanisms, action, or ecological principles is limited. Two types of empirical approaches are generally used:

- **Uncertainty factors** are derived numbers that are divided into measure of effects values to derive an estimated level of stressor that should not cause adverse effects to the assessment endpoint. An example might be an uncertainty factor of 10 to convert an acute LC_{50} value into a presumed NOAEL. Uncertainty factors should be used with caution, especially when used in an overly conservative fashion, as when chains of factors are multiplied together without sufficient justification.

- **Allometric scaling** is used to extrapolate the effects of a chemical stressor on one species to another species. Allometry is the study of change in the proportions of various parts of an organism as a consequence of growth and development. Processes that influence toxicokinetics (e.g., renal clearance, basal metabolic rate, food consumption) tend to vary across species according to allometric scaling factors that can be expressed as a nonlinear function of body weight. Allometric scaling factors are commonly used for human health toxicity assessments (see for example Chapter 12), but have not been applied as extensively to ecological effects.

When sufficient information on stressors and receptors is available, process-based approaches such as population or ecosystem process models may be used. Process models allow information on individual effects (e.g., mortality, growth, reproduction) to be extrapolated to potential alterations in specific populations, communities, or ecosystems. Such models are particularly useful in evaluating hypotheses about the duration and severity of impacts from a stressor on an assessment endpoint (e.g., species diversity) that cannot be tested readily in a laboratory. Two types of process-based models are commonly used:

Exhibit 25-6. Reasons Why Contaminant Concentrations in Ambient Media May Not Be Correlated with Toxicity of Those Media
Variation in bioavailability • Due to variance in medium characteristics • Due to variance in contaminant age among locations (contaminants deposited to soil and sediments may become less bioavailable over time due to sequestration) • Due to variance in transformation or sequestration rates among locations **Variation in the form** of the chemical (e.g., ionization state) **Variation in the concentration** over time or space (i.e., samples for analysis may not be the same as those tested) • Spatial heterogeneity • Temporal variability (e.g., aqueous toxicity tests last for several days but typically water from only one day is analyzed) **Variation in the composition of releases** (concentrations of components of releases other than the individual air toxic that is believed to be the principal toxicant may vary over space and time, thereby obscuring the relationship) **Variation in co-occurring contaminants** (concentrations of contaminants from upgradient [background] sources may vary over time) **Inadequate detection limits** (if detection limits are too high, gradients of toxic effect may be observed even when the chemicals are at the "not detected" levels) **Variation in toxicity tests** • Inherent variation • Variation due to variance in medium characteristics (e.g., hardness, organic matter content, pH) *Source: Guidelines for Ecological Risk Assessment*[1]

- **Single-species population models** describe the dynamics of a finite group of individuals through time. They have been used extensively in ecology and fisheries management to assess the impacts of power plants and toxic chemicals on specific fish populations.

- **Community and ecosystem models** are particularly useful when the assessment endpoint involves structural (e.g., community composition) or functional (e.g., primary productivity) elements or when secondary effects are of concern.

Exhibit 25-7 provides further discussion of process-based models, highlighting a few models that have been applied in ecological risk assessment.

Exhibit 25-7. Process-based Model Applications in Ecological Risk Assessment

Process-based models can help the assessor understand the potential significance of toxicant effects to the population structure, and ecosystem models can help determine whether the effect may result in secondary effects on other species in the system that are linked in the food web or on overall ecosystem functions. Pastorok et al.[12] review a number of population, and community and ecosystem models, as well as software that implement these models.

Population models typically deal with the dynamics of the abundance or distribution of a single species, sometimes with explicit descriptions of endpoints in time and space. These models can be categorized as scalar abundance, life history, individual-based, and metapopulation models. The first two types of models are highlighted here:

- *Scalar abundance models*, which represent populations as a single scalar dimension without a breakdown of population age structure, are frequently used in screening assessments. These models include Malthusian population growth models and logistic population growth models.
- *Life history models* estimate population characteristics such as survival rates and fecundity as a function of age or size/morphological state. These models are important because toxicants can have a differential impact on different demographic sections of the same species. These models include deterministic and stochastic age- or stage-based models, which are implemented in software by programs such as *RAMAS*-Age®*, -Stage®, -Metapop®, or -Ecotoxicology®*; and *ULM®*.

Community and Ecosystem models are intended to describe ecological systems composed of interacting species. These models incorporate species dynamics and specific biological interactions (predator-prey, competition, dependence) to predict ecosystem endpoints such as species richness or the productivity of a multi-species assemblage. Pastorok et al. categorize these models as food web, aquatic, and terrestrial models.

- *Food web models* capture feeding relationships between all or some species in an ecological community, thus determining population dynamics as well as identifying key exposure pathways for bioaccumulative chemicals. These models include predator-prey models and population-dynamic food chain models, which are implemented in software such as *RAMAS Ecosystem®*, *Populus®*, and *Ecotox*.
- *Aquatic ecosystem models* are spatially aggregated models that represent biotic and abiotic structures in combination with physical, chemical, biological, and ecological processes in rivers, lakes, reservoirs, estuaries, or coastal ecosystems. A number of models exist for each type of aquatic ecosystem. The standard water column model or *SWACOM®* requires the use of laboratory data to predict changes in the parameters of an entire ecosystem. The extrapolation is accomplished with knowledge of toxicological modes of action, and by simulation of the effects of a toxic substance across different trophic levels according to the relationship between nutrients, phytoplankton, zooplankton, and fish. *AQUATOX* (http://www.epa.gov/ost/models/aquatox/) predicts the fate of various pollutants, such as nutrients and organic chemicals, and their effects on the aquatic ecosystem, including fish, invertebrates, and aquatic plants. The Comprehensive Aquatic Simulation Model (*CASM*) is a bioenergetics-based food web model that includes phytoplankton, periphyton, macrophytes, zooplankton, benthic invertebrates, fish, bacteria, and cyanobacteria.
- *Terrestrial ecosystem models* represent biotic and abiotic components in deserts, forests, grasslands, or other terrestrial environments, and often include physical, chemical, biological, and ecological processes. The primary endpoints of these models include the abundance of individuals within species or guilds, biomass, productivity, and food-web endpoints such as species richness or trophic structure.

25.3 Stressor-Response Profile

The final product of an ecological response analysis is a summary profile in the form of a written document or a component of a larger process model. The stressor-response profile should address the following questions:

- What ecological entities are affected? These may include single species, populations, general trophic levels, communities, ecosystems, or landscapes.

- What are the nature of the effects? The nature of effects should be germane to the assessment endpoints. For example, if a single species is affected, the effects should represent parameters (e.g., growth, reproduction) appropriate for that level of organization.

- Where appropriate, what is the time scale for recovery? Short- and long-term effects should be reported as appropriate.

- How do changes in measures of effects relate to changes in assessment endpoints (see Section 25.2.2 above)?

- What is the uncertainty associated with the analysis (see Section 25.4)?

25.4 Evaluating Variability and Uncertainty

The stressor-response profile described in the previous section should include an explicit description of any uncertainties associated with the ecological response analysis. If it was necessary to extrapolate from measures of effect to the assessment endpoint, both the extrapolation and its basis should be described. Similarly, if a TRV was calculated, the extrapolations, assumptions, and uncertainties associated with its development should be described. The discussion also should include any information about known or potential variability in a stressor-response profile (e.g., among different species or taxa).

Professional judgment often is needed to determine the uncertainty associated with information taken from the literature and any extrapolations used in developing a parameter to estimate stressor-response. All assumptions used to develop stressor-response relationships and TRVs should be stated, including some description of the degree of bias possible in each. Where literature values are used, an indication of the range of values that could be considered appropriate also should be indicated. A more thorough description of how to deal with variability and uncertainty in the risk assessment process is provided in Chapter 31.

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Chapter 26 Ecological Risk Characterization

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26.1 Introduction

Similar to human health risk characterization, ecological risk characterization combines information concerning exposure to chemicals with information regarding effects of chemicals to estimate risks. The major difference in ecological risk characterization is the necessity for estimating risks based on individual lines of evidence and then combining them through a process of weighing the evidence.[a] Another difference is that in human health assessment, we primarily consider health effects in the bodies of individual people. In ecological assessment, we consider various "health" issues that can range from actual health effects in the bodies of individual ecological receptors to something more attuned to the "health" of the ecosystem as measured by species richness and diversity. This chapter provides an overview of the approaches and methods used for ecological risk characterization. As before, additional information is provided in EPA's *Guidelines for Ecological Risk Assessment*,[(1)] and readers are referred to that document for a more complete discussion of available approaches and methods.

Risk characterization is the final phase of ecological risk assessment and is the culmination of the planning and scoping, problem formulation, and analysis of predicted or observed adverse ecological effects related to the assessment endpoints. It is also based on metrics of exposure and ecosystem and receptor characteristics that are used to analyze air toxics sources, their distribution in the environment, and the extent and pattern of contact. Risk characterization is used to clarify the relationships between stressors, effects, and ecological entities, and to reach conclusions regarding the occurrence of exposure and the likelihood of anticipated effects. The results of the analysis phase are used to develop an estimate of the risk posed to the ecologically valued entities that are the focus of the assessment endpoints.[(2)] After estimating the risk, the risk estimate is described in the context of the significance of any adverse effects and lines of evidence supporting their likelihood. Finally, the uncertainties, assumptions, and qualifiers in the risk assessment are identified and summarized, and the conclusions are reported to risk managers.

Conclusions presented in the risk characterization should provide clear information to risk managers in order to be useful for environmental decision making. If the risks are not sufficiently defined to support a management decision, risk managers may elect to proceed with another iteration of one or more phases of the risk assessment process. Re-evaluating the conceptual model (and associated risk hypotheses) or conducting additional studies may improve the risk estimate.

Characterization of ecological risk includes risk estimation, (usually a quantitative risk estimate; see Section 26.2), risk description (Section 26.3), and documentation of results (Section 26.4).

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[a]Consistent with EPA's *Guidelines for Ecological Risk Assessment,*[(1)] the term "lines of evidence" includes a "weight of evidence" in order to emphasize that both qualitative evaluation and quantitative weighting may be used.

26.2 Risk Estimation

Several general techniques are available for characterizing ecological risks associated with air toxics that persist and bioaccumulate. These are divided broadly into single-point comparisons, comparisons incorporating the entire stressor-response relationship, comparisons involving variability in exposure and/or effects, and process models. Each is described in a separate subsection below. EPA's *Guidelines for Ecological Risk Assessment*[1] provides additional discussion and examples of these techniques.

26.2.1 Single-Point Exposure and Effects Comparisons

The simplest approach for comparing exposure and effects estimates for air toxics ecological risk assessments is the Hazard Quotient (HQ) approach (also referred to as the "quotient method"), which is similar to that used for human noncancer health risk assessments (see Chapter 13). In this approach, modeled or measured concentrations of the chemical in each environmental medium are divided by the appropriate point estimate for ecological effects to yield a HQ for an individual chemical.

$$HQ = \frac{Oral\ Intake}{TRV} \quad or \quad HQ = \frac{EEC}{TRV} \quad or \quad HQ = \frac{BB}{TRV} \qquad \text{(Equation 26-1)}$$

where:

HQ	=	hazard quotient
Oral Intake	=	estimated or measured contaminant intake relevant to the oral intake-based TRV (usually expressed as mg/kg-day)
TRV	=	Toxicity reference value. This may be in terms of oral intake, media concentration, or body burden. As described elsewhere, it may be a result of a single study (e.g., NOAEL) or the result of integration of multiple studies (e.g., water quality criterion).
EEC	=	estimated or measured environmental media concentration at the exposure point (usually expressed as mg/L for water and mg/kg for soil and sediment)
BB	=	estimated or measured body burden (usually expressed as mg/kg wet weight)

As with human health assessments, the measure of oral intake, EEC, or BB must be in the same units as the TRV to which the measure is being compared.

As chronic risk will usually "drive" an ecological assessment, the HQ approach will usually be employed for chronic exposure scenarios using chronic duration TRVs. For initial screening, conservative exposure factors may be used (see Exhibit 24-2). As in human health risk assessment, an HQ greater than one indicates the potential for adverse ecological effects to occur, but does not predict their occurrence (see Chapter 13).

When ecological toxicity data for complex mixtures are unavailable, the hazard index (HI) approach[b] may sometimes be used in screening assessments, as scientifically appropriate, to assess potential ecological risks associated with simultaneous exposure to multiple air toxics.[1]

If the HI approach is used, the assumptions and associated limitations should be clearly documented. It may often be the case that a single chemical is responsible for the HI exceeding one, and the assessment can then focus on the HQ for that chemical. In more refined assessments, an alternative approach may be necessary.

As with human health assessments, a number of limitations restrict application of the HQ approach. While a quotient can be useful in answering whether adverse effects are likely to occur or not, it may not be helpful to a risk manager who needs to make a decision requiring an incremental quantification of ecological hazard. For example, it is seldom useful to say that a mitigation approach will reduce the value of a quotient from 25 to 12, since this reduction cannot, by itself, be clearly interpreted in terms of effects on an assessment endpoint. Quotients also may not be the most appropriate methods for predicting secondary effects (e.g., bioaccumulation, loss of prey species). Finally, in most cases the quotient does not explicitly consider uncertainty, such as extrapolation from the test species to the species or community of concern. Some uncertainties, however, can be incorporated into single-point estimates to provide a statement of likelihood that the effects point estimate exceeds the exposure point estimate (see Exhibit 26-1).[1]

State Water Quality Standards

Pursuant to Section 303 of the Clean Water Act, States have developed numerical water quality standards for the protection of aquatic ecosystems. These standards generally are considered regulatory requirements that must be met, and often are based on EPA's Ambient Water Quality Criteria (see Chapter 25). If persistent, bioaccumulative hazardous air pollutants (PB-HAPs) enter surface waters, one way to assess risk is to compare the EEC to a water quality standard using the HQ approach. State water quality standards can be accessed via EPA's national water quality standards database at http://www.epa.gov/ost/wqs/.

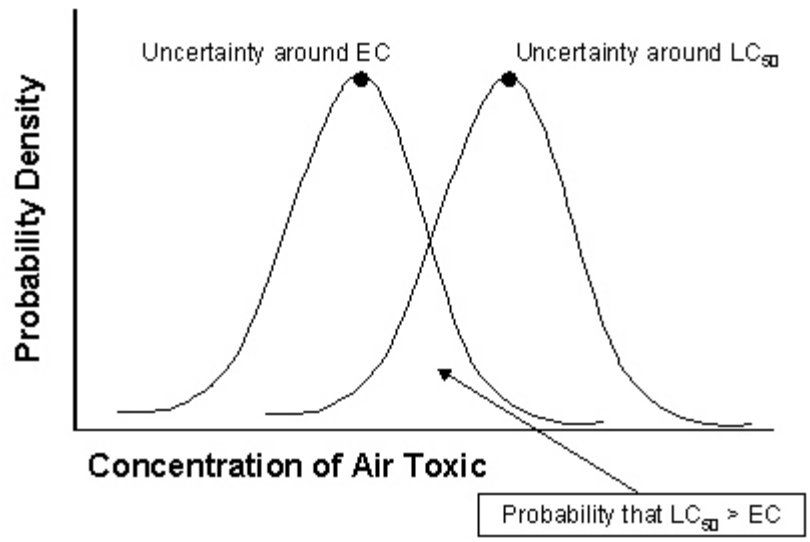
26.2.2 Comparisons Involving the Entire Stressor-Response Relationship

If a curve relating the intensity or level of the stressor to the magnitude of response is available (for example, see Exhibit 25-1), the risk characterization can examine risks associated with many different levels of exposure. These estimates are particularly useful when the risk management decision is not based on exceeding a pre-determined reference value or regulatory standard (e.g., a state water quality standard). This approach provides a predictive ability lacking in the hazard quotient approach, and it may be used in screening level assessments or subsequent more refined risk analyses. Because the slope of the effects curve relates the magnitude of change in effects to incremental changes in exposure, the ability to predict changes in the magnitude and likelihood of effects for different exposure scenarios can be used to compare different risk management options. Also, uncertainty can be incorporated by calculating uncertainty bounds on the stressor-response or exposure estimates. Limitations to this approach may include: lack of consideration

[b] The HI approach is termed the "quotient addition approach" in EPA's *Guidelines for Ecological Risk Assessment*[1]

for secondary effects, assuming the exposure pattern used to derive the stressor-response curve is comparable to the environmental exposure pattern; and failing to consider uncertainties such as extrapolations from tests species to the species or communities of concern.

Exhibit 26-1. Example Comparison of Point Estimates with Associated Uncertainties



26.2.3 Comparisons Involving Variability

If the exposure or stressor-response profiles describe the variability in exposure or effects, then many different risk estimates can be developed. Variability in exposure can be used to estimate risks to moderately or highly exposed members of a population being investigated, while variability in effects can be used to estimate risks to average or sensitive members of populations. As an example, exposure can vary by life-stage (e.g., exposure may be greater during spawning or migration). Likewise, effect may also vary by life-cycle (e.g., hatchlings may be more sensitive to a chemical than are adults). A major advantage of this approach is its ability to predict changes in the magnitude and likelihood of effects for different exposure scenarios and thus provide a means for comparing different risk management options. Limitations include the increased data requirements compared with previously described techniques and the implicit assumption that the full range of variability in the exposure and effects data is adequately represented. In addition, secondary effects are not readily evaluated with this approach. This risk estimation technique would likely be used in more refined risk assessments. (A discussion of probabilistic techniques, including Monte Carlo Simulation, is provided in Chapter 31.)

26.2.4 Process Models

Process models are mathematical expressions that represent understanding of the mechanistic operation of a system under evaluation. They can be useful tools in both analysis and risk characterization (process models are discussed briefly in Chapter 25). A major advantage of using process models is the ability to consider "what if" scenarios and to forecast beyond the limits of observed data that constrain approaches based solely on empirical data. Process models

also can consider secondary effects, and in some cases, the combined effects of multiple stressors. Process model outputs may be point estimates, distributions, or correlations. However, since process models are only as good as the assumptions on which they are based, the outputs from these models should be interpreted with care. The lack of knowledge on basic life histories for many species, and incomplete knowledge about the structure and function of natural ecosystems are some of the many uncertainties that need to be considered. These models are complex and, are usually reserved for more refined risk assessments.

Risk Assessment Frontiers: Integrating Human Health and Ecological Risk Assessment

Many tribal cultures view ecological and human health in an integrated way such that they cannot be easily separated. Similarly, there is some effort (especially in Canada) toward an integration of human health and ecological assessment, as well as decision-making, in a field known as **strategic environmental assessment**.[3] This approach has not been applied widely in the United States, and it remains to be seen how it will develop in the next few years.

The World Health Organization has published approaches to integrating human health and ecological risk assessments to improve data quality and understanding of cumulative risks for decision making.[4] This approach includes an integrated framework (modified from EPA's guidance)[1] and case studies.

EPA, in its *Framework for Cumulative Risk Assessment*,[5] offers a flexible structure for conducting and evaluating cumulative risk assessment. By "cumulative risk," EPA means "the combined risks from aggregate exposures to multiple agents or stressors." Agents or stressors may be chemicals, but they may also be biological agents or physical agents, or an activity that, directly or indirectly, alters or causes the loss of a necessity such as habitat.

26.3 Risk Description

The results of the risk characterization should be documented in the **risk description**, which includes an evaluation of the lines of evidence supporting or refuting the risk estimate(s) and an interpretation of the significance of the observed and/or predicted effects.

26.3.1 Lines of Evidence

The development of lines of evidence provides both a process and a framework for reaching a conclusion regarding confidence in the risk estimate. Confidence in the conclusions of a risk assessment may be increased by using several lines of evidence to interpret and compare risk estimates. These lines of evidence may be derived from different sources or by different techniques relevant to adverse effects on the assessment endpoints (e.g., hazard quotients, modeling results, or field observational studies). There are three principal categories of factors to consider when evaluating lines of evidence:

1. **Data adequacy and quality**. Data quality directly influences confidence in the results of a risk assessment and the conclusions that can be drawn from the study. Specific concerns include: whether the experimental design was appropriate for the questions being evaluated in the risk assessment; whether data quality objectives were clear and adhered to; and whether the analyses were sufficiently sensitive and robust to identify stressor-caused effects in light of natural variability of the attributes of the ecological receptors of concern.

2. **Relative uncertainty**. One major source of uncertainty comes from extrapolations (e.g., from one species to another; from one temporal scale to another; from laboratory to field effects). In general, the greater the number of extrapolations, the greater the uncertainty.

3. **Relationship to the risk hypothesis**. Finally, the relative importance of each line of evidence may be determined by how directly they relate to the risk hypothesis developed during planning and scoping. For example, lines of evidence based on a definitive mechanism rather than associations alone are likely to be relatively important.

The evaluation of lines of evidence involves more than just listing the evidence that supports or refutes the risk estimate. Each factor should be examined carefully, and its contribution in the context of the risk assessment should be evaluated. For example, data or study results are often not reported or carried through the risk assessment because they are of insufficient quality. If such data or results are eliminated from the evaluation process, however, valuable information may be lost with respect to needed improvements in methodologies or recommendations for further studies.

When lines of evidence do not point toward the same conclusion, it is important to investigate possible reasons for the disagreements. A starting point is to distinguish between true inconsistencies and those related to methodology (e.g., statistical powers of detection). For example, if a model predicts adverse effects that were not observed in the field, it is important to determine whether the model predictions were unrealistic, or the experimental design of the field study was inadequate to detect the predicted effects, or both.

26.3.2 Significance of the Effects

In this step, the significance of the observed or estimated changes in the assessment endpoints is interpreted in light of the lines of evidence evaluated above. In this context, significance refers to a conclusion as to whether the observed or estimated changes are considered "adverse." Adverse ecological effects represent changes that are undesirable because they alter valued structural or functional attributes of the ecological receptors of concern (e.g., the loss of a keystone species). This determination is difficult and is frequently based on professional judgment. The assessment of degree of adversity, along with other factors such as the economic, legal, or social consequences of the ecological change, may be considered in the risk management decision. Unless an endangered or threatened species is at issue, society is generally not concerned with the death of individual plants or animals, and therefore significance is generally assessed at the population, community, or ecosystem level(s). The following factors may be used to evaluate the degree of adversity (see also Exhibit 26-2):

- **Nature and intensity of effects**. This focuses on distinguishing adverse changes from those that are within the normal pattern of ecosystem variability or that result in little or no significant alteration of biota. For example, if survival of offspring will be affected, by what percentage will it diminish, and is that likely to have a major impact on population dynamics? It is important to consider both ecological and statistical information in evaluating the nature and intensity of effects. For example, a small change in a growth rate may not be statistically distinguishable from natural variation; however, its impact may be more significant for a population of slowly reproducing fish than for rapidly reproducing algae. When performing a more refined assessment, it is necessary to compare the potentially impacted ecosystem to a

non-impacted ecosystem (i.e., a "control" site) so there is a basis for statistical comparisons between the two systems.

Exhibit 26-2. Examples of Considerations for Determining Ecological Significance
• How large is the area where ecological criteria have been exceeded? • What proportion of the habitat is affected at local, county, State, and national levels? • Are the exposure concentrations and ecological criteria above background levels for the area of interest? • What types of ecological impacts have been associated with this pollutant or similar pollutants in the past? • Is the criterion or stressor-responsive curve based on high quality data (i.e., is there a high degree of confidence in the criterion)?

- **Spatial and temporal scale**. The spatial dimension encompasses both the extent and pattern of effect as well as the context of the effect within the broader ecosystem or landscape. Factors to consider include the absolute area affected, the percentage of area affected compared with a larger area of interest, and the relative importance of the affected area(s) to the ecological receptors of concern (e.g., are they critical breeding or overwintering areas?). For air toxics that persist and bioaccumulate, the temporal dimension of concern generally will be in the years to decades range, although effects in other time frames may be important in specific cases. Temporal responses for ecosystems may involve intrinsic time lags, so responses to a stressor (or risk mitigation effort) may be delayed.

- **Potential for recovery**. Recovery refers to the rate and extent of return of a population or community to some aspect of its condition prior to exposure to the stressor(s) of concern. Because ecosystems are dynamic, even under natural conditions, it is unrealistic to expect that a system will remain static at some level or return to exactly the same state that it was before it was disturbed. Thus, the "attributes" of a recovered population, community, or ecosystem should be carefully defined. In general, changes that preclude recovery or result in long recovery times are more significant than changes that allow rapid recovery. Note that different components of a community or ecosystem may recover at different rates. For example, stream chemistry may recover relatively rapidly after removal of a stressor, but re-establishment of predatory fish populations may take several years or more.

26.4 Risk Characterization Report

The information on estimates of ecological risk, the overall degree of confidence in the risk estimates, lines of evidence, and the interpretation of the significance of ecological effects generally is included in a **risk assessment or risk characterization report**. Exhibit 26-3 lists the elements that generally are considered in the risk characterization report. A risk characterization report may be brief or extensive, depending on the nature of and resources available for the assessment. The report need not be overly complex or lengthy; it is most important that the information required to support the risk management decision be presented clearly and concisely. To facilitate mutual understanding, EPA policy[6] requires that risk characterizations be prepared "in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency." It describes a philosophy of transparency, clarity, consistency, and reasonableness (TCCR), and

provides detailed approaches to achieving TCRR. Exhibit 26-4 provides an overview of the TCRR principles (these are the same principles listed in Chapter 13).

Exhibit 26-3. Possible Risk Characterization Report Elements
• Describe risk assessor/risk manager planning results. • Describe the scope of the assessment. • Review the conceptual model and the assessment endpoints. • Describe the measures of effect. • Discuss the major data sources and analytical procedures used. • Review the stressor-response and exposure profiles. • Assign risks to the assessment endpoints, including risk estimates and adversity evaluations. • Review and summarize major areas of uncertainty (as well as their direction) and the approaches used to address them: – Discuss the degree of scientific consensus in key areas of uncertainty; – Identify major data gaps and, where appropriate, indicate whether gathering additional data would add significantly to the overall confidence in the assessment results; – Discuss science policy judgments or default assumptions used to bridge information gaps and the basis for these assumptions; and – Discuss how the elements of quantitative uncertainty analysis are embedded in the estimate of risk.

Exhibit 26-4. Transparency, Clarity, Consistency, and Reasonableness Principles

Principle	Definition	Criteria for a Good Risk Characterization
Transparency	Explicitness in the risk assessment process	• Describe assessment approach, assumptions, extrapolations, and use of models • Describe plausible alternative assumptions • Identify data gaps • Distinguish science from policy • Describe uncertainty • Describe relative strength of assessment
Clarity	The assessment itself is free from obscure language and is easy to understand	• Employ brevity • Use plain English • Avoid technical terms • Use simple tables, graphics, and equations
Consistency	The conclusions of the risk assessment are characterized in harmony with EPA actions	• Follow statutes • Follow Agency guidance • Use Agency information systems • Place assessment in context with similar risks • Define level of effort • Use review by peers
Reasonableness	The risk assessment is based on sound judgment	• Use review by peers • Use best available scientific information • Use good judgment • Use plausible alternatives

26.5 Evaluating Variability and Uncertainty

An important part of the Risk Characterization Report is a discussion and assessment of variability and uncertainty in all aspects of the ecological risk assessment. Note that ecological risk assessments are subject to additional sources of uncertainty and variability as compared to multipathway human health risk assessments. In addition to the uncertainties associated with multimedia modeling and sampling, the ecological risk assessment involves many decisions regarding choice of ecological receptors of concern and associated assessment and measures of effect. Some of these may be at levels of organization above individual species (e.g., communities, ecosystems), where stressor-response relationships are poorly understood. Because many different species and higher taxonomic groups may be included in the assessment, selection of many parameter values such as bioconcentration factors, dose-response values, and dietary intake is more complex and uncertain for the ecological risk assessment as compared to the human health multipathway risk assessment.

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PART V

RISK-BASED DECISION MAKING

Introduction to Part V

Part V of this Reference Manual provides an overview of three components of risk-based decision making.

- Risk Management (Chapter 27) refers to the regulatory and other actions taken to limit or control exposures to air toxics, including the role of risk management in regulating hazards.

- Community Involvement (Chapter 28) is an integral part of many risk management strategies because good community involvement helps ensure that the strategy selected will have the highest likelihood of success. Various levels of community involvement are also required by many laws.

- Risk Communication (Chapter 29) describes the process of planning the risk assessment (during scoping) and conveying the results of the risk assessment in a way that meets the information requirements for the risk management decisions. This chapter discusses the importance of risk communication, and planning and implementing a risk communication strategy.

Chapter 27 Risk Management

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27.1 Introduction

This chapter introduces risk management, focusing on its role in addressing the risks that air toxics pose. It provides an overview of the types of risk management decisions related to air toxics, a discussion of how risks to individuals and populations are presented to the public, and options for implementing decisions (e.g., regulation, voluntary risk reduction activities).

Specifically, **risk management** refers to the regulatory and other actions taken to limit or control exposures to a chemical. **Risk assessment**, on the other hand, is a tool used to support risk management decisions by providing quantitative and qualitative expressions of risk, along with attendant uncertainties. Specifically, the risk assessment conveys a quantitative and qualitative description of the types of impacts that may occur from exposure to an air toxic, the likelihood that these impacts will occur given existing conditions, and the uncertainties surrounding the analysis. Risk management considers these principle factors along with a variety of additional information (which may include the cost of reducing emissions or exposures, the statutory authority to take regulatory actions, and the acceptability of control options) to reach a final decision.

27.2 Role of Risk Management in Regulating Hazards

Risk management may include implicit or explicit policy and value judgments. Therefore, one would expect there to be differences of opinion concerning what represents an appropriate risk management action. Even the most basic risk management decision can be highly controversial. A classic example is the decision(s) needed to answer the question **how clean is clean?** This question refers to a risk management decision that must establish a target level to which existing levels of contamination/pollution should be reduced. Establishing this level is not a trivial matter. Working through these issues can be complicated by the different values of the stakeholders and debates over individual perceptions about risk. As discussed below, many authors and organizations stress the importance of understanding risk management mandates, options, and concerns throughout the risk assessment process, from the initial problem formulation steps to the final risk characterization and risk communication. Many of the critical decisions in structuring the technical risk assessment depend on risk management concerns (e.g., what risk management options are feasible, what level of certainty in the risk estimate is acceptable).

Although the National Academy of Sciences and others stress the **distinction** between risk assessment and risk management, they also stress the **integration** of the two efforts (see Exhibit 27-1). Risk assessments are often designed and conducted with awareness of the risk management options available to decision-makers and the social, economic, and political context in which those decisions are to be made. Likewise, periodically reviewing the risk management options during the risk assessment effort ensures that the results of the risk assessment will provide meaningful input into the decision-making process. The National Research Council (NRC) of the National Academy of Sciences (NAS), in their 1983 study entitled *Risk Assessment in the Federal Government: Managing the Process* (the "Red Book"),[1] advocated a clear conceptual distinction between risk assessment and risk management, noting, for example, that maintaining the distinction between the two would help to prevent the tailoring of risk assessments to the political feasibility of regulating a chemical substance. However, the NRC also recognized that the choice of risk assessment techniques could not be isolated from society's

risk management goals. Ultimately, the risk assessors should be aware of risk management goals; however, the fundamental science performed in the risk assessment should be impartial and based on the factual base of information, to the extent possible.

Use of the Term "Safe"

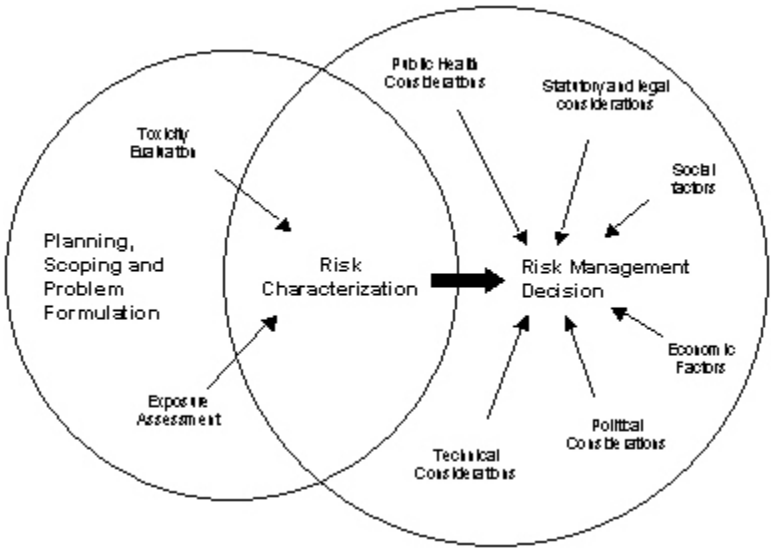
Safe: Condition of exposure under which there is a practical certainty that no harm will result to exposed individuals (as defined in EPA's *Terms of Environment*).

Safe: Free from harm or risk (as defined in the Merriam-Webster Collegiate Dictionary).

During government and community interactions and risk communication, it is important to be sensitive to perceived meanings of the term "safe." Regulators and scientists are often reluctant to use the term "safe," because many people understand "safe" to mean "zero risk." Ideally, one would like to eliminate all risks, but this is usually not a realistic expectation. Regulators commonly work to address the most important risks and decrease them to the level at which they believe the risks are smaller than the benefits of the activity causing the problem (in this case, risk from exposure to air toxics). They commonly refer to this level as "acceptably low risk."

However, community members may become frustrated with regulators who are reluctant to use the term "safe," potentially perceiving the regulators' choice of words as a dodge of the issue. Therefore, it is important for government representatives to address perceptions of the meaning of safe during risk communication and, as appropriate, use risk comparisons to help in communicating the concepts of safe versus acceptably low risk. Information on risk communication is provided in Chapter 29, and Section 29.4 provides specific information about risk comparisons.

Exhibit 27-1. Illustration of the Integration Between Risk Assessment and Risk Management

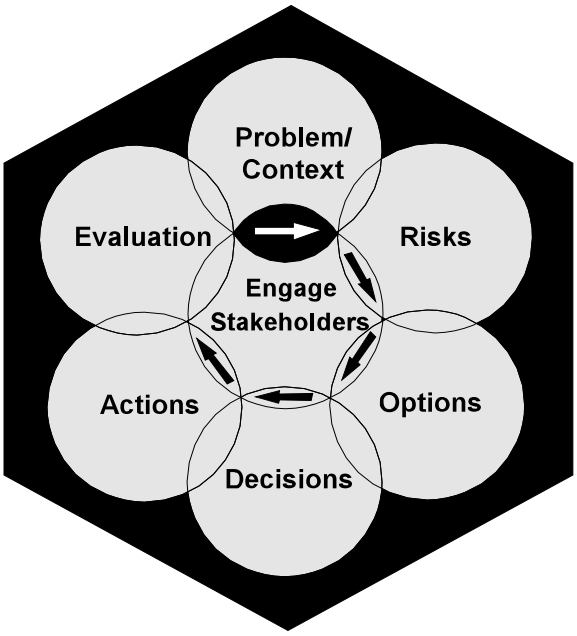


The NRC, in their 1994 report, *Science and Judgment in Risk Assessment* (the "Blue Book"),[2] noted that, while the Red Book emphasized the distinction between risk assessment and risk management, the purpose of separation was not to prevent any exercise of policy judgment when evaluating science or to prevent risk managers from influencing the type of information that assessors would collect, analyze, or present. The Blue Book concluded further that the science-policy judgments that EPA makes in the course of a risk assessment would be improved if there were more clearly informed by the Agency's priorities and goals in risk management. Protecting the integrity of the risk assessment, while building more productive linkages to make risk assessment more accurate and relevant to risk management, is essential.

The integration between risk assessment and risk management also has been emphasized by Presidential/Congressional Commission on Risk Assessment and Risk Management. In their Reports *Framework for Environmental Health Risk Management* and *Risk Assessment and Risk Management In Regulatory Decision-Making* (the two-volume "White Book"),[3] the Commission developed a six-stage integrated framework for environmental health risk management that can be applied to most situations (Exhibit 27-2):

1. Define the problem and put it in context;
2. Analyze the risks associated with the problem in context;
3. Examine options for addressing the risks;
4. Make decisions about which options to implement;
5. Take actions to implement the decisions; and
6. Conduct an evaluation of the action's results.

Exhibit 27-2. The CRARM Framework for Risk Management



The Commission noted that the process of examining risk management options does not have to wait until the risk analysis is completed, although a risk analysis often will provide important information for identifying and evaluating risk management options. In some cases, examining risk management options may help refine a risk analysis. The Commission also recommended that all of these steps involve stakeholders (see Chapter 28).

When discussing risk management, it is important to consider **where** and **how** changes or interventions may occur in the causal sequence of environmental impacts since interventions may reduce pollutants a number of ways along the critical path of environmental impacts. For example, interventions such as changing manufacturing processes, implementing emissions controls, or influencing worker behaviors that actively reduce exposure may have a positive mitigating effect on environmental impacts. In the discussion of risk management that follows, it is critical to keep in mind the range of ways in which environmental risks can be mitigated; it is up to the risk managers to determine the most feasible and critical "points of entry" along the path when developing a risk management strategy.

27.3 Types of Risk Management Decisions Related to Air Toxics

Two general categories of risk management decisions are relevant to air toxics: emissions control and siting.

- **Emissions control**. Emissions control decisions may involve "command-and-control" decisions (e.g., emissions limits) or incentives (e.g., tax credits for reduced emissions). EPA's preference is to encourage pollution prevention whenever feasible (see Exhibit 27-3). Emissions control decisions are most likely to involve formal risk assessments.

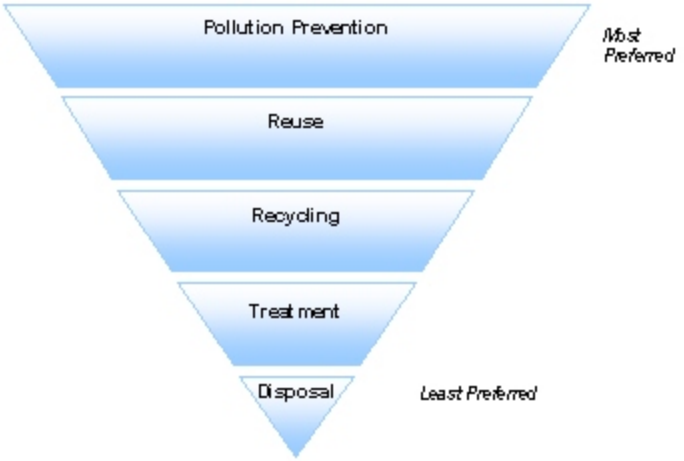
- **Siting/locating**. These decisions involve where to locate industrial facilities, businesses, waste disposal facilities, and transportation routes. Siting decisions are typically made by S/L/T governments through mechanisms such as zoning, deed restrictions and other property controls, and in some cases regulation. Many of these decision-making processes include public involvement in which citizens may seek to influence the final decision. Siting decisions may involve assessment of environmental impacts pursuant to the National Environmental Policy Act, other federal statutes, or similar state statutes. Siting decisions may increasingly involve air toxics risk assessments.

Not All Risk Management Decisions are Regulatory

Some risk management decisions are made by EPA or state, local and tribal (S/L/T) regulators pursuant to specific statutory criteria. However, government agencies may have limited authority to impact many other decisions. For example, some decisions are made by the individuals who own or operate the facilities that release air toxics, while others are made by citizens who are being impacted by emissions. Risk management decisions may need to consider looking beyond technological solutions.

Exhibit 27-3. Pollution Prevention Hierarchy

In the Pollution Prevention Act of 1990, Congress established a hierarchy for the handling of pollution (see graphic). The Act established as United States policy that pollution should be prevented or reduced at the source whenever feasible, that pollution that cannot be prevented should be recycled in an environmentally safe manner whenever feasible, and that pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible. Disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner.



Pollution prevention is the reduction or elimination of pollutants at the source. As defined in the Pollution Prevention Act, "source reduction" means any practice which (1) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal, and (2) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants. It includes equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control. Examples of the value of pollution prevention for reducing environmental risks at the community level are demonstrated by EPA's Environmental Justice through Pollution Prevention (EJP2) grant program. EPA encouraged community groups, tribes, and local governments to identify environmental problems and generate potential pollution prevention solutions for their communities.

Source: U.S. Environmental Protection Agency. 2002. *Environmental Justice Through Pollution Prevention Program.* Updated July 9, 2002. Available at: http://www.epa.gov/opptintr/ejp2/. (Last accessed April, 2004.)

27.4 Use of Risk Estimates in Decision-Making

Decision-makers have a number of options when deciding what types of risk estimates to consider as inputs to risk management decisions. Estimates of human health risk generally fall into two categories, estimated **cancer risk** and the estimated **noncancer hazard** magnitude of exposure concentration or dietary intake greater than a pre-established reference exposure level), as described in more detail in Chapters 13 and 22. Non-cancer hazard may be considered for both acute (short-term) and chronic (longer-term) exposures. In some cases, **ecological risk** may be a factor in decision-making.

In some situations, risk managers may choose to consider EPA's approach for assessing an "ample margin of safety." For cancer risks, EPA generally considers incremental risk (or probability) of cancer for an individual potentially exposed to one or more air toxics. In protecting public health with an ample margin of safety, EPA strives to provide maximum feasible protection against risks to health from HAPs by (1) protecting the greatest number of

persons possible to an individual lifetime risk level no higher than 1×10^{-6} (one in one million) and (2) limiting to no higher than approximately 1×10^{-4} (one in ten thousand) the estimated risk that a person living near a source would have if exposed to the maximum pollutant concentrations for 70 years. These goals are described in the preamble to the benzene National Emissions Standards for Hazardous Air Pollutants (NESHAP) rulemaking (54 *Federal Register* 38044, September 14, 1989) and are the goals incorporated by Congress for EPA's residual risk program under Clean Air Act (CAA) section 112(f). Exhibit 27-4 describes some of the key steps in the development of the 1×10^{-4} to 1×10^{-6} carcinogenic risk range.

For non-carcinogenic substances, on the other hand, risk managers may consider a reference level that is developed based on data from laboratory animal or human epidemiology studies (see Chapter 12), and to which uncertainty factors are applied. The reference level is usually an exposure level below which there are not likely to be any adverse effects from exposure to the chemical. Exposures above the reference level may have some potential for causing adverse effects. This concept may also be applied generally to ecological risks.

Risk estimate options generally revolve around estimates of individual risk, the number of people at different risk levels (population risk), and occasionally include the expected incidence of disease in the entire population. Risk estimates can be derived for the current population as currently distributed in an area or for a population size and geographic distribution that might occur in the future; similarly, they may focus on risk estimates for persons currently exposed or possible risks calculated for a hypothetical individual located where exposures are expected to be relatively high. It is important to note that risk estimates should strive to take into account both **indoor** and **outdoor** exposure to toxics, when possible.

- **Risk to a specified individual**. Most risk assessments focus on estimating individual risk rather than the incidence of adverse effects (e.g., numbers of predicted cancer cases per year) in a population. There are two general estimates of individual risk:

  - **High-end** risk estimates seek to determine a "plausible worst case" situation among all of the individual risks in the population. This estimate is meant to describe an individual who, as a result of where they live and what they do, experiences the highest level of exposure within some reasonable bounds. Reasonable maximum risk estimates are often defined conceptually as "above the 90th percentile of the population"[(4)] but not at a higher exposure level than the person exposed at the highest level in the population. When calculated using deterministic methods, the high-end individual is calculated by combining upper-bound and mid-range exposure factors (e.g., an average body weight, but high-end ingestion rate) so that the result represents an exposure scenario that is both protective and reasonable, but not higher than the worst possible case.

  - **Central-tendency** risk estimates seek to determine a reasonable "average" or "mid-range" situation among all of the individual risks in the population. Many risk management decisions related to exposure to radioactive substances (e.g., in nuclear power plants) are based on central-tendency risk estimates.

Exhibit 27-4. Development of the 1×10^{-4} to 1×10^{-6} Carcinogenic Risk Range

The 1970 CAA established Section 112 to deal with hazardous air pollutants. Once the EPA Administrator had identified such a pollutant and "listed" it, he/she was directed to set emission standards for sources emitting it at levels that would "provide an ample margin of safety to protect the public health." The regulation of benzene pursuant to Section 112 illustrates the evolution of risk-based decision-making for carcinogens and the consideration of the "ample margin of safety."

- EPA listed benzene as a HAP in June 1977 and indicated that the "relative risk to the public" would be considered in judging "the degree of control which can and should be required."

- In 1980, the first round of benzene standards followed the proposed procedures in EPA's 1979 draft airborne carcinogen policy, which reflected a technology-based approach to emission standard development with a limited role for quantitative risk assessment in establishing priorities and ensuring that the residual risks following the application of "best available technology" (BAT) were not unreasonable.

- In 1984, after "weighing all factors," EPA made several changes to the proposed benzene rules, arguing that the risks were "too small to warrant Federal regulatory action." These decisions were promptly challenged by the Natural Resources Defense Council, who argued about the uncertainties in the risk estimates and the inappropriate consideration of cost in regulatory decisions made under Section 112. The issues raised were similar to litigation already pending on amendments to the original vinyl chloride standards.

- On July 28, 1987, Judge Robert Bork, writing for the D.C. Circuit Court of Appeals, remanded the vinyl chloride amendments to EPA, finding that the Agency had placed too great an emphasis on technical feasibility and cost rather than the provision of an "ample margin of safety" as required by the statute. The opinion also laid out a process for making decisions, consistent with the requirements of the law. The Bork opinion held that EPA must first determine a "safe" or "acceptable" level considering only the potential health impacts of the pollutant. Once an acceptable level was identified, the level could be reduced further, as appropriate and in consideration of other factors, including cost and technical feasibility to provide the required ample margin of safety. The Court also held, however, that "safe" did not require a finding of "risk-free" and that EPA should recognize that activities such as "driving a car or breathing city air" may not be considered "unsafe."

- In September of 1989, after proposing several options and receiving considerable public comment, EPA promulgated emission standards for several categories of benzene sources. EPA argued for the consideration of all relevant health information and established "presumptive benchmarks" for risks that would be deemed "acceptable." The goal, which came to be known as the "fuzzy bright line," is to protect the greatest number of persons possible to an individual lifetime risk no higher than one in 1,000,000 and to limit to no higher than approximately one in 10,000 the estimated maximum individual risk. The selection of even "fuzzy" risk targets placed greater emphasis on the development and communication of risk characterization results.

Source: National Academy of Sciences' *Science and Judgment in Risk Assessment* (The Blue Book).[2]

Note that, when calculating deterministic risk estimates, both a high end and central tendency estimate of risk give the risk manager some sense of the range of risks in the population. When risks to a population are developed using probabilistic methods, this becomes a moot point, since the result is a distribution of risks across the population, which necessarily includes information about the full variability of risk across the population – including both high and central tendency risks. See Chapter 31 for more information on probabilistic approaches to risk assessment.

- **Risk to the total population**. Whether or not risk to the total population is considered by EPA may depend on the regulatory authority provided by the CAA. For example, Section 112(k) of the CAA requires EPA to develop an Urban Air Toxics Strategy to reduce HAPs from area sources to achieve a 75 percent reduction in cancer incidences attributable to such sources. Two general types of descriptors are used for population risk. One, sometimes termed **population at risk** is derived by determining the number of people in a population with a particular individual risk level (e.g., "1,340,000 people are exposed at the 1×10^{-6} level, and 320 people are exposed at the 1×10^{-4} level"). This is a useful estimate of the variability of risk in a population.

- **Incidence**, another descriptor used for population risk, is an estimate of the total number (incidence) of adverse effects in a population over a specified time period (e.g., a period of 70 years). A screening approach to deriving this estimate for a 70-year period involves multiplying the estimate of individual risk (central tendency and/or reasonable maximum) by the number of persons for which that risk estimate was predicted. For example, in a population of 200 million persons, an individual cancer risk of 1×10^{-4} (i.e., one in ten thousand) for everyone in the population would translate to an incidence of hundreds or thousands of excess cancer cases over a 70-year period (depending on the exposure assumptions). However, in a small population (e.g., a town of 200 persons), the same individual cancer risk to everyone would translate to an excess incidence of cancer of less than one over a 70-year period.

- **Present versus future scenarios**. Risks may be characterized using present or future scenarios. Use of present scenarios involves predicting risks associated with the current exposures to individuals (or populations) that currently reside in areas where exposures are predicted to occur. For example, a current population risk estimate would use the existing population within some specified area. The resultant risk estimates are associated with the presumption that the current exposure conditions exist for the current population over the period of time associated with the assessment (e.g., into the future). Use of future population scenarios involves estimating risks associated with exposure conditions to individuals that might reside, at some future point, in areas where potential exposures may occur (e.g., if a housing development were built on currently vacant land).

- **Potential risk**. Risks may be sometimes be characterized for hypothetical exposures. For example, in a screening air toxics modeling application, a potential risk estimate may be derived using the location where the maximum modeled exposure concentration occurs, regardless of whether there is a person there or not. This estimate may be considered along with the predicted individual risk associated with a currently populated area, such as the MIR, which reflects risk associated with the maximum exposure concentration at an actual residence or in a census block with a non-zero population (see Chapter 11).

27.5 Process for Making Risk Management Decisions

A number of different authors and organizations have identified key steps or factors to consider in making risk management decisions. The discussion in this section is taken largely from the risk management framework developed by the Presidential/Congressional Commission on Risk Assessment and Risk Management.[3] The Commissions's framework has six stages, each of which is briefly described below. The Commission also noted that the framework is conducted:

- In collaboration with stakeholders; and
- Using iterations if new information is developed that changes the need for or nature of risk management.

27.5.1 Define the Problem and Put it in Context

The problem/context stage is the most important step in the Risk Management Framework. It involves:

- Identifying and characterizing an environmental health problem, or a potential problem, caused by chemicals or other hazardous agents or situations;
- Putting the problem into its public health and ecological context;
- Determining risk management goals;
- Identifying risk managers with the authority or responsibility to take the necessary actions; and
- Implementing a process for engaging stakeholders.

These steps are all important, but may be conducted in different orders, depending on the particular situation. For example, when a federal or S/L/T regulatory agency is mandated by law to take the lead on an air toxics issue, the steps they take often will proceed in the order listed above, with the identity of the risk managers already clear, since the agency will have assumed that role from the start. On the other hand, in a community based effort to characterize the cumulative risk posed by multiple sources of air toxics in a neighborhood, stakeholders might have to engage in a collaborative stakeholder process first to identify resources as well as risk managers with the needed authority to act before the other steps can take place.

27.5.2 Analyze the Risks Associated with the Problem in Context

The nature, extent, and focus of a risk assessment should be guided by the risk management goals. The results of a risk assessment – along with information about public values, statutory requirements, court decisions, equity considerations, benefits, and costs – all can influence whether and how to manage the risks.

Risk assessment can be controversial, reflecting the important role that both science and judgment play in drawing conclusions about the likelihood of effects on human health and the

environment. Often, the controversy arises from what we do not know and from what risk assessments cannot tell us, because our knowledge of human vulnerability and of environmental impacts is incomplete, especially at the relatively low levels of chemical exposure commonly encountered in the general community.

Some Factors to Consider in Defining the Problem for an Air Toxics Risk Assessment

- **Risk**. The specific estimates of risk to be used as inputs to the decision should be defined as explicitly as possible. Are acute risks (e.g., short-term exposures) the primary concern, or are exposures over the longer-term more important? Are ecological risks a concern? How certain are we that our risk estimates are an accurate reflection of true exposure and risk?

- **Air toxics of concern**. What are the primary air toxics of concern? Are they more prevalent in indoor or outdoor environments? How many individual chemicals contribute to the risks that need to be managed? Do these chemicals exert their effects independently, or are some acting in a synergistic (or antagonistic) manner? Are all equally important, or will reducing exposures to a subset of these air toxics result in adequate risk reduction? How important is it to manage every chemical of concern versus only those that pose the greatest risk?

- **Sources**. What are the primary sources of the air toxics that need to be managed? Where are these sources located? How many are there? Are they all equally important, or will controlling a subset result in adequate risk reduction?

- **Exposure pathway considerations**. What exposure pathways/routes are most important? Are all equally important, or does a subset represent the greatest risk? Does control of each pathway require controls over all components of the pathway (e.g., emissions, exposure), or can the pathway be controlled by controlling a subset of these components?

- **Amount of emissions reduction desired/achievable**. What is the overall target for emissions/exposure reduction? How does this relate to risk reduction by the estimates identified above? Will partial reductions result in significant risk reduction, or is it more of an all-or-none situation? What technologies are available to achieve the desired level of risk reduction? How much do the various options cost?

- **Spatial and temporal factors**. Are releases of concern limited to a relatively brief period of time, or do data support the emissions being relatively continuous over a longer period of time? Are the released toxics specific to a single location or are there several wide-spread emission points? What is the fate and transport of the released chemicals? How does background risk relate to the risk reduction strategy?

- **Data gaps and uncertainties**. What are the main sources of uncertainty in the data used in the risk assessment? How do these uncertainties affect the risk management decision? Will more information reduce these uncertainties and can the uncertainty be addressed with available time and resources? Approaches for identifying and managing uncertainties associated with risk assessment are discussed in Chapters 13 and Part VII.

27.5.3 Examine Options for Addressing the Risks

This stage of the risk management process involves identifying potential risk management options and evaluating their effectiveness, feasibility, costs, benefits, unintended consequences, and cultural or social impacts. This process can begin whenever appropriate after defining the problem and considering the context. It does not have to wait until the risk analysis is completed, although a risk analysis often will provide important information for identifying and evaluating risk management options. In some cases, examining risk management options may help refine a risk analysis. Risk management goals may be redefined after risk managers and stakeholders gain some appreciation for what is feasible, what the costs and benefits are, and what contribution reducing exposures and risks can make toward improving human and ecological health.

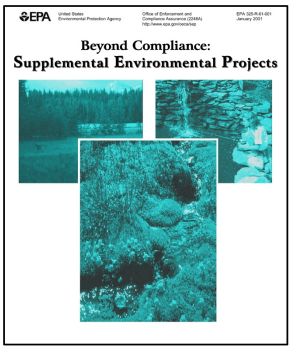
The Commission noted that stakeholders can play an important role in all facets of identifying and analyzing options. They can help risk managers:

- Develop methods for identifying risk-reduction options;
- Develop and analyze options; and
- Evaluate the ability of each option to reduce or eliminate risk, along with its feasibility, costs, benefits, and legal, social, and cultural impacts.

Chapter 28 provides an overview of community involvement and its role in risk assessment and risk management.

Alternative Solutions to Unique Problems

Project XL, which stands for "eXcellence and Leadership," is a national pilot program that allows state and local governments, businesses, and Federal facilities to develop with EPA innovative strategies to test better or more cost-effective ways of achieving environmental and public health protection. In January 2001, EPA signed the 50th XL Final Project Agreement. Although EPA is no longer accepting proposals for new XL projects, EPA will continue to fulfill each of its commitments under Project XL and will track and monitor the progress of each XL pilot for the duration of the project.
See www.epa.gov/projectxl for more information.



Supplemental Environmental Projects (SEPs) are part of enforcement settlements connected with violations of an environmental statutory or regulatory requirement. As part of the enforcement settlement, a violator voluntarily agrees to undertake an environmentally beneficial project in exchange for a reduction in the penalty. See www.epa.gov/compliance/civil/programs/seps for more information.

27.5.4 Make Decisions about Which Options to Implement

In most risk management situations, decision-makers will have a number of options from which to choose. Which option is optimal depends on the particular situation (and in some cases may be driven by statutory requirements). The following seven are fundamental characteristics of sound risk management decision making:

- Base the decision on the best available scientific, economic, and other technical information;
- Be sure the decision accounts for the problem's multisource, multimedia, multichemical, and multirisk contexts;
- Choose risk management options that are feasible, with benefits reasonably related to their costs;
- Give priority to preventing risks, not just controlling them;
- Use alternatives to command-and-control regulation, where applicable;
- Be sensitive to political, social, legal, and cultural considerations; and
- Include incentives for innovation, evaluation, and research.

Options to be considered for air toxics fall into the following general categories:

- **Regulatory approaches**. Pursuant to various sections of the CAA, Congress has authorized EPA to regulate air toxics. Many S/L/T governments have also authorized agencies to regulate air toxics. Regulatory approaches include enforceable requirements that identified sources must meet (or else be subject to legal action, such as fines) as well as emissions-trading type requirements that focus on controls over sources in total while allowing flexible emissions among individual sources.

- **Voluntary approaches**. EPA and other regulatory agencies are looking beyond regulatory approaches to reduce risks from air toxics. Non-regulatory (voluntary) approaches are frequently the preferred option in a number of cases. Decision-makers at S/L/T agencies may not currently have specific regulatory authority to address specific air toxics problems identified in a risk analysis (particularly in a novel analysis such as a multi-source, community-based risk assessment). The types of problems identified may not lend themselves to regulatory solutions (e.g., they may require changes in the behavior of the exposed population). Voluntary programs may also allow sources to significantly reduce overall risk at much lower cost than various regulatory options. Various incentives such as tax reductions or consumer rebates can be used to encourage voluntary responses.

- **Permits and related authorities**. Permits offer opportunities for both regulatory and voluntary risk-management strategies. Many sources release air toxics to the atmosphere pursuant to permits and related authorities. Permits generally need to be renewed periodically and/or modified if conditions at the source change beyond some specified

amount. This may provide an opportunity to re-write permit conditions so as to reduce high-risk emissions. This might be coupled with voluntary measures or other flexible solutions to result in overall risk reduction (see box). Agencies may also work with emission sources to incorporate voluntary measures or other flexible solutions into the permit.

Example Factors to Consider When Evaluating Risk Management Options

- **Risk reduction benefits to be realized**. Risk management decisions often focus on the *incremental* risk associated with the chemical or other hazard being regulated in the absence of background risks. However, background risk may be important in certain situations. For example, if a monitoring program measures concentrations of air toxics being transported into a given study area that result in risks above an "acceptable" level, no level of emissions control within the study area will be able to reduce risk to an "acceptable" level, and the community may wish to address the incoming air toxics via discussions beyond the local community.

- **Level of uncertainty in the analysis**. In the face of highly uncertain risks, decision-makers have to carefully weigh the consequences of two or more options: making a decision to control emissions or exposures only to find out later that there was little actual risk (e.g., incurring unnecessary "cost" to the community), or making a decision *not* to control emissions or exposures only to find out later that the risks were real and large (e.g., incurring potentially preventable harm to the community).

- **Implementation costs**, both for voluntary approaches (e.g., marketing, process changes, tax incentives) as well as to regulatory agencies, the regulated community, and the general community (consumers).

- **Technical feasibility**. Short of shutting down the emission source altogether, is there an available technology to reduce or eliminate emissions?

- **Legal feasibility**. Does the decision-making body have legal authority to both establish and enforce requirements?

- **Effectiveness/timing**. Will the option provide effective management of the problem within a reasonable time-frame?

- **Political feasibility**. Does the option have the necessary political support?

- **Community Acceptance**. Do the stakeholders buy-in to the proposed risk reduction alternatives?

Each of these factors may be more or less important depending on the context for the risk management decision. For example, the risk manager may be required by statute to weigh economic factors less than technical factors.

27.5.5 Take Actions to Implement the Decisions

Traditionally, implementation has been driven by regulatory agencies' requirements. Businesses and governments (e.g., local municipalities) are generally the implementers. However, the chances of success may be significantly improved when other stakeholders also play key roles. Depending on the situation, action-takers may include public health agencies, other public

agencies, community groups, citizens, businesses, industries, unions/workers, and technical experts. These groups can help:

- Develop and implement a plan for taking action;
- Explain to affected communities what decision was made and why and what actions will be taken; and
- Monitor progress.

27.5.6 Conduct an Evaluation of the Action's Results

At this stage of risk management, decision-makers and other stakeholders review what risk management actions have been implemented and how effective they have been. Evaluating effectiveness involves monitoring and measuring, as well as comparing the actual benefits and costs to estimates made in the decision-making stage. The effectiveness of the process leading to implementation should also be evaluated at this stage. Evaluation provides important information about:

- Whether the actions were successful, whether they accomplished what was intended, and whether the predicted benefits and costs were accurate;
- Whether any modifications are needed to the risk management plan to improve success;
- Whether any critical information gaps hindered success;
- Whether any new information has emerged that indicates a decision or a stage of the process should be revisited;
- Whether the process was effective and how stakeholder involvement contributed to the outcome; and
- What lessons can be learned to guide future risk management decisions or to improve the decision-making process.

27.6 Information Dissemination

The Presidential/Congressional Commission on Risk Assessment and Risk Management noted that effective risk communication is critical to successful implementation of the risk management framework.[3] Risk communication engages both the communicator and the audience in listening and in explaining information and opinions about the nature of risk and other topics that express concerns, opinions, or reactions to risk messages.[5] The Commission made the following recommendations with respect to risk communication:

- The complex and often confusing process of communicating information about risks to diverse affected parties must be improved;

- Decisions about how to allocate resources to reduce risks can be made and explained partly on the basis of risk comparisons;

- The use of "bright lines" which distinguish between contaminant emissions and exposures associated with negligible risk levels and those associated with unacceptable risk levels, needs to be clarified;

- Moving from command-and-control regulation to non-regulatory approaches to risk reduction can increase both efficiency and effectiveness; and

- Criteria for judicial review, a common element in major regulatory actions, should be reaffirmed.

Chapter 29 provides an overview of risk communication and it's role in risk assessment and risk management.

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Chapter 28 Community Involvement

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28.1 Introduction

Community involvement can be an important aspect of the risk assessment and risk management process. Participation of local stakeholders, at various levels and in various forms, can help ensure a better understanding of the risk assessment results and will promote buy-in to the selected risk reduction strategies. Encouraging and facilitating community involvement also is sometimes required by law.

This chapter provides a broad overview of community involvement in air toxics risk assessment and risk management and identifies helpful references on this topic. Also included throughout this chapter are descriptions of successful air toxics projects and programs where community involvement was a central component of that success.

This chapter describes the key tools, resources, and other considerations for an effective study area-specific approach. It is not, however, intended to provide all the information about conducting community involvement activities. If additional information is needed, contact the community involvement specialist for your agency.

28.2 Why is Community Involvement Important?

When performing an air toxics risk assessment in a particular geographic area, the **community** is often thought of as the people who live within the area of impact of air toxic sources. However, other parties in the area, such as local industry, also may consider themselves part of the community.

In addition to the people who actually live and work in an area, a number of other stakeholders also may have a stake in the community's concerns (e.g., local officials, health professionals, local media). It is often helpful, when dealing with a community, to keep in mind that many different people (not just the people who live there) may have an interest in the risk assessment and management work being undertaken.

As noted above, many laws recognize and accommodate the idea that government decisions should be open to citizen input before a decision is finalized. This is realized through the required public meetings and public comment periods associated with many government actions. For example, the Clean Air Act (CAA) has a number of requirements to provide an opportunity for the public to review and comment on Agency proposals. In some cases, the public is brought in at an even earlier stage.

When risk assessors and risk managers have the opportunity to do so, they should consider including the public as early as possible in the process. Doing so can lead to some very positive benefits. For example, if the community participates early on and throughout the process, they will be in a better position to understand what assessors and risk managers are doing, and there is a better chance that they will believe that the work being done is in their best interest. The process works best when the community appreciates that assessors and managers are working with them and respecting their input (keeping them informed and involved). Ultimately, a community that is involved early on in the process is a community that may be more willing to support the risk assessment process and results. This may, in turn, foster the development of risk reduction strategies the community as a whole can live with and have a stake in.

In contrast, excluding the public from the process may result in community resentment and rejection of even a sound risk assessment and risk management approach. A "guardian-like" attitude toward the community that treats people as unknowledgeable and incapable of meaningful participation does not foster trust and can eventually undermine the process.

In addition to fostering the trust and acceptance of the community, there are many other positive reasons for early and ongoing involvement. For example, important unrecognized sources of emissions and exposure pathways may be identified through the community involvement process. Ultimately, it is important to recognize that community members know their community and understand the types of solutions that will be most accepted – after all, they live there!

28.3 When to Involve the Community

When appropriate, community involvement should begin at the earliest possible stage and span the entire risk and assessment and management process. The level of participation that community members have in some of the more technical phases of the assessment may be tailored to their background, expertise, and interest; however, this does not mean the community cannot serve an important role in the technical phase, as well. The approach taken, as well as the assumptions and limitations of the analysis, should be clearly explained to the community and their input should be valued in return.

For certain CAA requirements, the question of when to involve the public is established by law. For example, in the Title V permitting process the permitting agency must provide a public notice and an opportunity to comment on a draft new or revised permit when:

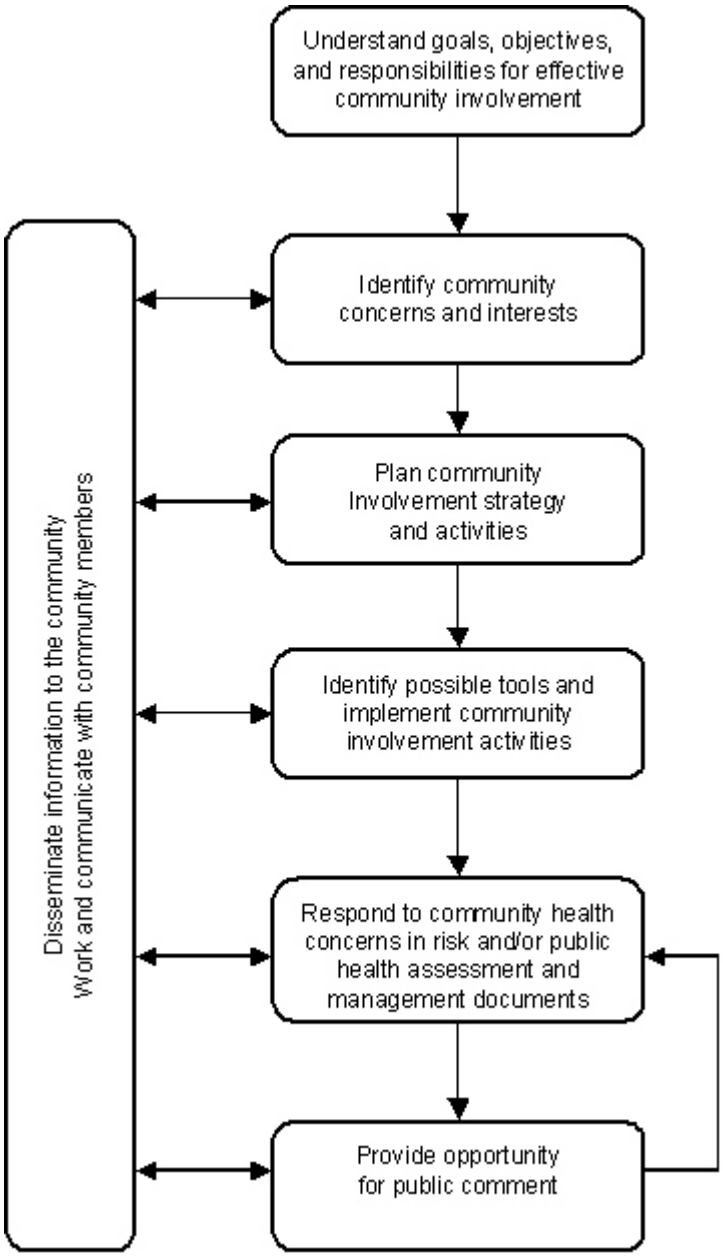
- A facility applies for its first Title V permit;
- A Title V permit is renewed (5 years after issuance);
- The permit is reopened because there is a material mistake in the permit or an update to the permit is needed because of new requirements (review is limited to the part of the permit that is being revised); and
- The facility makes a significant change in its operations and applies for a revision to its permit (review is limited to the part of the permit that is being revised).

For a community-level effort that may include non-regulatory aspects, on the other hand, a community involvement plan will need to be tailored to specific local needs, particularly if the ultimate risk reduction efforts will likely involve voluntary action on the part of industry and/or citizens. As noted above, involving the community at the beginning of and throughout the process will greatly enhance the likelihood that the air toxics risk reduction plan will receive community support (even if the community does not agree with all aspects of the analysis).

28.4 How to Involve the Community

Many different approaches have been developed for involving the community in a risk analysis and management strategy. Exhibit 28-1 illustrates the general framework used both by some programs in EPA and by the Agency for Toxic Substances and Disease Registry (ATSDR). This framework emphasizes the need for involving the community throughout the process.

Exhibit 28-1. ATSDR's Components of Effective Community Involvement



Source: Community Involvement in ATSDR's Public Health Assessment Process (see box of additional references at the end of this chapter)

In identifying community concerns and interests, it often is useful to develop a "conceptual map" of the key organizations and decision-making processes in a community. The map would include information such as who speaks for various parts of the community, who serves in formulating perspectives, and what is the process for obtaining consensus within the community.

TIP: Identify local associations or groups by asking community members, respected "elders," or other associations. This also can go a long way in demonstrating a commitment to involving and mobilizing all stakeholder groups, which helps to build trust and creates a more successful community-involvement process. ***But***, in seeking out community members, do not rely solely on existing community organizations. Very often community members are not well organized or represented by existing groups. Just because there is not an organization or group in the study area does not mean that you can bypass that part of the community.

28.4.1 Understand Goals, Objectives, and Responsibilities for Effective Community Involvement

At a minimum, goals and objectives for community involvement should include the following items. All study areas are different, however, and this list is just a suggested starting point (and may need to be expanded).

- Earning trust and credibility through open and respectful communications;
- Including the community in the design and implementation of risk assessment and risk management;
- Helping community members understand what the process involves;
- Assisting communities in understanding the possible health impact of exposure to air toxics;
- Informing and updating communities about risk management activities; and
- Promoting collaboration between decision-makers, communities, and other agencies and stakeholders when carrying out risk management activities.

To reach these goals and objectives, the following key principles are important:

TIP: Local public health providers, such as county health departments and hospitals can be a key partner in the risk analysis and management processes. These organizations often have resources (staff and funding) that can be used in community health activities. Because they are locally based, involving them as key partners in the process can create strong local leaders to promote sustainable activities once a study is complete.

- **Be aware of confidentiality and privacy issues**. Any personal information that analysts or decision-makers receive from community members should be respected, as appropriate.

- **Be aware of special needs and cultural differences**. When conveying information about air toxics and the risk management process, agencies should be aware of non-English speaking community members and other citizens who may need help in understanding complicated messages. Also, be sure to consider cultural symbolism. There are notable examples of the use of a symbol that is acceptable in one culture but that has an unacceptable meaning in another.

- **Maintain effective communication**. As part of the trust-building process, analysts and risk managers should keep community members informed of progress, opportunities for community involvement, how community input will be used, how community members can help to reduce exposures, and upcoming issues and events.

- **Respect community knowledge and values.** It is important to recognize that community knowledge can provide valuable information for the deliberative processes of risk assessment and risk management and potentially help to address data gaps. It is particularly important to try to understand people's interests (what they care about) during the process (more discussion of this subject is provided in the next section).

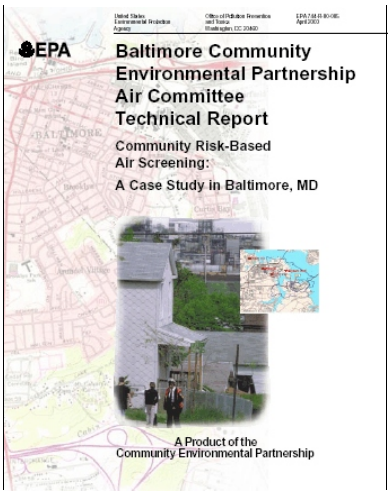
28.4.2 Identify Community Concerns and Interest

One important activity that risk assessors and risk managers can do at the outset of any study is simply to listen to the community. Since their concerns may or may not match those of the assessors and managers, the initial phase of community involvement often involves a fair amount of listening and discussion to help both groups develop a common understanding of what will and will not be studied during the course of the assessment. In those instances where a community concern is outside the scope of what can be studied (e.g., occasional combined stormwater/sewer overflows that cause odors), a willingness on the part of the assessment team to at least help identify resources or connect them to agencies that can address these concerns will go a long way to building trust and credibility. Not listening and not responding to community concerns at the outset may make the process of air toxics assessment and risk reduction more difficult in the long run and may set expectations that are ultimately not met.

28.4.3 Plan Community Involvement Strategy and Activities

Planning a community involvement strategy and activities is one of the most critical components for effective community involvement. The type and nature of communication and involvement activities will depend on (1) the needs and interests expressed by the community during the previous stages, (2) the potential public health issues, and (3) the resources available for communication and involvement activities. Exhibit 28-2 provides a broad list of issues to be considered when developing a community involvement strategy. Not all of these issues must have solutions initially; however, they may need to be addressed eventually.

Community Involvement Example. *Southern Baltimore & Northern Anne Arundel County Community Environmental Partnership (CEP).* In 1996, the residents, businesses, and organizations of five Baltimore, MD neighborhoods joined with local, State, and Federal governments in a CEP to begin a new effort to find ways to improve the local environment and economy. This CEP conducted a comprehensive screening of the cumulative concentration of air toxics from all the industrial and city facilities in and around the neighborhoods and developed a first-for-Maryland survey of cancer incidence at the neighborhood level. Based on this work, the CEP began work with local facilities on pollution prevention. The work of the Baltimore CEP was a learning experience for all of the people who participated. The Partnership tried a lot of new things - some of them worked and some didn't. Lessons learned from this work were carefully documented. The risk screening methodology and lessons learned are being translated into a how-to manual for community use. For more information on this manual and other CEPs, see http://www.epa.gov/oppt/cahp.


EPA

Baltimore Community Environmental Partnership Air Committee Technical Report

Community Risk-Based Air Screening:

A Case Study in Baltimore, MD

A Product of the Community Environmental Partnership

28.4.4 Identify Possible Tools and Implement Community Involvement Activities

An enormous number of tools and activities exist that risk assessors and managers can use to encourage community involvement – more than can be described here (the additional resources listed at the end of this chapter, however, should provide most of any team's needs in this regard). They range from the simple phone call, to block parties (at which food may be provided), to the complex mapping of emissions sources and populations. How many and which tools and activities should be used or initiated for a given situation depends on the phase of the risk or public health assessment and management process, the level of community interest, and the degree of hazard a study area poses. The formation of a partnership with stakeholders or community-based coalitions can be an effective way to involve the community, access technical expertise, achieve consensus, leverage resources, and obtain results.

Exhibit 28-2. Issues to Consider When Developing Community Involvement Strategies

Community health concerns:
- How many community members are concerned about the study area?
- What is the level of the community's concern?
- Is the level of community concern higher (or lower) than the actual risk would suggest?
- Are community concerns unknown?
- Would a physician enhance outreach at community meetings?
- Is information/outreach/health education available now or can this wait until reports are generated?

Demographics:
- How many community members are potentially affected?
- Are there any potentially sensitive populations that may be exposed?
- Do socio-demographic data suggest need for additional resources, such as translation?
- How do the community members receive information (e.g., newspaper, radio, word-of-mouth)?

Community interest in the risk assessment and management process:
- How involved in the process would the community like to be?
- How would the community like to be kept updated and informed (e.g., newsletters, e-mails)?
- How many community groups or activist groups are involved? How active are they?
- Should the risk assessment/management team facilitate the creation of a community group if one has not been formed?
- Can information be disseminated at cultural centers? Informal gatherings?

Media support:
- What has the community already heard from the media? Are there misconceptions that need to be dispelled?
- Will media support require more community involvement resources than usual?

Support of the community:
- Are there Native American communities affected by the pollution? Should a relevant agency be involved?
- Does the pollution involve an environmental justice issue, air toxics "hot spot," or other type of special sites?
- What past experiences has the community had with "the government"? Other agencies?
- Is there a higher than average need for resources, such as for more frequent community updates?
- How active will any regional agency representatives or other agencies be in community involvement efforts?

Exhibit 28-2. Issues to Consider When Developing Community Involvement Strategies (Continued)
Public health: • Is the study area a designated public health hazard? Is hazard acute or chronic? • Are environmental health risks largely unknown? • Is the study area considered a high priority? By whom? • Is there already some risk or health outcome results? Are biological data available? • Is a health connection plausible between contaminant exposures and community health concerns? • Are data available for review now ? When will they be available? • Are there toxics reduction steps already in process? **Community culture and setting**: • What are the current community priorities and projects? • What are the community organizations? • Who are the community leaders (unelected)? • What activities constitute community life? **Other**: • How many people on the study area team? Does everyone know their role? • What is the time-frame for report development and communication? • Will any special clearances will be required? At what levels? • Will document or graphics development resources be needed? • Are there schools or locations where community meetings can be held?

28.4.5 Provide Opportunity for Continued Public Interaction

While a risk assessment is underway, primary communication and involvement goals include updating the community on the status of the assessment, obtaining ongoing feedback on the process, obtaining additional information as needed or available from the community for the assessment, and recommending public health actions, if needed, about how community members can reduce exposures. Throughout this process, the risk assessment/management team should continue to listen to community concerns and clearly explain how they will respond to these concerns. The team also should leverage community outreach resources whenever possible. For instance, federal agencies, state health and environmental agencies, local health departments, citizens' advisory groups, and medical advisory groups may have funds for involving community members in the risk assessment/management process. Collaborating with partner organizations can strengthen community outreach depth and coverage.

Generally, community involvement strategies are situation-specific – risk assessment/management teams should determine which community

Non-English Speakers and Other Special Needs?

To ensure the participation of everyone in the community, agencies often use one or more of the following strategies:

- Offer translators and signers at community meetings, and check for wheelchair accessibility.
- Provide additional sessions of meetings that are offered exclusively in the community's secondary language(s).
- Seek out advocates for the severely disabled or others with special needs.
- Provide education and outreach materials in both English and secondary languages.
- Develop understandable and culturally appropriate messages and materials.

involvement strategies are appropriate given the potential seriousness of the risk, the abilities and involvement of the community, and the resources available for communication, training, and outreach. If resources for community outreach are limited, the team may wish to consider how they can best prioritize resources for community involvement.

When resources are limited, the team should look for community outreach opportunities during other community activities, if it would be culturally acceptable. For a determination of cultural acceptability, ask community leaders or "trusted elders."

Finally, some community analyses foster highly interactive relationships with community members and other stakeholders. For example, the risk assessment and risk management teams may establish ad hoc working groups to work on specific issues. These groups may include advisory members from the community or their representatives (e.g., community consultants) and may be more or less formal, as the circumstances require.

28.4.6 Release of Risk Assessment and Risk Management Documents

At the end of the analysis phase, the next stage of community involvement generally begins (i.e., after a draft risk assessment is written). Since the process of data gathering, analysis, and risk assessment preparation can take many months to years, community interest may have decreased significantly. However, once the risk assessment is ready for release, public interest often peaks again. To help ensure a fair and balanced release of information, the risk assessment/management team and their partners may consider using a more formal process to release the risk assessment. For example, the team may release the draft for a period of time for people to read and comment. During the review period, meetings may be held to help describe the results and how the analysis was done. Once the risk assessment document is finalized, there typically is a need to communicate the key results, limitations, and recommendations through a variety of materials including fact sheets, press releases, public meetings, and websites. The risk management strategy may be presented in a similar fashion, with a draft and final document presented to – if not also partly written by – the community.

If an agency or other parties will be conducting any follow-up activities in the area (such as additional environmental sampling or emissions monitoring, cost analyses, health education, health studies), then additional appropriate community involvement may be planned.

Additional References

Public Health Assessment Guidance Manual (2002 Draft Update) describes the process that ATSDR uses to sort through the many hazardous waste sites in the U.S. and to determine where, and for whom, public health actions should be undertaken. Chapter 4 addresses community involvement and communication. See www.atsdr.cdc.gov/HAC/PHAManual/cover.html.

The Annual EPA Community Involvement Conference brings together public participation and community involvement professionals from across all EPA programs, as well as their local, State, Federal, and tribal partners. Conference presentations are designed to emphasize the process of public participation and community involvement by focusing on techniques and approaches used in EPA's national and regional community involvement programs. See epancic.org for upcoming conferences as well as the proceedings of past conferences.

Public Involvement in Environmental Permits: A Reference Guide (2000) at www.epa.gov/permits/publicguide.htm was developed by EPA to help make it easier for state and local agencies to facilitate public participation in environmental permitting decisions for businesses and facilities under your authority. This guide provides basic information about public participation requirements and gives examples under several major permits issued by EPA's air, water, and waste programs. This guide also details what public participation activities are required under these programs, as a minimum, as well as those suggested activities that serve to augment the regulatory requirements.

Air Toxics Community Assessment and Risk Reduction Projects Database at yosemite.epa.gov/oar/CommunityAssessment.nsf/Welcome has been compiled to provide a resource of planned, completed, and ongoing community level air toxics assessments across the country. By sharing information about efforts at the local level to measure, understand, and address air toxics emissions, this database will help ensure that communities designing and implementing their own assessments will be able to build upon past efforts and lessons learned.

Community Involvement in ATSDR's Public Health Assessment Process (2002) provides an overview of how ATSDR works to involve communities in the public health assessment (PHA) process. It describes how ATSDR develops community involvement strategies and plans community involvement activities.

Additional References (continued)

Superfund Community Involvement Web Site provides communities with a range of tools, including guidance documents and other information to increase their understanding of Superfund and the services available to them (e.g., the Technical Outreach Services for Communities Program, Technical Assistance Grants). See www.epa.gov/superfund/action/community/index.htm.

Superfund Community Involvement Handbook (2002) presents legal and policy requirements for Superfund community involvement and additional suggestions for involving the community in the Superfund process. This handbook also provides guidance for community involvement outside of Superfund. See www.epa.gov/superfund/tools/cag/ci_handbook.pdf for more information.

Community Culture and the Environment: A Guide to Understanding a Sense of Place (2002) addresses the social and cultural aspects of community-based environmental protection. The document offers a process and set of tools for defining and understanding the human dimension of an environmental issue. The report, published by EPA's Office of Water, is available on the web from EPA's publication Web site. The report number is EPA/842/B-01/003.

Community Air Screening How To Manual: A Step-by-Step Guide to Using a Risk-based Approach to Identify Priorities for Improving Outdoor Air Quality (to be published in 2003) is being developed by the EPA's Community Assistance Technical Air Team to make air quality assessment tools more accessible to communities. It will present and explain a step-wise process that a community can follow to form a partnership, identify and inventory all local sources of air pollutants, review these sources to identify the hazards and potential risks, and set priorities and develop a plan for making improvements.

References

1. Agency for Toxic Substances and Disease Registry (ATSDR). 2002. Public Health Assessment Guidance Manual (Update): Draft for Public Comment.. Available at: http://www.atsdr.cdc.gov/HAC/PHAManual/cover.html.

Chapter 29 Risk Communication

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29.1 Introduction

The purpose of an air toxics **risk assessment** is to evaluate the magnitude and extent of exposure to air toxics and the potential effects on humans and the environment. Risk assessments aid the process of developing risk management alternatives that minimize risk and maximize environmental benefits.

What is Risk Communication?
Risk communication is the way in which decision-makers communicate with various interested parties about the nature and level of risk, and about the risk reduction strategies to reduce the risk.

The purpose of **risk communication** is to help in the planning of the risk assessment and to convey the results of the risk assessment in a way that effectively supports risk management decisions; this is so that the risk management decisions both meet the goals of the project and provide some comfort level for stakeholders. Good risk communication strategies are a fundamental aspect of developing trust among various stakeholders and the community and are often considered an important first step that can begin even before conducting the risk assessment. Involving the community, establishing and maintaining relationships, and networking with other partners (e.g., agencies, organizations, officials, the media) are key elements in a risk communication strategy. Tailoring communications to the cultural diversity of the community is important because it may help establish the trust necessary to complete a risk assessment that meets all stakeholder and community needs. Risk management rooted in voluntary measures requires effective risk communication to get buy-in.

The subject of risk communication overlaps considerably with related topics discussed in Chapter 13, including EPA's philosophy of transparency, clarity, consistency, and reasonableness (TCCR) as described in its *Policy For Risk Characterization*.[1]

This chapter provides an overview of information developed by the Agency for Toxic Substances and Disease Registry (ATSDR) and other authors to assist the risk assessment team in communicating the context and results of the risk assessment to the public. Readers are encouraged to consult the references at the end of this chapter for a more complete discussion of this important topic. ATSDR also has an excellent website on risk communication resources (See http://www.atsdr.cdc.gov/HEC/primer.html).

Effective Risk Communication:
- Can determine and respond to community concerns;
- Can reduce tension between concerned communities and agency staff; and
- Can explain health risk information more effectively to communities.

ATSDR has published a handbook on risk communication for its staff.[2] Although focused on agency staff, this handbook clearly and effectively outlines the detailed steps necessary in order to develop an effective risk communication plan, and is applicable to all risk assessors and risk management teams. The tools and information in the ATSDR handbook (and discussed in this Chapter) will help the risk assessment team:

- Develop a communication strategy;
- Conduct community outreach and evaluation;
- Develop communication messages; and
- Interact effectively with the news media.

Why is Risk Communication Important?

1. Provides an opportunity to communicate health risks in a caring, concerned, and well-planned manner
2. Involves the community in the risk management process
3. Helps alleviate fear or anger and establish trust

29.2 Risk Perception

If people perceive themselves to be at risk, their perception is unlikely to change even if they are not being exposed or harmed. Elements that affect risk perception include experience, culture, level of education, outrage factors, who is affected/how they are affected (equal treatment), and the level of control exercised on an event or events. People's perceptions of the magnitude of risk also are influenced by factors other than numerical data. According to Covello[3] and other authors:[4]

- Risks perceived to be voluntary are more accepted than risks perceived to be imposed.
- Risks perceived to be under an individual's control are more accepted than risks perceived to be controlled by others.
- Risks perceived to have clear benefits are more accepted than risks perceived to have little or no benefit.
- Risks perceived to be fairly distributed are more accepted than risks perceived to be unfairly distributed.
- Risks perceived to be natural are more accepted than risks perceived to be manmade.
- Risks perceived to be generated by a trusted source are more accepted than risks perceived to be generated by an untrusted source.
- Risks perceived to be familiar are more accepted than risks perceived to be exotic.
- Risks perceived to affect adults are more accepted than risks perceived to affect children.

Two-way risk communication works best. Non-experts want access to information and to gain knowledge. Technical experts and officials also want to learn more about non-experts' interests, values and concerns. The audience includes government, industry, citizens, and both technical and non-technical people. They can all be included in the process as partners.

29.3 Your Risk Communication Strategy - The Overall Plan

In general, planning a risk communication strategy includes the following steps:

- Determine the goals of the communication effort;
- Identify communication restraints;
- Identify the audience(s);
- Identify audience concerns;

- Identify what the audience(s) knows about the issues, both correct information and misinformation;
- Design the message(s) to be sent out to the community;
- Design the "channels"/choose the best methods to reach people;
- Prepare to deliver/present the message;
- Anticipate communication problems;
- Evaluate the program; and
- Modify program as needed.

When working through this process, it is important to know and understand the communication limits and purpose, know your audience, and whenever possible, pretest your message(s). You also should communicate early, often, and fully and remember that for many of the people in your audience, perception is reality.

A good communication strategy also will use tested principles of good presentation, such as the use of simplified language to present important content and the ability to be objective (not subjective) and balanced. Presentations also should not be limited to just one form or just one medium.

Try to use spokespersons who can communicate knowledgeably, honestly, clearly, and compassionately and will listen and deal with specific concerns. Finally, it is important to make sure that the information provided in the risk communication strategy is conveyed to all segments of the audience at a level that they can understand and that the communication materials are honest and up-front about uncertainties. It is often better to say "I don't know" than to hedge.

The ability to establish constructive communication will be determined, in large part, by whether or not the audiences perceive the speaker to be trustworthy and believable. Public assessment of how much we can be trusted and believed is based upon four factors:[1]

- Empathy and caring;
- Competence and expertise;
- Honesty and openness; and
- Dedication and commitment.

29.4 Risk Comparisons

Many successful risk communication efforts have had one major thing in common – a portrayal that puts the calculated exposure risks from an assessment in perspective, with risk ranges the public can easily relate to and understand.

Risk comparisons can help to put risks into perspective. However, irrelevant or misleading comparisons can harm trust and credibility. Thus, while risk comparisons are commonly used, they should be used with caution, because some kinds of risk comparisons are more likely to be perceived as pre-conceived judgments about the acceptability of risks.[1] Guidelines for risk comparisons have been published,[5] and provide rankings of risk comparisons in terms of their acceptability to the community. The highest-ranking comparisons are those that presume a level of trust between the risk communicator and the public, and that consider the factors that people use in their perception of risk. Exhibit 29-1 describes several example risk comparison rankings.

The general rule-of-thumb is to select from the highest-ranking risk comparisons whenever possible. When there is no choice but to use a low-ranking risk comparison, do so cautiously, being aware that it could backfire. The fifth rank, which risk assessors rarely use, consists of comparisons of unrelated risks (e.g., involuntary vs. voluntary risks). These comparisons have been found to be very problematic. For example, the risk of driving without a seat belt is a voluntary risk, while exposure to air toxics is generally considered involuntary by community members. Covello et al. [5] provide specific examples of each of the comparison ranks, as associated with a manufacturing facility (http://www.psandman.com/articles/cma-4.htm). Risk comparison charts are also provided in Appendix B of that document (http://www.psandman.com/articles/cma-appb.htm), although the authors do not recommend their use in public presentations.

Exhibit 29-1. Relative Acceptability of Risk Comparisons

- **First-rank risk comparisons (most acceptable)**
  - Of the same risk at two different times
  - With a standard
  - With different estimates of the same risk
- **Second-rank comparisons (less desirable)**
  - Of the risk of doing something versus not doing it
  - Of alternative solutions to the same problem
  - With the same risk experienced in other places
- **Third-rank comparisons (even less desirable)**
  - Of average risk with peak risk at a particular time or location
  - Of the risk from one source of an adverse effect with the risk from all sources of the same effect
- **Fourth-rank comparisons (marginally acceptable)**
  - With cost; or one cost/risk ratio with another
  - Of risk with benefit
  - Of occupational risk with environmental risk
  - With other risks from the same source
  - With other specific causes of the same disease, illness, or injury
- **Fifth-rank comparisons (rarely acceptable – use with caution)**
  - Of risks that may seem unrelated to community members (e.g., smoking, driving a car, lightning)

EPA has included risk comparisons in some air toxics analyses. For example, the results section of EPA's *National-Scale Air Toxics Assessment* (http://www.epa.gov/ttn/atw/nata/) discusses general U.S. background risks from air toxics, originating from both mobile sources and other background sources:

- **Mobile Sources**. For on-road and non-road mobile sources, EPA estimates that more than 100 million people live in areas of the U.S. where the combined upper-bound lifetime cancer risk from all air toxics compounds exceeds 10 in a million. This risk estimate is dominated by the emissions of benzene, formaldehyde, acetaldehyde, and 1,3 butadiene. Regarding effects other than cancer, acrolein emissions are estimated to lead to exposures above the

reference concentration (i.e., a hazard quotient above 1.0) for approximately 200 million people in the U.S. EPA expects that in 2007, existing standards affecting emissions of air toxics compounds from new vehicles will reduce exposure from on-road sources by about 50 percent from 1996 levels, and that substantial reductions also will occur for non-road emissions.

- **Background Sources**. EPA estimates that combined upper-bound cancer risks associated with air toxics compounds from background sources are less than 100 in 1 million throughout the U.S. However, the entire U.S. population is estimated to exceed an upper-bound cancer risk level of 10 in a million due to background sources alone (note that in this study background concentrations include both uncontrollable emissions [e.g., persistent historic emissions, international or global pollutant transport, contributions from natural sources and emissions that can be controlled such as long-range pollutant transport within the U.S.]).

29.5 Implementing Risk Communication Strategies

In order to implement risk communication strategies, agencies may need to plan approaches to public presentations and working with the media. The purpose of communication with the public is to inform, educate, and enhance cooperative problem solving and conflict resolution.

29.5.1 Presentation of Risk Results

Risk communication strategies also consider the meaning of the information (e.g., will the listener understand how to use the information in forming opinions, making decisions, and taking actions). When risks are calculated for air toxics and the risk results are presented to the public, the community may not be familiar with quantitative risk data and what it means for them. In order to prevent panic and to encourage participation in and buy-in of risk management decisions, risk communication strategies are developed that not only reassure the community, but also explain the potential risks and uncertainties in an understandable, clear, and honest way. Effective communications also provide information in a community-compatible language or form. For example, if the community speaks Spanish, then the communications could be in Spanish as well as English. Similarly, if the community includes Native Americans, the communications could be in the appropriate language and employ appropriate symbolism. The effective communication of risks will allow stakeholders to better participate in management decisions that weigh the benefits of different alternatives against the costs of achieving "acceptable" levels of risks and the costs of disruptions associated with implementation.

When developing messages, it is important to consider the following questions:

- What does the community already know?
- Is this information factual?
- What does the community want to know?
- What does the community need to know?
- Can the information be misunderstood?

When developing a public education campaign, it is generally most effective if the campaign highlights no more than three primary messages. More than three primary messages may convolute the focus of the education campaign. Those developing public education campaigns

may wish to test their risk communication messages with trusted audience members before releasing them to the public. This can ensure that the messages are on-target and help avoid community objections that decision-makers may not have anticipated. It also is important to ensure that the message is culturally attuned and fits the language needs of the audience. "Outrage reducers" are outlined by risk communication specialist Peter Sandman (www.petersandman.com).

When developing risk-communication messages, decision-makers should (1) review the concerns and worries of their audience; (2) cover WHO, WHAT, HOW, WHEN, WHERE and WHY; and (3) develop messages that are consistent with their actions.

Different messages and channels may be needed for different audiences. To communicate effectively, the risk communicator should try to understand the audience's values, concerns, and perceptions. Credibility is enhanced by the degree to which the risk communicator correctly identifies, anticipates, and empathizes with the specific concerns of his or her audience(s), which may include:

- Health concerns;
- Safety concerns;
- Environmental concerns;
- Economic concerns;
- Aesthetic concerns;
- Lifestyle/cultural concerns;
- Data and information concerns;
- Fairness/Equity concerns;
- Trust and credibility concerns;
- Process/value concerns (e.g., who makes decisions and how); and
- Risk management concerns.

Audiences may include:

- Environmental groups;
- Civic organizations;
- Professional and trade organizations;
- Educational and academic groups;
- Religious groups;
- Other government agencies;
- Neighborhood/school organizations;
- Industries; and
- Other organizations.

It may be worthwhile to develop audience profiles for key audiences. Profiles describe the members of the audience, whom they trust and go to for information (decision-makers can seek these people out for advice on communicating with the community), what their prevailing attitudes and perceptions are, and what concerns and worries motivate their actions.

It is important to clearly communicate scientific information and uncertainty:

- Provide all information possible, as soon as possible;
- Communicate when there is progress being made;
- Maintain your relationship with the community;
- Be honest about what you do not know;
- Explain how you will work together to find the answers;
- Help the audience understand the process behind your findings;
- Avoid acronyms and jargon;
- Carefully consider what information is necessary; and
- Use familiar frames of reference to which the audience can relate.

Public interactions may also include availability sessions, informal discussions, or poster sessions. Presentations can occur in a variety of venues some of which are better suited than others to different situations. Determining the best channels for your message depends on understanding when to use which tool and knowing how the community prefers to receive information. Message delivery channels include:

1. **Presentations**: Speeches to public groups. Benefit: offers the audience a chance to ask questions; reaches many people at one time. Limitations: if poorly presented, can distort community perception; cannot sufficiently address individual concerns; can become argumentative or confrontational.

2. **Open Houses/Availability Sessions**: Informal meeting where public can talk to staff on a one-to-one basis. Benefit: allows for one-to-one conversation; helps build trust and rapport.

3. **Small Group Meetings**: Sharing information with interested community members and government officials. Benefit: allows two-way interaction with the community. Limitations: may require more time to reach only a few people; may be perceived by community groups as an effort to limit attendance; be sure your information is identical or you may be accused of telling different stories to different groups.

4. **Briefings**: Can be held with key officials, media representatives, and community leaders; generally not open to the public. Benefit: allows key individuals to question risk assessment staff before release of public information. Limitations: should not be the only form of community communication; bad feelings may arise if someone feels that they were left off the invite list.

5. **Community mailings**: Sends information by mail to key contacts and concerned/involved members of the community. Benefit: delivery of information quickly; may require less planning than a meeting. Limitation: no opportunity for feedback.

6. **Exhibits**: Visual displays to illustrate health issues and proposed actions. Benefits: creates visual impact. Limitations: one-way communication tool, no opportunity for community feedback.

7. **Fact Sheets**: To introduce new information. Benefit: brief summary of facts and issues; provides background for information discussed during a meeting. Limitations: one-way communication tool; needs to be well-written and understandable.

8. **Newsletters**: To inform community of ongoing activities and findings. Benefit: explains findings; provides background information. Limitations: can backfire if community members do not understand or misinterpret contents.

9. **News Release**: Statement for the news media to disseminate information to large numbers of community members. Benefit: reaches large audience quickly and inexpensively. Limitations: may exclude details of possible interest to the public; can focus unneeded attention on a subject.

10. **Public Meetings**: Large meeting open to the public where experts present information and answer questions and community members ask questions and offer comments. Benefit: allows community to express concerns and agency to present information. Limitations: can intensify conflicts, rather than resolve controversies.

Presentations require a careful balancing act between effectively conveying key messages and avoiding a range of pitfalls. Important "Dos" and "Don'ts" to avoid presentation pitfalls, are outlined in Exhibit 29-2.

29.5.2 Working with the Media

The media can be a primary source of information on risks to the public. Effective news media relations have many benefits, complementing other communication efforts. What people read, see, or hear in news coverage can lend credibility to agencies associated with air toxics risk assessment, and can help to make it a familiar topic for public discussion. News coverage can inform people about air toxics issues and help them ask appropriate questions. Skill in media relations can help risk communications avoid or dispel rumors, respond to criticism, defuse controversy, and even turn adversity to advantage.

News coverage is crucial to engaging the attention of decision-makers and earning the support of opinion leaders. Also, because the news media pay distribution costs, helping journalists cover the issues is a cost-effective way to communicate.

The best approach to the media, as with the public, is to be open and honest, provide information tailored to the needs of each type of media, such as graphics and other visual aids, and provide background material. Journalists also should welcome such materials as fact sheets, press kits, and lists of experts. Establishing an information center also can be an effective way to make materials available to the news media (and to the general public). It also is very important that the material and discussions you have with the media clearly articulate the messages that you want to find their way into print or onto the TV or radio.

Like other communication efforts, working with the news media is done best when it is based on a strategy and follows a systematic process. A good strategy seeks opportunities to match the goals and objectives of the organization with the interests of journalists. As in other communication strategies, assessing the needs of the audience – journalists – is important to reaching them effectively.

After you determine that the rules of your organization concerning contacts with the media have been met, here are a few suggestions on how to deal with news reporters:

- When a reporter calls, be sure to get a name and media affiliation; if what the reporter wants is not clear to you, ask for a clear explanation; if you are uneasy with a reporter's query, decline in a friendly way to continue the conversation.

- Reporters are often under deadline pressure, but you can take enough time to respond effectively; don't get pressured into hasty comments that might backfire.

- Do not hesitate to ask for more information about a story before responding to a request for an interview.

In working with journalists, it is vital to develop good interpersonal relationships. How can you do that? One rule of thumb followed by experienced practitioners is to adhere to the "Five Fs" – Fast, Factual, Frank, Fair, and Friendly (Exhibit 29-3).[6]

- **Interviews**. Frequently, the best way to get a message out is through an in-person interview. You should generally assume that all statements you make are "on the record." Exhibit 29-4 outlines some techniques to prevent poor transmittal of your message.

- **Press Releases**. Press releases may not be an effective way to transmit a message. However, in some cases, releases that are targeted to particular media outlets and purposes can be useful. For example, the publication of a report on air toxics risk might be newsworthy and of concern to the community, and thus would be sent to local community newspapers. Remember that your press release should emphasize, upfront, the messages that you want to get out to the public.

- **Other Platforms**. You may have the opportunity to communicate your message through other platforms such as:
  - Letters to the Editor. Keep them short, to the point, and prompt.
  - Commentaries. Radio broadcasts and newspapers print a number of opinion pieces each day. Bear in mind that submissions are numerous, acceptances rare.
  - Talk Radio (and TV). Talk shows may request experts to address various environmental issues.

Exhibit 29-2. Presentation Dos and Don'ts
• **Pitfall**: **Jargon** **Do**: Define all technical terms and acronyms. **Don't**: Use language that may not be understood by even a portion of your audience. • **Pitfall**: **Humor** **Do**: Direct it at yourself, if used. **Don't**: Use it in relation to safety, health, or environmental issues. • **Pitfall**: **Negative Allegations** **Do**: Refute the allegation without repeating it. **Don't**: Repeat or refer to them. • **Pitfall**: **Negative Words and Phrases** **Do**: Use positive or neutral terms. **Don't**: Refer to national problems (problems unrelated to the issue at hand), i.e., "This is not Love Canal." • **Pitfall**: **Reliance on Words** **Do**: Use visuals to emphasize key points, but be culturally correct for the audience. **Don't**: Rely entirely on words. • **Pitfall**: **Temper** **Do**: Remain calm. Use a question or allegation as a springboard to say something positive. **Don't**: Let your feelings interfere with your ability to communicate positively. • **Pitfall**: **Clarity** **Do**: Ask whether you have made yourself clear. **Don't**: Assume you have been understood. • **Pitfall**: **Abstractions** **Do**: Use examples, stories, and analogies to establish a common understanding, but test them out first to make sure they are clear, make your point, and are culturally acceptable. • **Pitfall**: **Nonverbal Messages** **Do**: Be sensitive to nonverbal messages you are communicating. Make them consistent with what you are saying. **Don't**: Allow your body language, your position in the room, or your dress to be inconsistent with your message. • **Pitfall**: **Attacks** **Do**: Attack the issue. **Don't**: Attack the person or organization. • **Pitfall**: **Promises** **Do**: Promise only what you can deliver. Set and follow strict orders. **Don't**: Make promises you can't keep or fail to follow up. • **Pitfall**: **Numbers** **Do**: Emphasize performance, trends, and achievements. **Don't**: Focus on or emphasize large negative numbers.

Exhibit 29-2. Presentation Dos and Don'ts (continued)

Pitfall: **Guarantees**
Do: Emphasize achievements made and ongoing efforts.
Don't: Say there are no guarantees.

Pitfall: **Speculation**
Do: Provide information on what is being done.
Don't: Speculate about worst cases.

Pitfall: **Money**
Do: Refer to the importance you attach to health, safety, and environmental issues; your first obligation is to public health.
Don't: Refer to the amount of money spent as a representation of your concern.

Pitfall: **Organizational Identity**
Do: Use personal pronouns ("I," "we").
Don't: Take on the identity of a large organization.

Pitfall: **Blame**
Do: Take responsibility for your share of the problem.
Don't: Try to shift blame or responsibility to others.

Pitfall: **"Off the Record"**
Do: Assume everything you say and do is part of the public record.
Don't: Make side comments or "confidential" remarks.

Pitfall: **Risk/Benefit/Cost Comparisons**
Do: Discuss risks and benefits carefully (consider putting them in separate communications).

Pitfall: **Risk Comparison**
Do: Use them to help put risks in perspective.
Don't: Compare unrelated risks.

Pitfall: **Health Risk Numbers**
Do: Stress that true risk is between zero and the worst-case estimate. Base actions on federal and state standards, when possible, rather than risk numbers.
Don't: State absolutes or expect the lay public to understand risk numbers.

Pitfall: **Technical Details and Debates**
Do: Focus your remarks on empathy, competence, honesty, and dedication.
Don't: Provide too much detail or take part in protracted technical debates.

Pitfall: **Length of Presentations**
Do: Limit presentations to 15 minutes.
Don't: Ramble or fail to plan the time well.

Source: ATSDR Risk Communication Primer[2]

Exhibit 29-3. The "Five Fs" of Media Relations
Fast. Respect journalists' deadlines. If a journalist telephones for information, return the call immediately, even if it is past normal office hours. A phone message returned the next day is often too late. By then, the story already may have been aired or printed. **Factual**. Be factual, and make the facts interesting. Stories are to be based on facts. Journalists also appreciate a dramatic statement, creative slogan, or personal anecdote to help illustrate your point. Give the source of any facts and statistics provided. **Frank**. Be candid. Never mislead journalists. Be as open as possible and respond frankly to their questions. As long as there is an explanation of the reason, most journalists will understand and respect a source even if he or she is not able to answer a question completely or at all. **Fair**. Organizations should be fair to journalists if they expect journalists to be fair to them. Favoring one news outlet consistently, for example, will lose the confidence of the others. **Friendly**. Like everyone else, journalists appreciate courtesy. Remember their names; read what they write; listen to what they say; know their interests; thank them when they cover the issues in a factual, unbiased way.

Exhibit 29-4. Interviewing Techniques
• Always think carefully before you answer a question. People often ramble - and say something they wish they hadn't if they answer too quickly. Take a moment to consider what you want to say. If you need more time, ask for the question to be repeated. • Don't talk just to keep a conversation going with a reporter. Experienced reporters will be silent because often people they interview will talk to fill awkward voids and then say something they don't mean to say. • Ask the reporter to make your affiliation clear in the story. • Listen carefully to questions and respond clearly. Avoid jargon. If you have a key idea that you want to get across, repeat it several times, perhaps using different words. This is especially useful for broadcast: no matter how the tape is edited, you will make your point. • Don't hurry: speak slowly, and in short, concise sentences. State your position in simple, easy-to-understand language. Use everyday examples and analogies, when possible. • Never talk down to a reporter. You are partners in getting your message across. Arrogance will come across negatively to an audience. An "attitude" can turn an interview into a confrontation. • Don't lose your temper! No matter how antagonized you feel, recognize that this can be a tactic to get you to say something you do not wish to say. • If you don't know the answer to a reporter's question, or cannot answer, just refrain from answering. A lie or bad guess will return to haunt you. You will lose credibility. • Some reporters may ask to tape an interview over the telephone. This is a common practice for radio reporters to obtain "sound bites" and to get accurate quotes. The reporter should inform you of the taping before it begins. Do not repeat an allegation – it could be taken out of context.

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PART VI

SPECIAL TOPICS

Introduction to Part VI

Part VI of this Reference Manual provides an overview of three special topics related to air toxics risk assessment.

- Public Health Assessment (Chapter 30) provides an overview of the process by which public health agencies may evaluate the public health implications posed by the emissions from air toxic sources in a community. The public health assessment, if performed, is a complementary process to risk assessment.

- Probabilistic Risk Assessment (Chapter 31) discusses the process by which probability distributions are used to characterize variability or uncertainty in risk estimates, a process aimed at describing risks as a distribution (or range) of potential outcomes.

- Use of Geographical Information Systems (GIS) in Risk Assessment (Chapter 32) provides an overview of the software and geographic data that allow efficient storage, analysis, and presentaiton of spatially explicit and geographically referenced information that can help in the process of conducting risk assessments and reporting results

Chapter 30 Public Health Assessment

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30.1 Introduction

An adjunct to conducting air toxic risk assessments is public health assessments, which uses public health tools (e.g., health questionnaires, epidemiology) to investigate the incidence and prevalence of disease and to find out the current or past health of individuals. While public health methods are not always used for air toxics risk assessments, they can provide useful information to answer the question of whether there is evidence that there is a public health concern, particularly if disease rates are elevated in the assessment area.

Air toxics risk assessment, the main topic of this manual, focuses on assessing the potential risk that people have for experiencing adverse health effects from exposure to air toxics. The outcome of a risk assessment is a statement about the likelihood that exposure may result in disease (e.g., the probability of people developing cancer). The risk assessment process links the potential exposures to emissions from (often) specific sources to the likelihood of disease occurring.

However, in any community, concerns about more than just estimates of the likelihood of risk often come up. For example, communities where risk assessments are being performed often express concern about current health effects that may have resulted from past exposures. Questions like "was my cancer caused by air pollution" are often on the minds of people who live where an air toxics risk assessment is being performed.

The risk assessment process, while a powerful predictive tool for evaluating public health impacts from air pollution, is not amenable to answering these types of questions. Nevertheless, questions about disease and past exposures will inevitably come up as the air toxics risk assessment study moves forward. The risk assessment and risk management team will almost always have to explain that their assessment tool (risk assessment) is not being used to answer questions about existing cases of disease.

To help risk assessors and other stakeholders respond to these types of questions, this chapter provides information on a complementary process to risk assessment called **Public Health Assessment** or **PHA**. It is taken largely from the ATSDR *Public Health Assessment Guidance Manual*.[1] A PHA for air toxics is an analysis and statement of the public health implications posed by a source or group of sources of air toxics on a given geographic area. It usually is conducted by a public health agency such as the Agency for Toxics Substances and Disease Registry or ATSDR (a federal Agency within the Centers for Disease Control and Prevention) or one of their partner state or local public health agencies. PHAs *are not* generally performed by EPA or state, local, or tribal air agencies since PHAs often rely on specialized medical and epidemiological expertise and due to the difficulty facing these agencies in obtaining and reviewing medical information for individuals. PHAs are normally performed:

- In response to a request by concerned community members or physicians;
- In response to a real or perceived increase in a health problem noted during routine disease surveillance systems; and/or
- As part of a broader program such as a proactive analysis of region-specific air quality.

The types of air toxics assessments most likely to include a PHA are those where the pollutants have a clearly identifiable effect, where the exposure is relatively widespread, or where there is a high level of public concern. A PHA will not necessarily be needed every place an air toxics risk assessment is performed. However, the use of the PHA process, in conjunction with the risk assessment process, is becoming a more common practice for the purpose of providing holistic evaluations of air toxics impacts on communities.

PHAs are performed by ATSDR at each Superfund site on the National Priorities List. ATSDR also performs PHAs when petitioned. The term **public health assessment** (**PHA**) as used here, refers to a broad range of assessment types – from screening-level health consultations to comprehensive epidemiological assessments – that are commonly performed by ATSDR in its work. The PHA process, while commonly thought of as a Superfund-related activity, is amendable to a wide range of exposure scenarios, including the evaluation of air toxics impacts at the community level.

A PHA may involve an assessment of relevant **environmental data**, **health outcome data** (e.g., cancer statistics), and **community concerns** generally associated with a study area where air toxics are or have been released. A PHA identifies populations living or working on or near areas for which more extensive public health actions or studies are indicated and is generally more qualitative, more focused on actual, measurable harm, and past and current exposures.

This chapter describes the history of PHAs, what they are, how they compare to and work in concert with risk assessments, and how they are conducted. Several case studies are included to help illustrate the diversity of PHAs and how they compare with and are used with risk assessments.

30.2 History of Public Health Assessment

PHA as a tool for characterizing and protecting the health of a society can be traced back thousands of years. The ancient Babylonians, Egyptians, Greeks, and Romans were among the first known civilizations to describe associations between diseases and sources such as place, water conditions, climate, eating habits, and housing. One of the first documented public health "assessments" (though later proven incorrect) connected the presence of "bad air" around swamps and marshes with the prevalence of malaria, one of the world's most devastating diseases. (It was determined later that the prevalence of malaria was associated not with air, but with mosquitos, the transmission vector for the disease, which breed in standing water associated with those places.) Infectious diseases continued to dominate public health concerns until the industrial revolution, although the problems of poor urban air quality from the use of coal were well documented as early as the end of the 16th century.

The earliest "bad air"?

The modern use of PHA for air toxics in the U.S. probably began in the mid-1900s in response to events such as the incapacitating smog episodes in Los Angeles in the 1940s, the polluted air inversion that killed 20 people in Donora, Pennsylvania in 1948, and the atmospheric nuclear weapons tests in Nevada in the 1950s. Myriad state and local public health agencies shouldered much of the burden of air pollutant health assessment at first. Then, at the federal level, the Federal Air Pollution Control Act of 1955 authorized the Public Health Service (PHS) to conduct

research and technical assistance and work towards a better understanding of the causes and effects of air pollution.

In 1980, ATSDR was created specifically to conduct PHAs at hazardous waste (Superfund) sites. That role has expanded over time to address additional pollution sources, including air toxics. ATSDR is not a regulatory agency like EPA, but rather is a public health agency that conducts assessments and makes recommendations to EPA and others when specific actions at study areas in question are needed to protect the public's health. ATSDR conducts PHAs when petitioned by concerned community members, physicians, state or federal agencies, or tribal governments. State and local public health agencies also play an important role with regard to PHAs for air toxics and other hazards.

30.3 Relationship of Public Health Assessment to Risk Assessment

Both the PHA and the quantitative risk assessment address the potential human health effects of environmental exposures, but they use different approaches and have different purposes. As illustrated in Exhibit 30-1, the PHA tends to be less quantitative than the risk assessment and to focus more on actual past and current exposures. The PHA evaluates observed health outcome and related data (e.g., cancer clusters, breathing problems, toxics residues in biologic samples) to determine whether rates of disease or death are or could be elevated in a community and, if so, whether these outcomes are due to a specific source. The risk assessment, on the other hand, starts with a specific source and evaluates estimated potential health outcomes, or risks. The PHA's subsequent conclusions generally complement the risk assessment process and help inform the decisions that the state, tribal, or local agency is reaching about a given study area. Similarly, the risk assessment provides considerable data to the PHA.

In addition to its focus on health outcome data, such as cancer or asthma incidence, the PHA also helps put community-provided data and information and community concerns into perspective, which in turns helps both (1) the community better understand whether they have been exposed to hazardous substances and, if so, what that means in terms of possible health outcomes, and (2) the decision-maker better determine what needs to be done to prevent or further study these exposures (e.g., emissions reductions, health education, biologic monitoring).

The PHA may use similar techniques to those of the quantitative risk assessment, but primarily as tools either to clearly rule out the existence of public health hazards, to determine that a clinical disease is really likely in the community, or to identify areas for additional study. At a minimum, the PHA helps to identify a baseline in the level of disease in a community so that later studies will have a basis for comparison.

Exhibit 30-1. PHAs and Risk Assessments: Differences and Similarities

In a PHA...	In a risk assessment...
OVERALL	
More qualitative More community involvement Conduct less frequently	More quantitative Less community involvement Conducted more frequently
EXPOSURE ASSESSMENT	
Similar for air sampling and modeling Biomonitoring possible Past, current/future	Air sampling Fate/transport modeling Future/hypothetical
TOXICITY ASSESSMENT	
Similar (for health effects screening)	Similar (for toxicity)
CHARACTERIZATION	
Margin for exposure comparisons Public health implications Needed public health actions Informs the risk assessment	Modeled risk Informs the PHA

30.4 What Is Public Health Assessment?

A PHA is an evaluation of relevant **environmental data**, **health outcome data**, and **community concerns** associated with a study area where hazardous substances have been released. A PHA identifies populations living or working on or near areas for which more extensive public health actions or studies are indicated.

PHAs can range from simple to complex, with the former activity often termed a **health consultation** rather than PHA. This more simple form generally is conducted in response to a

ATSDR Definition of PHA

The evaluation of data and information on the release of hazardous substances into the environment in order to assess any [past], current, or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects (42 *Code of Federal Regulations*, Part 90, published in 55 *Federal Register* 5136, February 13, 1990).

specific question or request for information pertaining to a hazardous substance or facility. It often contains a time-critical element that necessitates a rapid response. More complex forms of a PHA can involve a wide geographical area, many pollution sources, and take months or years to complete.

Understanding and responding to study area-specific community health concerns is an important part of the PHA process. These investigations can be conducted to confirm case reports, determine an unusual disease occurrence, and explore potential risk factors. One frequently cited concern is the **disease cluster** – the occurrence of a specific disease or condition above the expected number for a given geographic location and time period (e.g., the high incidence of leukemia in a given area). The health agency needs to learn what people in the area know about a source and source-related exposures and what concerns they may have about its impact on their health. Therefore, starting early in the assessment process, the health agency generally gathers information and comments from the people who live or work near the source(s), including area residents, civic leaders, health professionals, and community groups. Throughout the PHA process, the health agency should communicate with the public about the purpose, approach, and results of its public health activities.

The PHA process is iterative and dynamic and may lead to a variety of products or public health actions. The findings may be communicated in public health assessment or public health consultation documents, which serve as an aid for developing additional public health actions. The audience for such products often includes environmental and public health agencies, communities, and the public health agency itself.

During the course of the PHA process, the public health agency may identify the need to prevent or better define exposures or illnesses in a particular community. The agency's response to such a need might include:

- Issuing a **public health advisory** (if there is an urgent health threat);
- Initiating an **exposure investigation** (to better define study area exposures);
- Recommending a **health study** (to identify elevated illness or disease rates in a community); and/or
- Conducting **health education** (for the study area community or health professionals within the community).

The PHA process also can serve as a triage mechanism, enabling the public health agency to prioritize and identify additional steps needed to answer public health questions. The science of environmental health is still developing, and sometimes information on the health effects of certain substances is not available. When this occurs, rendering certain questions unanswerable by the available literature, the public health agency will suggest what further research studies and/or health education services are needed.

30.5 How Is a Public Health Assessment Conducted?

PHAs generally are conducted by public health agency assessors, often supported by a multi-disciplinary team of scientists, health communication specialists, health educators, and/or medical professionals. The health agency solicits and evaluates information from other local, state, tribal, and/or federal agencies; parties responsible for operating sources at a particular study area; and the community. All of these stakeholders play an integral role in the PHA process. The public health agency promotes a team approach to ensures that information used in the assessment is accurate and up-to-date, ensure that community concerns are identified and addressed, and fosters cooperative efforts in implementing recommendations and public health activities.

Many technical resources exist that provide details about conducting a PHA (see Exhibit 30-2), and, thus, only a broad overview is provided here. One of the most comprehensive resources is the ATSDR *Public Health Assessment Guidance Manual*.[1] The ATSDR manual focuses on site-specific PHAs such as Superfund sites; nevertheless, it also can be used to assess air emissions within a limited geographical area. As described in detail in the ATSDR manual, the steps of a PHA — whether conducted by ATSDR or a state or local public health agency, and whether comprehensive or limited to a screening assessment – can be multifaceted and interactive. Exhibit 30-3 illustrates this by providing an overview of a typical PHA process. The following subsections describe this process in more detail.

30.5.1 Conduct Scoping

The first step is to establish an overall understanding of the study area and begin to identify the most pertinent issues. The objective is to quickly gain some baseline information about the study area and start developing a strategy for conducting the PHA. To help ensure a consistent approach across study areas, the following steps are followed during this initial phase:

- Initiate study area scoping by performing an initial review of permits and other sources of study area information, identifying any past health agency or partner activities, identifying and communicating with study area contacts, and determining the need for a study area visit to observe actual conditions and speak with study area representatives.

- Define roles and responsibilities of team members (internal and external).

- Establish communication mechanisms (internal and external) by developing a schedule for team meetings, thinking about how to present the findings of the assessment, and developing health communication strategies.

- Develop a study area strategy for completing the various steps in the PHA process and develop a strategy, identifying the tools and resources that might be needed to evaluate the study area, communicate the findings, and implement public health actions.

- Based on information obtained during study area scoping, develop an approach that focuses on the most pertinent public health issues.

Exhibit 30-2. Selected Public Health Assessment Resources
• Agency for Toxic Substances and Disease Registry (ATSDR; www.atsdr.cdc.gov), which publishes the *Public Health Assessment Guidance Manual* (current draft is available online; *Guidance for ATSDR Health Studies* (1996; available online), *Environmental Data Needed for Public Health Assessments* (1994, available online), and other guidance. • National Institute of Environmental Health Sciences (NIEHS; www.niehs.nih.gov), which publishes *Environmental Health Perspectives* and sponsors multidisciplinary biomedical research, prevention and intervention efforts, and communication strategies that encompass training, technology transfer, and community outreach. • American Public Health Association (APHA; www.apha.org), which publishes the *American Journal of Public Health* and provides many other resources related to environmental public health. • National Association of County and City Health Officials (NACCHO; www.naccho.org), which publishes the *Protocol for Assessing Community Excellence in Environmental Health* (2000) and *Assessment to Action: Improving the Health of Community Affected by Hazardous Waste* (2002). • National Association of Local Boards of Health (NALBOH) (www.nalboh.org), which maintains an up-to-date database of contact information for all local boards of health, provides technical assistance to existing boards of health, and will soon publish the *Environmental Health Primer*.

30.5.2 Obtain Study Area Information

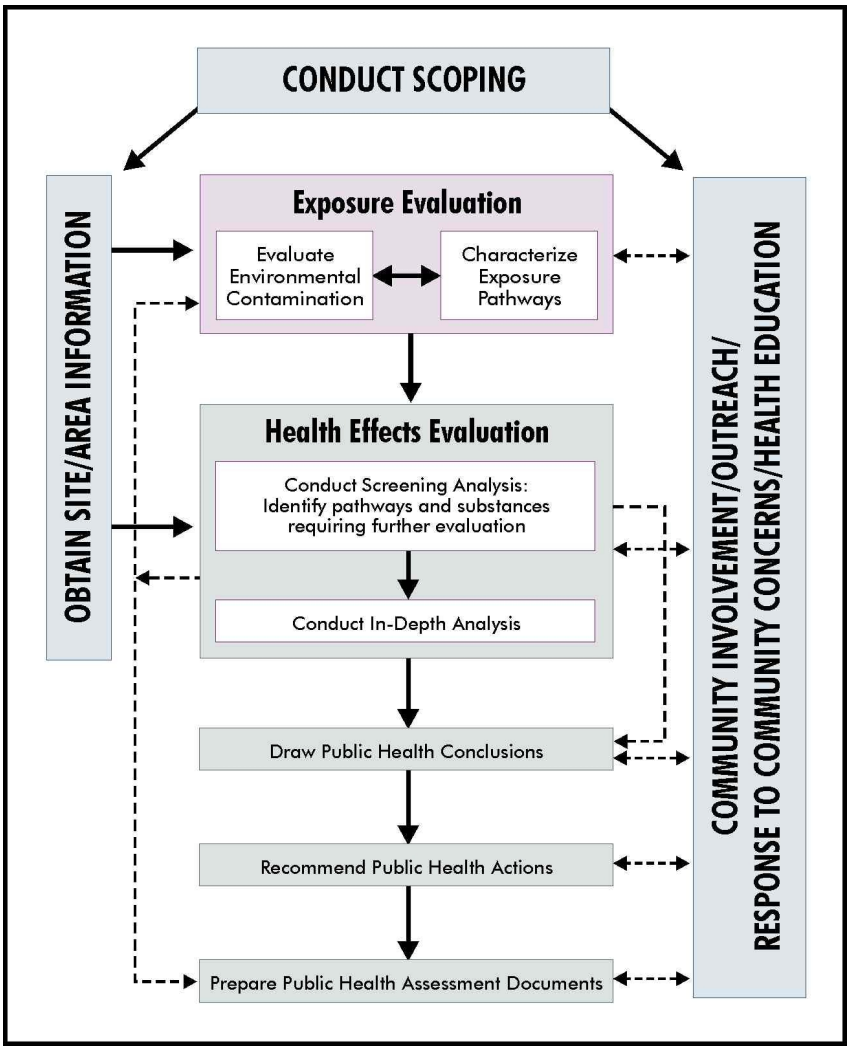
Throughout the PHA process, various team members will collect information about the study area, although the initial collection of information is typically the most intensive. Information sources typically include interviews (in-person or via telephone); study area-specific investigation reports prepared by federal, state, and local environmental and health departments; and study area visits. Gathering pertinent study area information requires a series of iterative steps, including gaining a basic understanding of the study area, identifying data needs and sources, conducting a study area visit, communicating with community members and other stakeholders, critically reviewing study area documentation, identifying data gaps, and compiling and organizing relevant data to support the assessment.

30.5.3 Community Involvement/Outreach/Response to Community Concerns

The community associated with a study area is both an important resource for and a key audience in the PHA process. Community involvement activities should be developed and implemented with the following objectives in mind:

- Earning trust and credibility through open, compassionate, and respectful communications.
- Helping community members understand what the PHA process involves and what it can and cannot do.
- Providing opportunities for communities to become involved in the PHA activities.
- Promoting collaboration between the public health agency, communities, and other agencies.
- Informing and updating communities about the health agency's work.
- Assisting communities in understanding the possible health impact of exposures to hazardous substances.

Exhibit 30-3. Overview of a Typical Public Health Assessment Process



Chapter 28 of this reference manual provides a more detailed discussion of community involvement and outreach.

30.5.4 Exposure Evaluation

For the exposure evaluation, public health assessors review environmental data to determine the sources of pollutants and exposure pathways/routes. The conceptual model described in Chapter 6 should be a reasonable starting point for the PHA exposure evaluation. Generally, the public health agency involved does not collect its own environmental sampling data, at least at first, but rather reviews information provided by federal, state, and local government agencies and/or their contractors, businesses, and the public. Assessors can indicate what further environmental sampling may be needed and may collect environmental and biologic samples when appropriate. This step involves two key substeps:

- **Evaluate Environmental Contamination Data**. This step involves determining what pollutants people may be exposed to and in what concentrations. This evaluation involves assessing the quality and representativeness of available monitoring data and measurements or modeled estimates of exposure point concentrations. This is an important way to ensure that any public health conclusions and recommendations for the study area are based on appropriate and reliable data. Both sampling data and modeling techniques described in Chapters 9, 10, 18, and 19 are sometimes used to generate data for PHAs. Evaluation of environmental contamination data typically proceeds simultaneously with the exposure pathway evaluation.

Exposure Investigations

When a PHA exposure evaluation concludes that additional exposure information is needed, an exposure investigation generally is conducted. An exposure investigation is the collection and analysis of study area-specific information to determine if human populations have been exposed to air toxics. This information may include environmental sampling, exposure-dose reconstruction, biologic or biomedical testing, and/or evaluation of medical information.

- **Characterize Exposure Pathways**. During the exposure pathway characterization, the assessor evaluates who may be or has been exposed to study area contaminants, for how long, and under what conditions. This involves identifying and studying the following five components of a "complete" exposure pathway: a source of air toxics; a mechanism for release into the air and, in some cases, transfer between media (i.e., the fate and transport of environmental contamination); an exposure point or area; an exposure route (e.g., ingestion, dermal contact, inhalation); and a potentially exposed population. The overall purpose of this evaluation is to understand how people might become exposed to study area contaminants and to identify and characterize the size and susceptibility of the potentially exposed populations. If no complete or potentially complete exposure pathways are identified, no public health hazards exist and there is no need to perform further scientific evaluation. When complete environmental or biologic data are lacking for a study area, an exposure investigation may be recommended to better assess possible impacts to public health.

30.5.5 Health Effects Evaluation

If the exposure evaluation shows that people have been or could be exposed to pollutants such as air toxics, the public health assessor will evaluate whether this contact could have resulted in harmful effects. Assessors use existing scientific information to determine the health effects that may result from exposures. Public health agencies recognize that children, because of their play activities and their growing bodies, may be particularly vulnerable to exposures to air toxics. Developing fetuses also may be more vulnerable to such exposures. Thus, the impact to children and developing fetuses is considered first when evaluating the health threat to a community. The health effects evaluation is composed of two basic substeps: a screening analysis and a more in-depth analysis.

- **Screening Analysis**. Screening is a first step in understanding whether the detected concentrations to which people may be exposed are harmful. The screening analysis is a fairly standard process developed to help health assessors sort through the large volumes of environmental data for a study area. It enables the assessor to safely rule out substances that are not at levels of health concern and to identify substances and pathways that need to be

examined more closely. For complete or potential exposure pathways identified in the exposure pathway evaluation, the screening analysis may involve comparing media concentrations at points of exposure to "screening" values (based on protective default exposure assumptions) and estimating exposure doses based on study area-specific exposure conditions. The assessor then compares estimated doses with health-based guidelines to identify substances requiring further evaluation. Exhibit 30-4 describes several of the ATSDR-derived comparison values available. See Chapter 12 for how these values are used in an air toxics risk assessment.

Exhibit 30-4. Definitions of ATSDR-Derived Comparison Values
Environmental Media Evaluation Guides (EMEGs). EMEGs are estimated contaminant concentrations that are not expected to result in adverse noncarcinogenic health effects based on ATSDR evaluation. EMEGs are based on ATSDR MRLs and conservative assumptions about exposure, such as intake rate, exposure frequency and duration, and body weight. Minimal Risk Levels (MRLs). An MRL is an estimate of daily human exposure to a substance (in mg/kg/day for oral exposures and parts per million [ppm] for inhalation exposures) that is likely to be without noncarcinogenic health effects during a specified duration of exposure based on ATSDR evaluations. Cancer Risk Evaluation Guides (CREGs). CREGs are estimated contaminant concentrations that would be expected to cause no more than one excess cancer in a million (10^{-6}) persons exposed during their lifetime (70 years). ATSDR's CREGs are calculated from EPA's cancer slope factors (CSFs) for oral exposures or unit risk values for inhalation exposures. These values are based on EPA evaluations and assumptions about hypothetical cancer risks at low levels of exposure. Reference Media Evaluation Guides (RMEGs). ATSDR derives RMEGs from EPA's oral reference doses, which are developed based on EPA evaluations. RMEGs represent the concentration in water or soil at which daily human exposure is unlikely to result in adverse noncarcinogenic effects.

- **In-depth Analysis**. For those pathways and substances that were identified in the screening analysis as requiring more careful consideration, the assessor will examine a host of factors to help determine whether study area-specific exposures are expected to result in illness. In this in-depth analysis, exposures are studied in conjunction with substance-specific toxicologic, medical, and epidemiologic data. Through this analysis, the assessor will be answering the following question: Based on available exposure, toxicologic, epidemiologic, medical, and study area-specific **health outcome data**, are adverse health effects expected in the community?

Answering this last question can be very challenging. For example, evaluating epidemiological data involves addressing a number of criteria to assist in judging the causal significance of associations revealed in studies (epidemiology is described in more detail in Exhibit 30-5). Individual criteria, if met, support a causal relationship but do not prove it. The more criteria that are met, the more likely it is that an observed health effect is causally related to the exposure under study. The criteria for evaluating causation are:

- **Time sequence**. Exposure must precede the onset of the disease. A logical sequence of events must be demonstrated.

Exhibit 30-5. What Are Epidemiologic Data and How Might They Be Used in an In-Depth Analysis?

Epidemiologic data are one of the key distinguishing features of PHAs compared to most quantitative risk assessments. Understanding the strengths and weaknesses of the various types of epidemiologic studies will help determine the suitability of a particular study in supporting and drawing study area and substance-specific public health conclusions. Because of the inherent limitations and uncertainties associated with environmental epidemiologic evaluations (generally due to the lack of adequate exposure data or sample size), however, *epidemiologic data should be used with caution*. The health assessor should call upon an epidemiologist to assist in evaluating the applicability and usability of literature-based or study area-specific epidemiologic data. The types of epidemiologic data that may be available and how they may be used are briefly summarized below, in order of greatest potential utility:

- **Analytical studies**, such as case-control or cohort studies, evaluate the role of various risk factors in causing illness or disease by relying on comparisons between groups. Depending on the quality of the study, it may provide insight to the study area-specific exposure situation under evaluation. Study area-specific analytical studies that meet certain design criteria examine study area-specific exposures and health outcomes in community members. When available, these studies are the most relevant to the PHA. These data are rarely initially available, but the PHA process may lead to a recommendation to collect such data. Depending on the individual study design and health outcome studied, results may provide some insight on the presence or absence of a particular illness of concern in the community. Unfortunately, establishing a definitive link with a study area-related exposure is generally difficult if not impossible.

- **Descriptive (or ecological) studies** examine differences in disease rates among populations over time or in different geographical locations and may be helpful in identifying plausible associations between a particular substance and disease. However, descriptive studies provide limited information on causal relationships (i.e., the degree of exposure or causal agent).

- **Case reports** that describe an effect in an individual or small group can be considered in the in-depth analysis, but may have limited usefulness due to the generally small size of the affected population and sometimes anecdotal nature of the reports.

- **Strength of association**. The stronger the association, the more likely it is causal. The relative magnitude of the incidence of disease in those exposed compared to the incidence in those who are not exposed can be a valuable measure of the strength of the association.

- **Dose-response relationship**. The probability and/or severity of the effect should increase with increasing intensity and duration of exposure.

- **Specificity of association**. If the effect is unusual or is specific to the studied exposure, a causal relationship is more easily demonstrated.

- **Consistency**. A relationship should be reproducible (i.e., observed in other studies or analyses).

- **Biologic plausibility (or coherent explanation)**. The link between the "cause" and the effect should make sense biologically, by what is known about the disease and the exposure under study. The findings should be validated by what is known about animal models.

Similarly, biologic sampling results (biomarkers) need to be interpreted with caution. Specifically, issues to consider include: (1) as with environmental sampling data, biologic data need to be collected by trained professionals and analyzed in a standard way; (2) detected levels may not be the result of study area-related exposures (e.g., blood lead levels resulting from non-air toxics sources such as flaking paint); (3) results will likely only represent a snapshot of conditions in time; (4) the association between detected levels and clinical effects may not be understood based on scientific knowledge; (5) "normal" ranges, particularly for trace elements, may not be known; and (6) the people tested may not be fully representative of the exposed population, resulting from a small sample size and variations in exposures across the exposed population due to different activity patterns.

30.5.6 Draw Public Health Conclusions

Upon completing the exposure and health effects evaluations, the assessor will draw conclusions regarding the degree of hazard posed by a study area - that is, they will conclude either that the study area does not pose a public health hazard, that the study area does pose a public health hazard, or that insufficient data are available to determine whether any public health hazards exist. The process also involves assigning a **hazard conclusion category** for the study area or for an individual exposure pathway (Exhibit 30-6).

Exhibit 30-6. Summary of ATSDR Conclusion Categories

Category	Definition
1. Urgent Public Health Hazard	Applies to study areas that have certain physical hazards or evidence of short-term (less than 1 year), study area-related *exposure to hazardous substances that could result in adverse health effects and require quick intervention to stop people from being exposed.*
2. Public Health Hazard	Applies to study areas that have certain physical hazards or evidence of chronic, study area-related *exposure to hazardous substances that could result in adverse health effects*.
3. Indeterminate Public Health Hazard	Applies to study areas *where critical information is lacking* (missing or has not yet been gathered) to support a judgment regarding the level of public health hazard.
4. No Apparent Public Health Hazard	Applies to study areas where exposure to study area-related chemicals might have occurred in the past or is still occurring, but the *exposures are not at levels expected to cause adverse health effects*.
5. No Public Health Hazard	Applies to study areas where *no exposure* to study area-related hazardous substances exists.

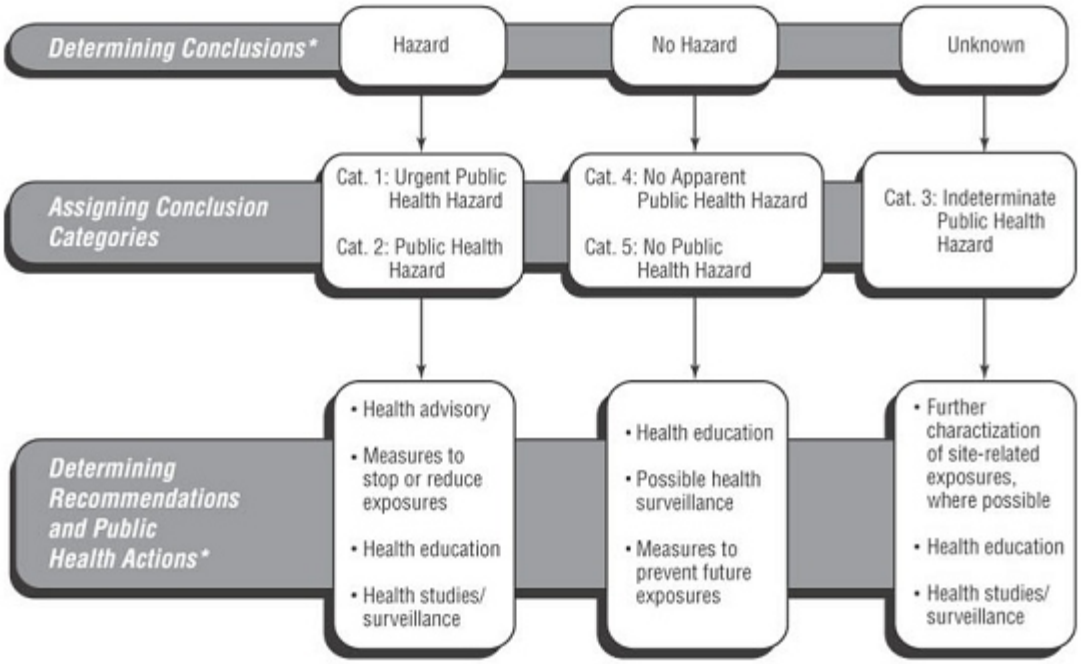
30.5.7 Recommend Public Health Actions

After drawing conclusions, the public health assessor – usually in cooperation with other team members and stakeholders – will develop recommendations for actions, if any, to prevent harmful exposures, obtain more information, or conduct other public health actions. These actions generally will be detailed in a public health action plan, which will ultimately be part of the PHA document (or possibly the public health consultation document) developed for the study area. Note that some public health actions may be recommended earlier in the process. See Exhibit 30-7 for an overview of the conclusions and recommendations process.

30.5.8 Prepare PHA Documents

The public health assessor may develop various materials during the PHA process to communicate information about the assessment, including outreach materials, health advisories that alert the public and appropriate officials to the existence of an imminent public health threat, and, at the end of the assessment process, a report that summarizes the approach, results, conclusions, and recommendations. This report generally is either a **public health assessment** (PHA) document or a **public health consultation** (PHC).

Exhibit 30-7. Overview of Typical PHA Conclusion and Recommendation Process



*Some conclusions and recommended public health actions may come early in the public health assessment process.

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1. Agency for Toxic Substances and Disease Registry (ATSDR). 2002. Public Health Assessment Guidance Manual (Update): Draft for Public Comment.. Available at: http://www.atsdr.cdc.gov/HAC/PHAManual/cover.html.

Chapter 31 Probabilistic Risk Assessment

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31.1 Introduction

Probabilistic risk assessment (PRA) uses probability distributions to characterize variability or uncertainty in risk estimates. In a PRA, one or more variables in the risk equation is defined as a probability distribution rather than a single number. Similarly, the output of a PRA is a range or probability distribution of risks experienced by the receptors. Note that the ability to perform a PRA often is limited by the availability of distributional data that adequately describe one or more of the input parameters. For example, data often are insufficient to assess toxicity in a probabilistic manner (and therefore, dose-response values such as inhalation unit risks (IURs) and reference concentrations (RfCs) are included in a PRA analysis as point values). This general lack of data impacts both human health and ecological receptors.

The primary advantage of PRA is that it can provide a quantitative description of the degree of variability or uncertainty (or both) in risk estimates for both cancer and noncancer health effects and ecological hazards. The quantitative analysis of uncertainty and variability can provide a more comprehensive characterization of risk than is possible in the point estimate approach.

Another significant advantage of PRA is the additional information and potential flexibility it affords the risk manager. Risk management decisions are often based on an evaluation of high-end risk to an individual – for deterministic analyses, this is generally developed by the combination of a mix of central tendency and high-end point values for various exposure parameters (see Part II, Chapters 9 and 13). When using PRA, the risk manager can select a specific upper-bound level from the high-end range of percentiles of risk, generally between the 90th and 99.9^{th} percentiles.

PRA may not be appropriate for every analysis. The primary disadvantages of PRA are that it generally requires more time, resources, and expertise on the part of the assessor, reviewer, and risk manager than a point estimate approach. The chief obstacle to using PRA in air toxics risk assessments is usually the lack of well-documented frequency distributions for many input variables.

A detailed discussion of PRA is beyond the scope of this document. Two documents provide more detailed introductory information and guidance and should be reviewed if a PRA is contemplated:

U.S. EPA. 2001. *Risk Assessment Guidance for Superfund (RAGS), Volume III - Part A, Process for Conducting Probabilistic Risk Assessment*. Office of Solid Waste and Emergency Response. December. EPA 540-R-02-002, OSWER 9285.7-45, PB2002 963302, available at: http://www.epa.gov/superfund/programs/risk/rags3a/index.htm.

National Council on Radiation Protection and Measurements (NCRP). 1996. *A Guide for Uncertainty Analysis in Dose and Risk Assessments Related to Environmental Contamination*. NCRP Commentary No. 14, May 1996.

This chapter provides a general overview of PRA as it applies to air toxics risk assessment. It revisits the tiered approach to risk assessment, introduces calculation algorithms, and identifies advanced statistical methods currently available to support risk policy decisions.

31.2 Tiered Approach for Risk Assessment

The tiered approach is a process for a systematic, informed progression to increasingly more complex risk assessment methods including PRA. Exhibit 31-1 presents a schematic representation of the tiered approach. Higher tiers reflect increasing complexity and, in many cases, will require more time and resources. Higher tiers also reflect increasing characterization of variability and/or uncertainty in the risk estimate, which may be important for making risk management decisions. Central to the concept of a systematic, informed progression is an iterative process of evaluation, deliberation, data collection, work planning, and communication. All of these steps should focus on deciding: (1) whether or not the risk assessment, in its current state, is sufficient to support risk management decisions (a clear path to exiting the tiered process is available at each tier), and (2) if the assessment is determined to be insufficient, whether or not progression to a higher tier of complexity (or refinement of the current tier) would provide a sufficient benefit to warrant the additional effort.

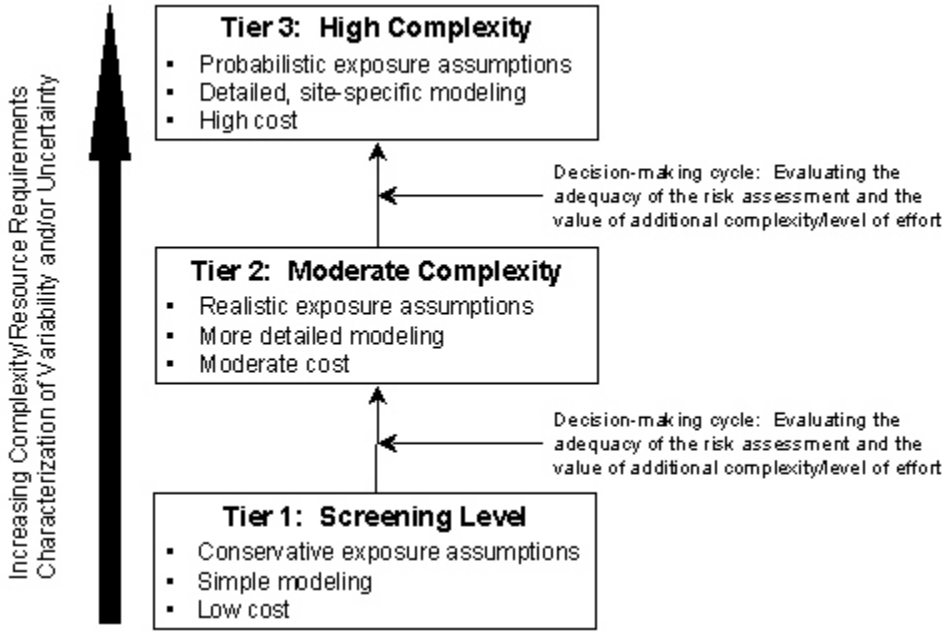
- The problem formulation step precedes Tier 1 and includes scoping and refinement of the conceptual site model, including exposure pathways/routes, and identifying chemicals of potential concern (COPCs).

- In Tier 1, deterministic (point estimate) risk assessment is then performed using the basic methodology described in Part II (inhalation) and/or Part III (multipathway) of this Reference Manual. In deciding whether the results of a deterministic risk assessment are sufficient for decision-making or whether more refined analyses should be implemented, two factors generally are considered: (1) the magnitude of the estimates of risk (i.e., the value of hazard indices [HIs] or cancer risks for COPCs), and (2) the level of confidence in these estimates. In a Tier I deterministic risk assessment, quantitative risk estimates can be easily calculated, but the level of confidence associated with these calculations can be difficult to assess. For example, variability in exposure levels among individual members of the population can generally only be assessed semi-quantitatively by considering central tendency and high-end exposure estimates. Uncertainty can often be evaluated only as confidence limits on certain point estimates (e.g., the concentration term).

  In some cases, the results of a Tier 1 risk analysis may be sufficient for decision-making. For example, a deterministic analysis may indicate very low levels of risk for some air toxics. If the assessment is considered to be overly conservative (even in light of uncertainties), this may be sufficient for a “no action” decision for those chemicals. The same analysis may indicate a very high potential for risk for other air toxics. EPA generally recommends that the risk manager proceed to higher tiers only when site decision-making would benefit from additional analysis beyond the point-estimate risk assessment (i.e., when the risk manager needs more complete or certain information to complete the risk management process).

Thus, only the combinations of COPC-exposure pathway-receptors of highest potential concern are generally analyzed using higher level techniques such as PRA.

Exhibit 31-1. Example of a Tiered Approach for Risk Assessment



Adapted from Volume III of EPA's Risk Assessment Guidance for Superfund[1]

- Tier 2 is represented as an intermediate-level analysis using more realistic exposure assumptions (e.g., use of actual receptor locations) and more detailed modeling (e.g., a model that requires additional site-specific inputs). Although not depicted, Tier 2 could incorporate a sensitivity analysis to identify the most important parameters that are driving the risk estimate for specific receptors or population groups. Tier 2 also could incorporate limited (one-dimensional) Monte Carlo techniques.

- Tier 3 is represented as an advanced analysis using probabilistic techniques such as two-dimensional Monte Carlo analysis. Results of sensitivity analyses (Tier 2 or Tier 3) could be used to assess risk distributions for the high-end individuals within the population. The one-dimensional Monte-Carlo simulation does not separate variability and uncertainty associated with the risk estimates. If necessary, separate analyses of uncertainty and variability can be performed in Tier 3. Techniques such as two-dimensional Monte Carlo simulation can be used to estimate the relative impact of natural variability and lack of data on the overall uncertainty in the risk estimate, and can be used to direct additional data gathering or to support mitigation decisions.

The deliberation cycle provides an opportunity to evaluate the direction and goals of the assessment as new information becomes available. It may include evaluations of both scientific and policy information. (Also note that, while a three-tiered approach was provided in Exhibit

31-1, the tiered approach is really more of a continuum from a point where the analysis is done with little data and conservative assumptions to a point where there is an extensive data set and fewer assumptions. In between, there can be a wide variety of tiers of increasing complexity, or, as discussed in Chapter 3, there may only be a few reasonable choices between screening methods and highly refined analyses. The three tiered approach is only provided here as an illustration of the concept, not a prescriptive, fixed methodology.)

31.3 Methods for Probabilistic Risk Assessment

As discussed in previous chapters, there are a number of approaches available for analyzing uncertainty in risk assessments. For simple screening level analyses, or analyses where there are only a few major sources of uncertainty, sensitivity analyses may be used to estimate the impacts of likely variations in the key parameter values. Where scenario uncertainty is important (that is, there are multiple sequences of events that could contribute to risk), decision tree or Bayesian statistical analysis are commonly used. The most common numerical technique for PRA (analyses in which a large number of variables need to be evaluated simultaneously) in large-scale air risk assessments is Monte Carlo simulation. Monte Carlo simulation integrates varying assumptions, usually about exposure, to come up with possible distributions (or ranges) of risk instead of point estimates. A continuous probability distribution can be displayed in a graph in the form of either **probability density functions** (PDFs) or corresponding **cumulative distribution functions** (CDFs); however, for clarity, it is recommended that both representations be presented in adjacent (rather than overlaid) plots.

Exhibit 31-2 illustrates a PDF and CDF for a normal probability distribution for adult body weight. Both displays represent the same distribution, but are useful for conveying different information. PDFs are most useful for displaying (1) the relative probability of values; (2) the most likely values (e.g., modes); and (3) the shape of the distribution (e.g., skewness, kurtosis, multimodality). CDFs can be used to display (1) percentiles, including the median; (2) high-end risk range (e.g., 90th to 99th percentiles); (3) confidence intervals for selected percentiles; and (4) stochastic dominance (i.e., for any percentile, the value for one variable exceeds that of any other variable). Note that it is helpful to include a text box with summary statistics relevant to the distribution (e.g., mean, standard deviation).

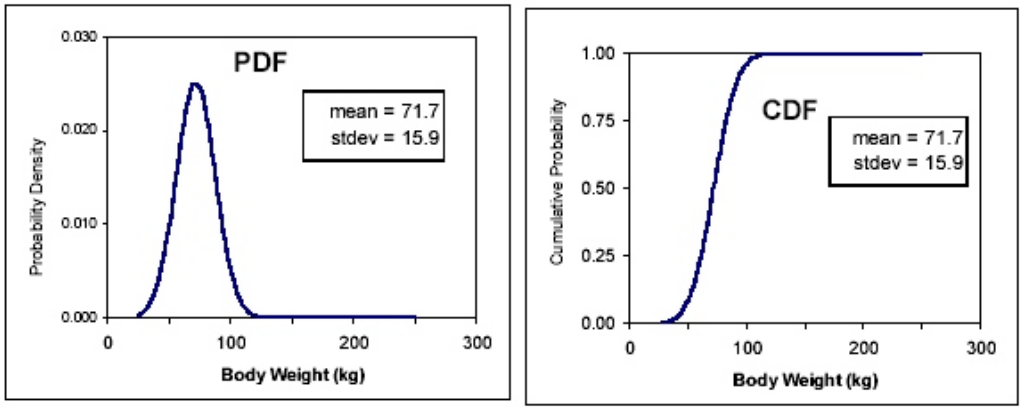
These results expressed as probability distributions help risk managers decide whether and what actions are necessary to reduce risk. Monte Carlo simulation has been widely used to explore problems in many disciplines of science as well as engineering, finance, and insurance.[1] The process for a Monte Carlo simulation is illustrated in Exhibit 31-3. In its general form, the risk equation can be expressed as a function of a toxicity term (as a point value) and multiple exposure variables (V_n) represented as distributions (not point values):

$$\text{Risk} = f(V_1, V_2, V_3, \ldots V_n) \times \text{Toxicity} \qquad \text{Equation 31-4}$$

The first decision(s) the risk assessor has to make is which of the "Vs" are going to be evaluated probabilistically. Ideally, every model input that is variable or uncertain should be evaluated to provide a comprehensive characterization of uncertainty in exposure estimates. In practice, the

number of variables that can be addressed systematically is severely limited by lack of data related to variability, uncertainty, or both. Sensitivity analyses can often be used to focus the analysis on the variables that contribute most to the overall uncertainty in risks.

Exhibit 31-2. Examples of Probability Density and Cumulative Distribution Functions



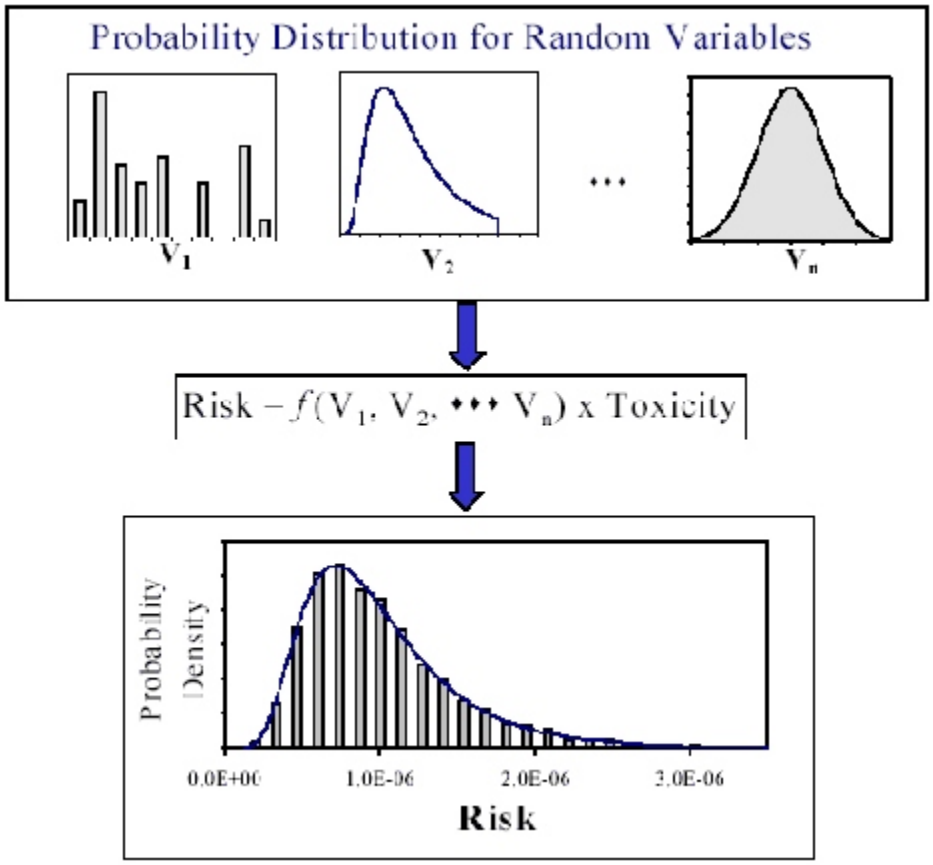
Example of a normal distribution that characterizes variability in adult body weight (males and females combined). The arithmetic mean = 71.7 kg, and standard deviation = 15.9 kg. Body weight may be considered a continuous random variable. The left panel shows a bell-shaped curve and represents the PDF, while the right panel shows an S-shaped curve and represents the CDF. Both displays represent the same distribution (including summary statistics), but are useful for conveying different information.
Source: Finley and Paustenbach[2]

Solutions for equations with PDFs are typically too complex for even an expert mathematician to calculate the risk distribution analytically. However, numerical techniques applied with the aid of computers can provide very close approximations of the solution. This is illustrated here for the simplified case in which the assessment variables are statistically independent, that is, the value of one variable has no relationship to the value of any other variable. In this case, the computer selects a value for each variable (V_n) at random from a specified PDF and calculates the corresponding risk. This process is repeated many times (e.g., 10,000), each time saving the set of input values and corresponding estimate of risk. For example, the first risk estimate might represent a hypothetical individual who drinks 2 L/day of water and weighs 65 kg, the second estimate might represent someone who drinks 1 L/day and weighs 72 kg, and so forth. Each calculation is referred to as an **iteration**, and a set of iterations is called a **simulation**.

Each iteration of a Monte Carlo simulation should represent a plausible combination of input values (i.e., exposure or ecotoxicity variables), which may require using bounded or truncated probability distributions. However, risk estimates are not intended to correspond to any one person. The "individuals" represented by Monte Carlo iterations are "virtual," and the risk distributions derived from a PRA allow for inferences to be made about the likelihood or probability of risks occurring within a specified range for an exposed human or ecological

population. A simulation yields a set of risk estimates that can be summarized with selected statistics (e.g., arithmetic mean, percentiles) and displayed graphically using PDF and CDF for the estimated risk distribution.

Exhibit 31-3. Conceptual Model of Monte Carlo Analysis



Random variables (V_1, V_2, ...V_n) refer to exposure variables (e.g., body weight, exposure frequency, ingestion rate) that are characterized by probability distributions. A unique risk estimate is calculated by sampling each set of the random values and calculating a result. Repeated sampling results in a frequency distribution of risk can be described by a probability density function. In human health risk assessments, the toxicity term is usually expressed as a point estimate. In ecological risk assessments, the toxicity term may be expressed as a point estimate or as a probability distribution.

31.4 Presenting Results for Probabilistic Risk Assessment

The complexity of risk evaluation, and particularly of probabilistic methods, may pose a significant barrier to understanding among the affected and interested parties (and thus to the utility of the analysis). In the past, regulatory decisions have been evaluated primarily in terms of point estimates of risk and simple dichotomous decision rules (e.g., "If the point estimate of risk

is above a certain level, take a certain action. If not, take another action."). In contrast, it may not be intuitively obvious, even to relatively sophisticated audiences, how to relate the outputs of quantitative uncertainty evaluation to a particular decision. For example, important aspects of a regulatory decision may rest on relatively subtle statistical distinctions (e.g., the difference between a 95th percentile risk estimate and a 95th percent upper confidence limit on a risk estimate), and the challenges in presenting such information can be formidable. In its recent guidance, EPA has begun to define concrete approaches to presenting risks and uncertainty information to decision-makers and stakeholders.[5]

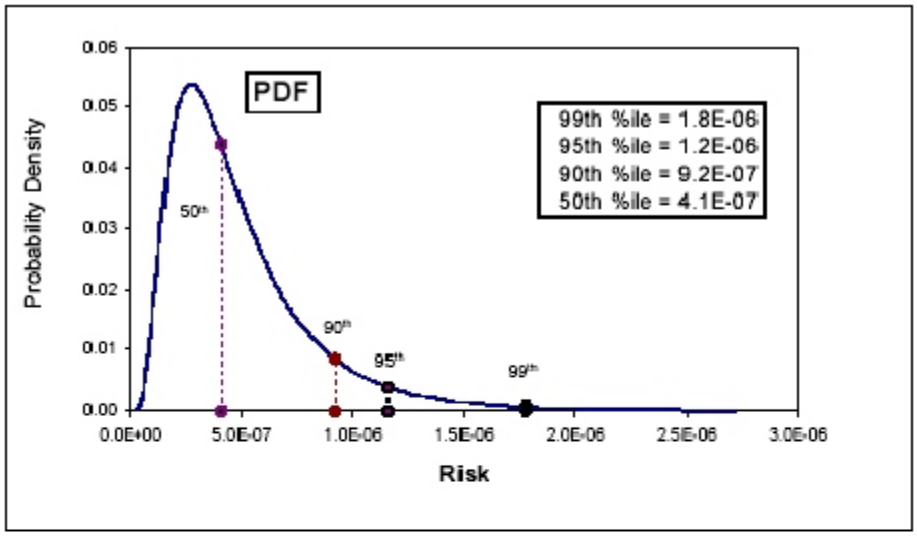
The key factors for successful communication of PRA include early and continuous involvement of affected and interested parties, a well-developed communication plan, good graphics, a working knowledge of the factors that may influence perceptions of risk and uncertainty, and a foundation of trust and credibility. A certain amount of training for interested stakeholders will likely be necessary to help them understand the complexities of not only risk assessment in general, but the intricacies of higher levels of analysis. Part III of this Reference Manual provides guidance on community involvement and risk communication.

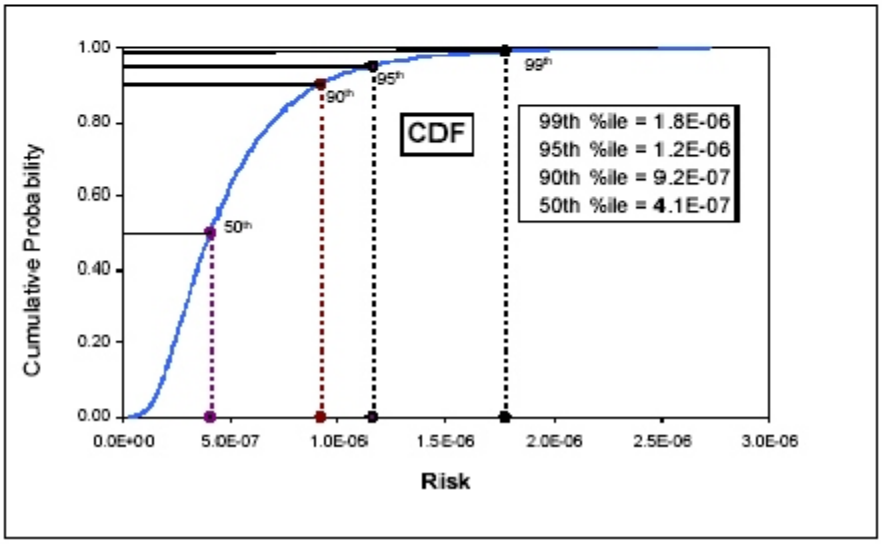
When summarizing results of PRA, graphs and tables should generally also include the results of the point estimates of risk (e.g., central tendency and high-end).

Consistent with EPA's guidance on risk characterization,[3] the central tendency and high-end cancer risks and noncancer hazards, along with decision points, should be highlighted on graphics. The discussions accompanying the graph should emphasize that these values represent risks to the average and high-end individuals, respectively, and serve as a point of reference to EPA's decision point. The distribution of risks should be characterized as representing variability among the population based on differences in exposure. Similarly, graphics that show uncertainty in risk estimates can be described using terms such as "confidence interval," "credible interval," or "plausible range," as appropriate. The graphics need not highlight all percentiles. Instead, selected percentiles that may inform risk management decisions (such as the 5th, 50th, 90th, 95th, and 99th percentiles) should be the focus. Exhibit 31-4 presents an example of a PDF for variability in risk with an associated text box for identifying key risk descriptors.

By understanding the assumptions regarding the inputs and modeling approaches used to derive point estimates and probabilistic estimates of risk, a risk communicator will be better prepared to explain the significant differences in risk estimates that have been developed. Special emphasis should be given to the model and parameter assumptions that have the most influence on the risk estimates, as determined from the sensitivity analysis.

Exhibit 31-4. Example of Presenting the Results of a Probabilistic Risk Assessment





Hypothetical PRA results showing a PDF (top panel) for cancer risk with selected summary statistics for central tendency and high-end percentiles. This view of a distribution is useful for illustrating the shape of the distribution (e.g., slightly right-skewed) and explaining the concept of probability as the area under a curve (e.g., most of the area is below $1x10^{-6}$, but there is a small chance of $2x10^{-6}$). Although percentiles can also be overlayed on this graphic, a CDF (bottom panel) may be preferable for explaining the concept of a percentile.

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Chapter 32 Use of Geographic Information Systems (GIS) in Risk Assessment

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32.1 Introduction

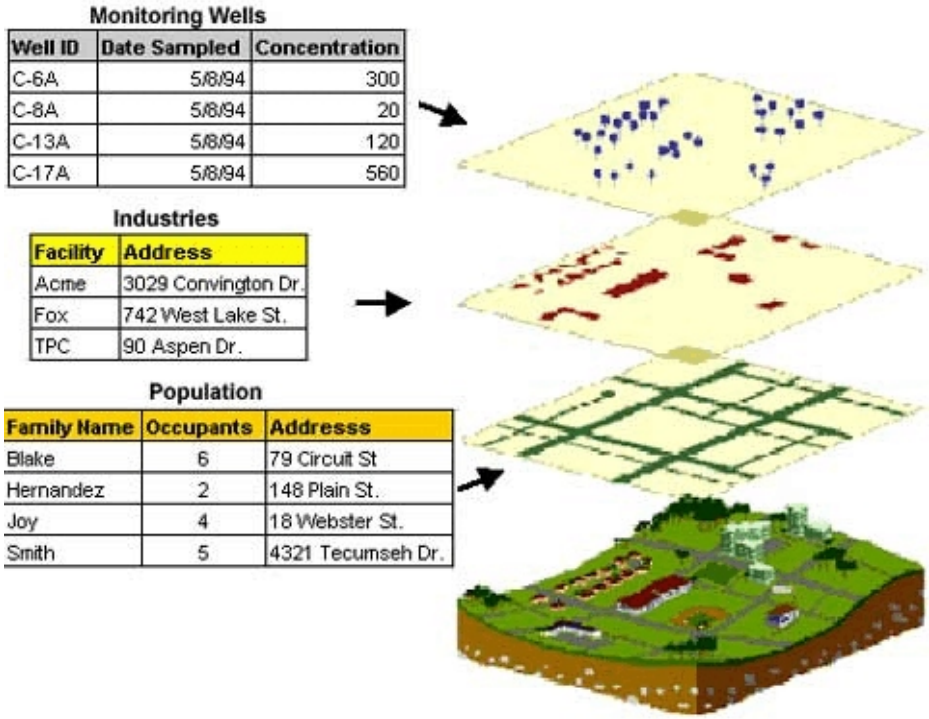
A **geographic information system (GIS)** can be defined as an organized collection of software and geographic data that allow efficient storage, analysis, and presentation of spatially explicit and geographically referenced information. Traditional methods of processing such data have been extremely labor intensive, such as manually digitizing a map from an aerial photograph and then adding information about chemical contaminants. A GIS provides a powerful analytical tool that can be used to create and link spatial and descriptive data for problem solving, spatial modeling and presentation of results in tables or maps. For air toxics risk assessment, GIS can be a powerful tool for displaying and analyzing data during the planning, scoping, and problem formulation phases, during the exposure assessment, and displaying and evaluating the results of the risk characterization. It is also a very helpful means for communicating information to risk managers and other stakeholders.

GIS data generally consist of two components: (1) graphical data about geographic features (e.g., rivers, land use, political boundaries), and (2) tabular data about features in the geography (e.g., population, elevation, modeled ambient concentrations of air toxics). GIS combines these different types of data using a "layering" technique that references each type of data to a uniform geographic coordinate system (usually a grid such as latitude and longitude coordinates). Layered data can then be analyzed using special software to create new layers of data (see Exhibit 32-1).

Over the last several years, GIS applications have evolved from very specialized and expensive analyses that required specialized computers (e.g., supercomputers and workstations) to user-friendly desktop applications utilized by everyday users to do such mundane tasks as print maps or driving directions. Libraries of geographical information developed for general use (e.g., topographical maps, infrastructures, natural resources), and for use by EPA and other regulatory agencies, can be easily downloaded from different servers and used in air toxics risk assessments. One example of a GIS Web-based application is EPA's Envirofacts system[1] which provides website access to several EPA databases that provide information about environmental activities that may affect air, water, and land anywhere in the United States (with much of the data available in GIS format).

This chapter provides an overview of GIS and its application to air toxics risk assessment. More detailed information is provided in the Agency for Toxic Substances and Disease Registry (ATSDR)/Southern Appalachian Assessment GIS (SAAGIS) publication *Introduction to ArcView and Spatial Analysis Techniques for Public Health Professionals*.[2]

Exhibit 32-1. Example Conceptual Model Using GIS



Example of layering within a GIS. The location of monitoring wells, industries, and potential receptors (homes) are all referenced to the same geographic coordinates. This allows spatial analysis of the overlap of sources, contaminant plumes, and receptors, as well as a visual means to communicate complex data sets.

32.2 Selecting a GIS

After risk assessors decide to use a GIS, they must choose a software system. A variety of GIS software is available from commercial vendors. A key feature in selecting a GIS is identifying a minimal set of capabilities needed. Important functional capabilities to consider include: data capture, data storage, data management, data retrieval, data analysis, and data display.[3]

- **Data Capture**. All data used in a GIS must have a spatial component. This means that all information brought into the system must be geo-referenced (i.e., correspond to some physical location). Data capture is the process of incorporating map and attribute data into the GIS. **Geocoding**, which is the conversion of analog data to geo-referenced digital format, is a common way for GIS users to bring map and attribute data into their GIS analyses. Two common methods of geocoding are scanning and digitizing. Both involve taking non-digital information (e.g., a hard-copy map), and converting it into a digital format. In addition to paper files, GIS users often import files from common formats such as AutoCAD DXF. The

newly imported digital information (e.g., the boundary of a state), is geo-referenced by coordinates so that it corresponds to a physical location.

In addition to graphical data, GIS incorporates tabular data for objects included in a data layer. For example, the graphical data associated with a home could consist of its size and location. The tabular data associated with that home consists of attributes such as who lives there, when it was built, where its water supply comes from, and what type of heating system it uses. These attributes would be listed in a table that is linked to the physical location of the house by the GIS. While obtaining geographical base layers that show boundaries is essential, data capture also involves attribute data, which necessitates that the GIS software package have some level of database manager associated with the program. A useful program will generally have features that allow it to import common database files such as those from dBASE®, Access®, Excel®, and Paradox®. The different software packages will vary in their ability to check the characteristics of the databases.

- **Data Storage**. A GIS can incorporate a tremendous amount of data into a map. Space is a key issue related to data storage in a GIS. With the decrease in cost of disk storage, the development of high-density storage media (e.g., CD-ROM), and the incorporation of compression methods, space is not as critical an issue as it has been in the past. However, GIS is still relatively memory-intensive. GIS microcomputer software can take up tens of megabytes of space without data, and a more complete workstation version may use hundreds of megabytes of space. Add to this the datasets with very high resolution (that can move into the gigabyte range in size), and there is a the potential for a significant storage problem. Some storage problems can be resolved by establishing data sets on a common server, accessible to multiple users.

- **Data Management**. A powerful GIS is one which has the ability to manage both map and attribute data. Every GIS is built around the software capabilities of a database management system (DBMS). A DBMS is software that is capable of storing, selecting, retrieving, and reorganizing attribute information. It allows data entry, data editing, and supports several different types of output. Functions include the ability to select records based on their value. Several database functions can work independently of the GIS functions.

- **Data Retrieval**. A GIS will support the retrieval of features by their attributes or by their spatial characteristics. A basic retrieval based on spatial characteristics is used to show the position of a single feature. In addition, a GIS is capable of allowing the operator to use the map as a query vehicle. A simple way of doing this is to point to a feature and retrieve the list of attributes for that feature. The database management function also is important for the data retrieval capacity because it allows for the selection and retrieval based on an attribute. **Buffering** is one retrieval operation that defines a GIS. Buffering allows the user to retrieve features within a specified distance of a point, line, or area. **Overlay** is another spatial retrieval operation in which non-overlapping regions are joined to create a new area. More sophisticated retrieval operations also are available.[2]

- **Data Analysis**. GIS systems vary a great deal in their data analysis capabilities. Basic tasks that should be included in a GIS are: spreadsheet and database analysis, computing new attributes, generating summary statistics, creating reports, statistics such as mean and variance, significance testing, and plotting residuals. In addition, selected geometric tests should be included (e.g., point-in-polygon analysis, surface partitioning).

- **Data Display**. GIS software displays information visually as data layers of a map. GIS users must select the correct map projection to make sure that their maps are not distorted. For example, large areas, such as continents, must be projected with the earth's curvature taken into consideration. Small areas can be projected essentially as flat. GIS software gives users as wide variety of map projection options to ensure that maps are as accurate as possible. Section 32.4.2 discusses map projections in further detail.

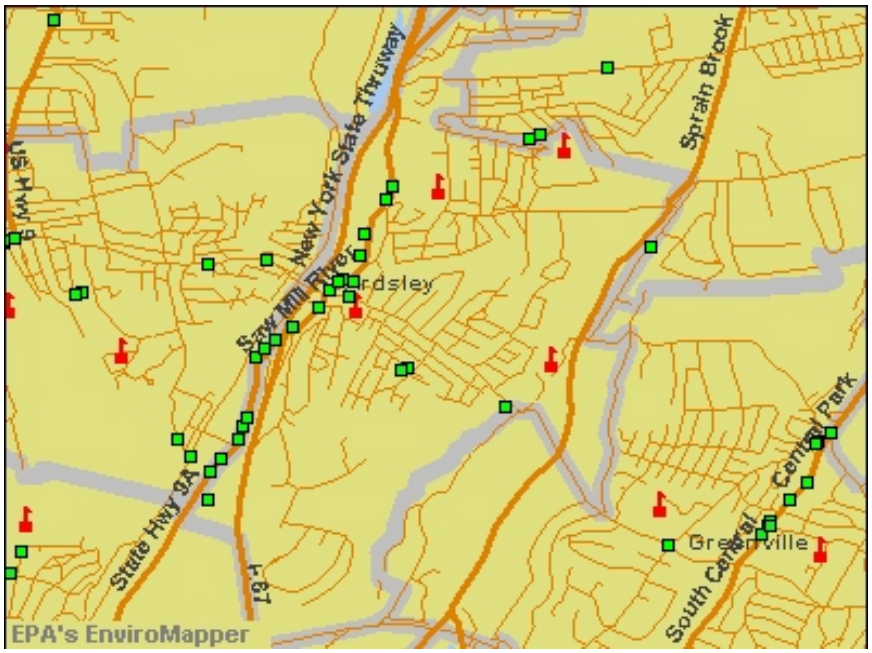
  Different data sources and agencies provide digital data that has been processed using different coordinate systems and map projections. Risk assessors may want to use data layers from many different sources to create a single map. For example, a topography layer from the U.S. Geologic Survey might be combined with a layer showing census blocks from the U.S. Census and a layer showing lead smelters from EPA. Software that can handle a variety of coordinate systems and map projections is essential to GIS capability to overlay layers created from many different sources.

32.3 Acquiring and Using Demographic Data

Demography is the study of the size, composition, distribution, and change in population. Geographers focused on population studies are also interested in the spatial distribution of demographic characteristics.[4] Data from the U.S. Bureau of the Census decennial census is the most common source of residential population information for states, the District of Columbia, and many U.S. territories (e.g., Puerto Rico, U.S. Virgin Islands, American Samoa, and Guam). These data also provide the base for current year population estimates and projections. Risk assessors are often interested in using demographic data because it allows them to identify sensitive sub-populations, such as children or the elderly. A GIS lets risk assessors combine demographic data with data on the location of sources (or estimated ambient air concentrations) to visualize where human health is potentially at risk (see Exhibit 32-2).

Within a GIS, political and statistical geographic area boundary files are linked to the attribute data (e.g., age, race, housing value) describing residents and housing units in that area using Federal Information Processing Standard (FIPS) codes. These codes provide unique identifiers for various geographic areas. When analyzing census data that is nested within the data hierarchy (e.g., census blocks within census tracts), it is best to include the FIPS codes for the larger geographic areas in that hierarchy to ensure that you are using a unique identifier. For example, connecting the FIPS codes for block 201, census tract 12, Fulton county, state of Georgia, results in the unique identifier "13089001200201" for that block. Because the codes are nominal numerals, it is best to treat them as character data (or strings) rather than numbers in the GIS database (although this may not be consistent across data sources).

Exhibit 32-2. Illustration of the Use of GIS to Identify Sensitive Receptors Close to Emissions Sources



In this map, the squares represent hazardous waste sites, and the flagged symbols represent schools. Schools and other locations where sensitive subpopulations may occur that are close to air toxics emissions sources may be of particular interest in a risk assessment.

32.3.1 U.S. Census Data

U.S. census data describing the residential population and housing in the U.S. provide the most complete picture of our nation and its subareas, which makes them very valuable demographic data. Exhibit 32-3 shows the type of information collected in the 2000 census. Many of the Census 2000 data files are available for use in GIS.

32.3.2 Current and Small-Area Demographic Estimates

An issue with census data is that the information represents a "snapshot" in time (generally based on April 1 of the census year). As one moves forward in time, such data may be less reflective of the actual demographic conditions in the study area. This problem is more pronounced for small-area data (e.g., census tracts and block groups). While the census data typically are appropriate for screening-level assessments (e.g., some air quality models include the 2000 census data), more refined assessments may require more current information, which is available from several commercial sources.

Exhibit 32-3. Information Collected in the 2000 Census	
During census years, households received and were asked to respond to one of two census forms – the "short form," which gives the "100-percent component," or the "long form," which gives the "sample component." Questions on the short form were also found on the long form and thus, were (theoretically) asked of every household in the nation. Basic population and housing data were gathered in this way. More detailed population information was obtained from the long form sent to a sample of households. On average, approximately one in six households received the long form. The rate varied from one in two households in some smaller areas, to one in eight households for more densely populated areas.	
100 Percent Component from the Short Form	
Population • Name • Household relationship • Sex • Age • Hispanic or Latino origin • Race	**Housing** • Tenure – owned or rented
Sample Component from the Long Form	
Population *Social characteristics* • Marital status • Place of birth, citizenship, year of entry to the U.S. • School enrollment and attainment • Ancestry • Residency five years ago (migration) • Language spoken at home and ability to speak English • Veteran status • Disability • Grandparents as care givers *Economic characteristics* • Labor force status • Place of work and journey to work • Occupation, industry, and class of worker • Work status in 1999 • Income in 1999	**Housing** • Units in structure • Year structure built • Number of rooms and number of bedrooms • Year moved into residence • Plumbing and kitchen facilities • Telephone service • Vehicles available • Heating fuel • Farm residence *Financial Characteristics* • Value of home or monthly rent paid • Utilities, mortgage, taxes, insurance, and fuel costs
Source: U.S. Census. *Census 2000 Basics*. Available at: http://www.census.gov/mso/www/c2000basics/00Basics.pdf	

A number of commercial entities provide annual small-area population and housing estimates and projections. Estimates are calculated using the most recent decennial census as the population base and incorporating other, often proprietary, data sources to refine the estimates. In addition to providing updated demographics, some vendors have developed segmentation systems that classify the U.S. population into distinct lifestyle segments or clusters depending on residential location ("geodemographics"). The idea of clustering is based on the notion that, more often than not, people will choose to live near others like themselves. This is important to public health because assessors can be more efficient in identifying and understanding where potential hazards are concentrated, as well as developing messages that reach people living in those areas.

32.3.3 Public Health Applications

The use of census data is central for public health communication planning, program planning, implementation and information dissemination. For example, the Georgia Division of Public Health used demographic information to target mammography programs in factory towns classified as "Mines & Mills" because women in those communities were found to have higher rates of breast cancer.[5] As another example, the Centers for Disease Control (CDC) Office of Communication has collaborated with a number of centers on projects that integrate epidemiological and other data for communication planning including HIV status awareness and hantavirus prevention.[6] Because exposure to air toxics is often influenced significantly by proximity to sources, spatial information is essential to identifying areas where human health might be adversely impacted.

32.3.4 Data Access and Distribution

There are numerous sources for acquiring U.S. census data. In addition to the Census Bureau's data access tools, including Factfinder, its Web-based data dissemination system, many public and private organizations are including census data with GIS or mapping software (e.g., ESRI, EPA LandView, HUD Community 2020, Geolytics, Claritas, CACI). State governments, universities, and non-governmental organizations (e.g., CIESIN) are also sources for data. Costs associated with obtaining the data vary.

32.4 Cartographic Concepts

While spatial information and GIS can be extremely useful, people must have assistance in observing and studying the great amount and variety of information that is represented on maps. Geographic data are extensive and voluminous, so cartography, a technique that is fundamentally concerned with reducing the spatial characteristics of a large area, makes maps readable and meaningful. A map is more than a reduction of information to an understandable level. If it is well made, it is a carefully designed instrument for recording, calculating, analyzing, and in general, understanding the interrelation of things in their spatial relationship. This section provides an overview of cartography. A more complete discussion can be found in *The Geographer's Craft Project*.[7]

One of the most useful approaches to the study of cartography is to view maps as a form of visual communication – a special purpose language for describing spatial relationships. Cartography is related to, but different from other forms of visual communication. Cartographers must pay special attention to coordinate systems, map projections, and issues of scale and direction that are in most cases of relatively little concern to other graphic designers or artists. But, because cartography is a type of graphical communication, some insights to the demands of cartography can be gleaned from the literature of graphical communication and statistical graphics. By stressing cartography as a form of communication, it is easier to make the point that maps are really symbolic abstractions – or representations – of real world phenomena. In most cases, this means that the world represented on a map has been greatly simplified, or generalized, with symbols being used like words to stand for real things. Some of the most important decisions cartographers make in the process of cartographic design revolve around: (1) how much to simplify the situation being depicted; and (2) how to symbolize the relationships being represented. In order to make good choices, cartographers often ask themselves the following questions:

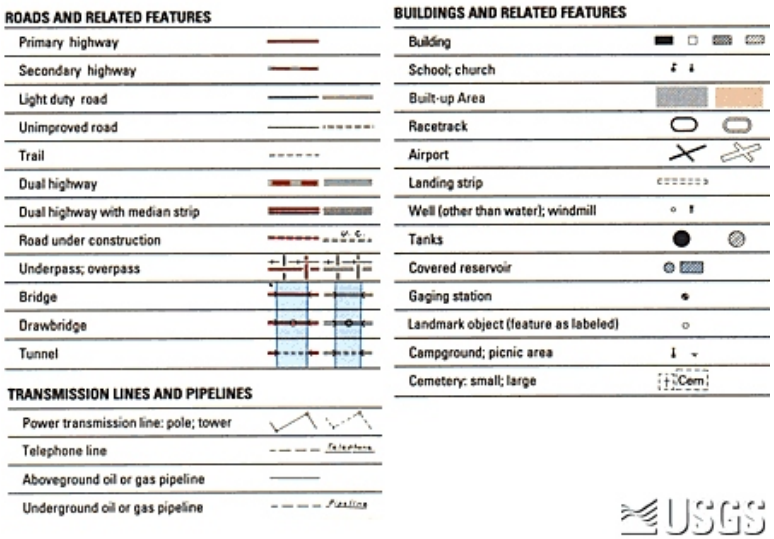
- What is the motive, intent, or goal of the map?
- Who will read the map?
- Where will the map be used?
- What data is available for the composition of the map?
- What resources are available in terms of both time and equipment?

By identifying the most important points to be conveyed by the map along with the map's main audience, cartographers can prioritize where to direct the audience's attention with larger symbols or brighter colors.

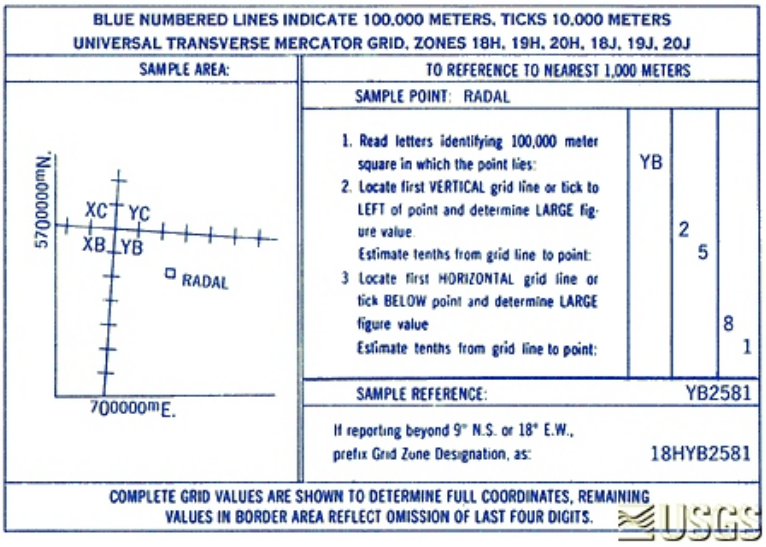
Basic Map Elements

A legend and symbols that inform the viewer of distance, scale, and direction, are basic elements to any map. The USGS (http://edc.usgs.gov/earthshots/slow/Help-GardenCity/legendstext) provides examples of common map legends.

Example U.S. Geological Survey (USGS) Topographic Map Legend



Example Legend for Universal Transverse Mercator (UTM) Projection Zones



32.4.1 Generalization, Simplification, and Abstraction

As noted above, cartography is a process of abstraction in which features of the real world are generalized or simplified to meet the demands of the theme and audience. Not all elements or details have a bearing on the pattern or process being studied and so some are eliminated to draw the reader's attention to those facts that are relevant. Too much detail can even hide or disguise the message of a map. The amount of detail that can be included is very much dependent on the scale at which the map will be produced (see Exhibit 32-4).

Map Making Tips

- Experiment with different layouts
- Think carefully about every element on your map and whether it has an essential function
- Less is more

32.4.2 Map Projections

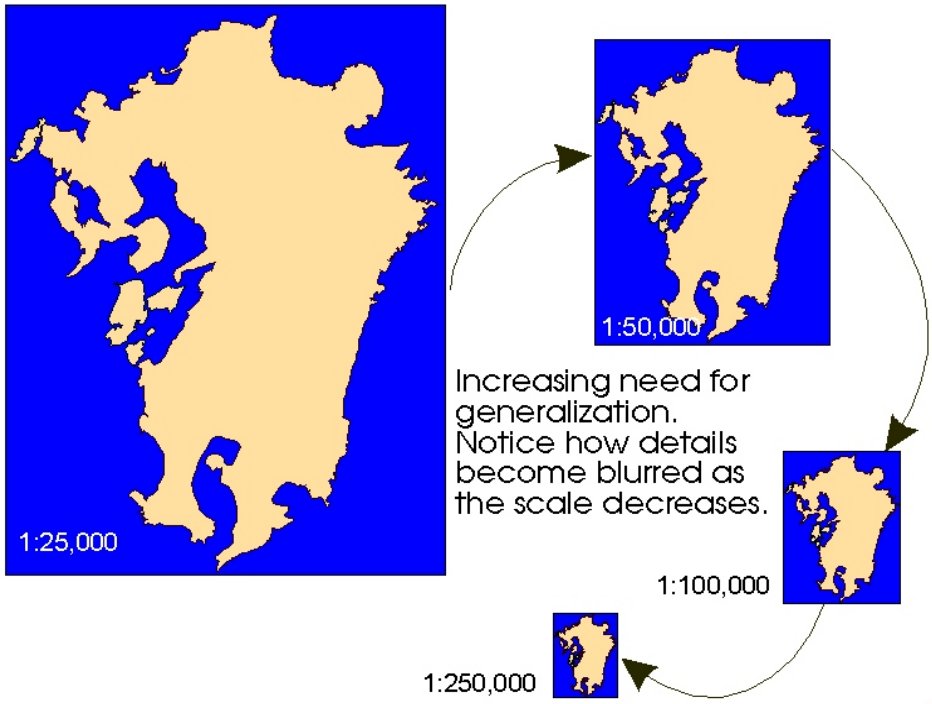
As section 32.2 notes, the projection used to create a map influences the representation of area, distance, direction, and shape. This is readily apparent when looking at a flat map of the world versus looking at a spherical map of the world (i.e., a globe). Maps that ignore the natural shape of the earth distort the places they are trying to represent. It should be noted when these characteristics (e.g., area, distance, direction, and shape), are of prime importance to the interpretation of any map. Some widely used locational reference systems such as the U.S. State Plane Coordinate system and Universal Transverse Mercator system are based on predefined projective geometries that are implicit in the use of the coordinate systems themselves. GIS software packages make it easy for users to choose an appropriate map projection.

32.5 Using the Internet as a GIS Tool

The internet can be a valuable resource for GIS users looking for data. Many federal agencies provide digital data free for download that can be used with GIS. The Census Bureau, EPA, and the United States Geological Survey are all good sources of GIS data. For example, in addition to demographic data, the Census bureau distributes what are called **T**opologically **I**ntegrated **G**eographic **E**ncoding and **R**eferencing (TIGER) files. The TIGER/Line files are a digital database of geographic features, such as roads, lakes, political boundaries, and census statistical boundaries, available for the entire United States. The database contains tabular information about these features such as their location in latitude and longitude, the name, the type of feature, and other important attributes. GIS clearinghouses, universities, and data supply companies are also good places to look for data. A Web search engine can help users locate sites that contain the type of data needed for a given project.

Once users locate relevant data, they must then get the data onto their computer. GIS coverages can take up a lot of computer memory, so choosing the right file transfer method is very important. Many websites allow direct downloads. This type of transfer involves clicking a link and specifying a target directory. Other data providers require users to go through a **file transfer protocol** (FTP) site. FTP sites allow people to exchange large data files more readily than with other protocols.

Exhibit 32-4. Effect of Scale on Detail and Abstraction



Finally, the internet can serve as a resource for users looking for technical support or advice. Most users will find that GIS software manufacturers offer online support. Some companies even have online courses.

32.6 Current GIS Applications at EPA

EPA is an excellent source of GIS data and information for risk assessors. Several offices and branches can serve as resources for those interested in learning more about GIS and its uses, especially in the areas of landscape, land cover, and land use. GIS helps EPA integrate geo-spatial data on a region (e.g., landscape, elevation, climate, slope) with information about potential exposures to give risk assessors a comprehensive picture of that region's hazards.

Because projected land use may be an important input to air models, risk assessors may want more information on landscape change models. For an overview on this subject, see EPA's *Projecting Land-Use Change: A Summary of Models for Assessing the Effects of Community Growth and Change on Land-Use Patterns.*[8]

32.6.1 ORD/ESD

EPA's Office of Research and Development/Environmental Sciences Division (ORD/ESD) conducts research, development, and technology transfer programs on environmental exposures to ecological and human receptors. GIS is an important tool for the type of chemical and physical stressors characterization conducted, especially with ESD's emphasis on ecological exposure. The Division develops landscape and regional assessment capabilities through the use of advanced spatial monitoring and analysis techniques, such as remote sensing and GIS. For more information, go to http://www.epa.gov/nerlesd1/.

32.6.2 ATtILA

Another EPA resource is the Landscape Ecology Branch's ATtILA program, which stands for *Analytical Tools Interface for Landscape Assessments*. The Branch uses ATtILA, which is a GIS, to conducts multiple-stressor regional assessments based largely on geo-spatial landscape data. As part of these assessments, ATtILA generates complicated landscape metrics, which are quantitative measurements of the environmental condition or vulnerability of an area (e.g., ecological region). ATtILA provides an interface that allows users to easily calculate many common landscape metrics regardless of their level of GIS knowledge, despite the complexity of developing the metrics. Four metric groups are currently included in the package (e.g., Landscape Characteristics, Riparian Characteristics, Physical Characteristics, and Human Stresses). ATtILA runs within ArcView®, and is designed to be flexible enough to accommodate spatial data from a variety of sources. More information is available at: http://www.epa.gov/nerlesd1/land-sci/northern_california/attila/background.html.

32.6.3 ReVA

Also from EPA's ORD is the Regional Vulnerability Assessment (ReVA) program. This program is an approach to regional scale, priority-setting assessment meant to expand cooperation among the laboratories and centers of ORD, by integrating research on human and environmental health, ecorestoration, landscape analysis, regional exposure and process modeling, problem formulation, and ecological risk guidelines. Currently, ReVA is working in the Mid-Atlantic region to predict future environmental risk. This will help EPA prioritize efforts to protect and restore environmental quality efficiently and effectively. ReVA is being developed to identify those ecosystems most vulnerable to being lost or permanently harmed in the next 5 to 25 years and to determine which stressors are likely to cause the greatest risk. The goal of ReVA is not exact predictions, but identification of the undesirable environmental changes expected over the coming years.

Many functions work together to provide ReVA's regional assessment capability. GIS puts into a spatial context data on stressors and effects from many sources. Research guides how to apply this data at the landscape and regional scale and helps EPA understand how socioeconomic drivers affect environmental condition. The transfer of data and analytical tools to regional managers is also critical for this tool to be useful. ReVA is considered a GIS because it is designed to analyze the spatial distribution of sensitive ecosystems by analyzing known

distributions of plant and animal populations or communities within ecosystems. Modern methods in landscape ecology and characterization help further identify the locations of ecosystems that are vulnerable to future stress through features such as topography (i.e. increased erosion potential) and habitat patch configurations. Multimedia assessments across water, air, terrestrial, and demographic variables are possible at various scales with this tool. For more information on ReVA, see http://www.epa.gov/reva/approach.htm.

32.7 GPS Technology

Global Positioning System (GPS) technology can be integrated with GIS. GPS technology allows users with the appropriate technology to obtain almost the exact location of any GPS receiver. This means that cars can get driving directions while moving, hikers can always know their exact position for navigating in and out of the wilderness, and the military can track movements of troops or vehicles. For risk assessments, the location of specific sources (i.e., vents) or receptor locations can be accurately determined with GPS. GPS is funded and controlled by the U.S. Department of Defense (DOD). While there are many thousands of civil users of GPS world-wide, the system was designed for, and is operated by the U.S. military.

The system works through specially coded satellite signals that can be processed in a GPS receiver, enabling the receiver to compute position, velocity, and time (see Exhibit 32-5). Four GPS satellite signals are used to compute positions in three dimensions and the time offset in the receiver clock (see Exhibit 32-6).

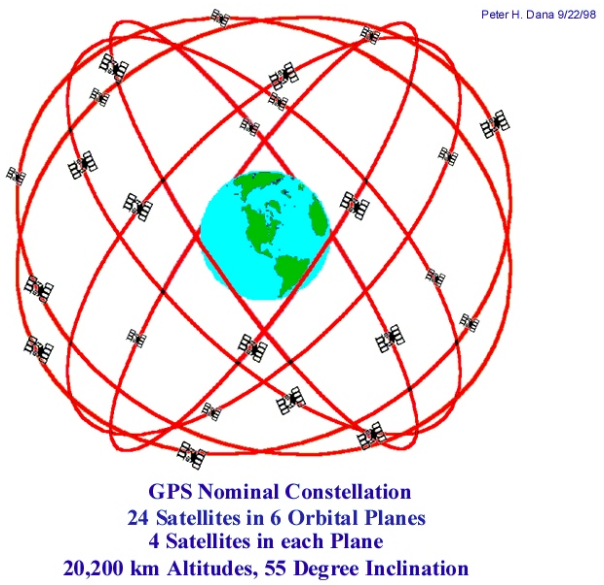
The GPS provides two levels of service – a Standard Positioning Service (SPS), and a Precise Positioning Service (PPS). Access to the PPS is restricted to U.S. Armed Forces, U.S. Federal agencies, and selected allied armed forces and governments. The SPS is available to all users on a continuous, worldwide basis, free of any direct user charge. A nationwide differential GPS service (NDGPS) is being established pursuant to the authority of Section 346 of the Department of Transportation and Related Agencies Appropriation Act. When complete, this service will provide uniform differential GPS coverage of the continental U.S. and selected portions of Hawaii and Alaska regardless of terrain, man-made, and other surface obstructions. NDGPS accuracy is specified to be 10 meters or better. Typical system performance is better than 1 meter in the vicinity of the broadcast site. Achievable accuracy degrades at an approximate rate of 1 meter for each 150 km distance from the broadcast site.[9]

Receiver costs vary depending on capabilities. Small civil SPS receivers can be purchased for under $200. Receivers that can store files for post-processing cost more ($2,000 to 5,000). Receivers that can act as DGPS reference receivers (computing and providing correction data) and carrier phase tracking receivers (and two are often required) can cost many thousands of dollars ($5,000 to $40,000).

Receivers are important because they are the intermediary part of the system that connect real world data to GIS. Satellites send signals to the receiver and users and store the information. Sometimes, the user will have to manually record position and time readings and then type those

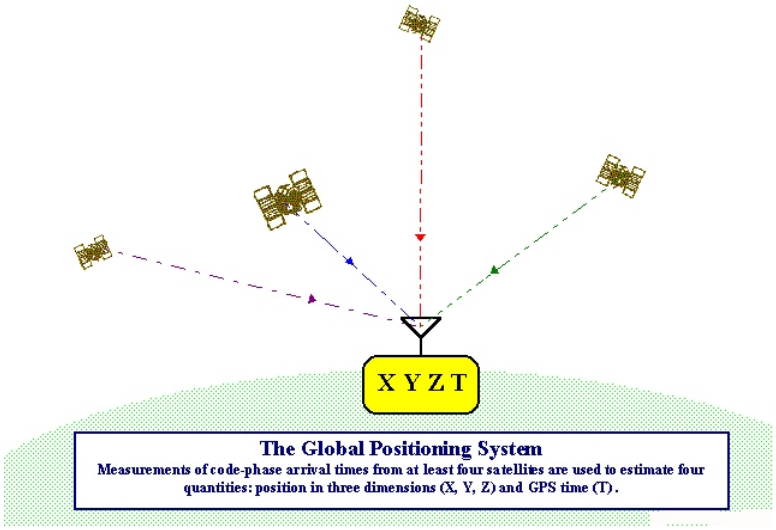
into a computer later. Other times the user can plug the receiver into a special port on her computer and download the digital data directly.

Exhibit 32-5. Global Positioning System (GPS) Satellites



GPS satellites orbit the Earth every 12 hours, sending signals to receivers around the world

Exhibit 32-6. Positioning and Time from Four GPS Satellites



Measurements of code-phase arrival times from at least four satellites are used to estimate four quantities: position in three dimensions (X, Y, and Z) and GPS time (T).

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9. U.S. Department of Defense and U.S. Department of Transportation. 2001. *2001 Federal Radionavigation Plan*, DOT/VNTSC/RSPA-01/3; DOD-4650.5. Available at: http://www.navcen.uscg.gov/pubs/frp2001/FRP2001.pdf. (Last accessed March 2004.)

Glossary

This list of glossary terms was compiled from existing EPA definitions and supplemented, where necessary, by additional terms and definitions. The wording of selected items may have been modified from the original in order to assist readers who are new to risk assessment more readily comprehend the underlying concept of the glossary entry. As such, these glossary definitions constitute neither official EPA policy nor preempt or in any way replace any existing legal definition required by statute or regulation.

A

Absorbed Dose – the amount of a substance that has penetrated the absorption barriers (e.g., skin, lung tissue, gastrointestinal tract) of an organism through either physical or biological processes.

Absorption - The process of taking in, as when a sponge takes up water. Chemicals can be absorbed through the skin into the bloodstream and then transported to other organs. Chemicals can also be absorbed into the bloodstream after breathing in or swallowing.

Absorption Barrier - Exchange barriers of the body that allow differential diffusion of various substances across a boundary. Examples of absorption barriers are the skin, lung tissue, and gastrointestinal tract wall.

Abiotic Degradation - Degradation via purely physical or chemical mechanisms. Examples include hydrolysis and photolysis.

Acceptable Risk - The likelihood of suffering disease or injury that will be tolerated by an individual, group, or society. The level of risk that is determined to be acceptable may depend on a variety of issues, including scientific data, social, economic, legal, and political factors, and on the perceived benefits arising from a chemical or process.

Accuracy - The measure of the correctness of data, as given by the difference between the measured value and the true or standard value.

Active Monitor - A type of personal exposure monitoring device that uses a small air pump to draw air through a filter, packed tube, or similar device.

Activity Patterns - A series of discrete events of varying time intervals describing information about an individual's lifestyle and routine. This information typically includes the locations visited, the amount of time spent in the locations, and a description of what the individual was doing in each location.

Acute Effect - Any toxic effect produced with a short period of time following an exposure, for example, minutes to a few days

Acute Exposure Limits - A variety of short-term exposure limits to hazardous substances, designed to be protective of human health. Published by different organizations, each limit has a different purpose and definition.

Acute Exposure - One dose (or exposure) or multiple doses (or exposures) occurring within a short time relative to the life of a person or other organism (e.g., approximately 24 hours or less for humans).

Actual Risk - The damage to life, health, property, and/or the environment that may occur as a result of exposure to a given hazard. Risk assessment attempts to estimate the likelihood of actual risk.

Additive Effect - The overall result of exposure to two or more chemicals, in which the resulting effect is equal to the sum of the independent effects of the chemicals. "Effects" or "Response Addition" is a method employed in EPA risk assessments of mixtures in which the components act or are presumed to act independently (without interaction).

Additive Dose - The overall result of exposure to two or more chemicals, when each chemical behaves as a concentration or dilution of the other chemicals in the mixture. The response of the combination is the response expected from the equivalent dose of an index chemical. The equivalent dose is the sum of component doses scaled by their toxic potency relative to the index chemical.

Adjusted Exposure Concentration - Also called a refined exposure concentration, an estimate of exposure concentration that has been refined, usually by application of an exposure model, to better understand how people in a particular location interact with contaminated media.

Administered Dose - The amount of a substance received by a test subject (human or animal) in determining dose-response relationships, especially through ingestion or inhalation.

Advection - In meteorology, the transfer of a property, such as heat or humidity, by motion within the atmosphere, usually in a predominantly horizontal direction. Thermal advection, for example, is the transport of heat by the wind. Advection is most often used to signify horizontal transport but can also apply to vertical movement. Large-scale horizontal advection of air is a characteristic of middle-latitude zones and leads to marked changes in temperature and humidity across boundaries separating air masses of differing origins.

Adverse Environmental Effect - Defined in the CAA section 112(a)(7) as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resource, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

Adverse Health Effect - A health effect from exposure to air contaminants that may range from relatively mild and temporary (e.g., eye or throat irritation, shortness of breath, or headaches) to permanent and serious conditions (e.g., birth defects, cancer or damage to lungs, nerves, liver, heart, or other organs), and which negatively affects an individual's health or well-being, or reduces an individual's ability to respond to an additional environmental challenge.

Affected (or Interested) Parties - Individuals and organizations potentially acted upon or affected by chemicals, radiation, or microbes in the environment or influenced favorably or adversely by proposed risk management actions and decisions.

Agent - A chemical, physical, or biological entity that may cause deleterious, beneficial, or no effects to an organism after the organism is exposed to it.

Aggregate exposure - The combined exposure of an individual (or defined population) to a specific agent or stressor via relevant routes, pathways, and sources.

Aggregate risk - The risk resulting from aggregate exposure to a single agent or stressor.

AirData - An EPA website (http://www.epa.gov/air/data/info.html) that provides access to yearly summaries of United States air pollution data, taken from EPA's air pollution databases. The data include all fifty states plus District of Columbia, Puerto Rico, and the U. S. Virgin Islands. AirData has information about where air pollution comes from (emissions) and how much pollution is in the air outside our homes and work places (monitoring).

Air Emissions - The release or discharge of a pollutant into the air.

Air Pressure (Atmospheric Pressure, Barometric Pressure) - The pressure experienced above the Earth's surface at a specific point as a result of the weight of the air column, extending to the outer limit or top of the atmosphere. Consequently, pressure declines exponentially with height, the rate of decrease being a function of the temperature of the atmosphere. Atmospheric pressure is generally measured, in meteorology, either in the SI unit hectopascals (hPa) or in the c.g.s. unit of the same size, the millibar (mb) using a mercury or aneroid barometer, or a barograph. In the U.S., surface atmosphere pressure is measured in inches of mercury (Hg).

Air Mass - A large volume of air with certain meteorological or polluted characteristics (e.g., a heat inversion or smogginess) while in one location. The characteristics can change as the air mass moves away.

Air Toxic - Any air pollutant that causes or may cause cancer, respiratory, cardiovascular, or developmental effects, reproductive dysfunctions, neurological disorders, heritable gene mutations, or other serious or irreversible chronic or acute health effects in humans. See hazardous air pollutant.

Ambient Medium (e.g., Ambient Air) - Material surrounding or contacting an organism (e.g., outdoor air, indoor air, water, or soil), through which chemicals can reach an organism.

Ambient Water Quality Criteria (AWQC) - A ecological benchmark level for aquatic contaminants, published by EPA Office of Water, which is designed to protect 95 percent of all aquatic species in freshwater or marine environments. Criteria have been developed for both acute and chronic exposures, although for a limited number of chemicals.

Ample Margin of Safety - This term has regulatory significance in EPA's air toxics program. It was interpreted by the Agency in the 1989 notice of final benzene NESHAP (FR54:38044-38072), and reiterated in the 1990 amendments to the Clean Air Act (sections 112(f) and 112(c)).

AMTIC - Ambient Monitoring Technology Information Center. An EPA website that contains information and files on ambient air quality monitoring programs, details on monitoring methods, monitoring-related documents and articles, information on air quality trends and nonattainment areas, and federal regulations related to ambient air quality monitoring. [http://www.epa.gov/ttn/amtic/, 2003]

Analysis - The systematic application of specific theories and methods, including those from natural science, social science, engineering, decision science, logic, mathematics, and law, for the purpose of collecting and interpreting data and drawing conclusions about phenomena. It may be qualitative or quantitative. Its competence is typically judged by criteria developed within the fields of expertise from which the theories and methods come.

Analysis Plan - A plan that provides all the details of exactly how each part of the risk assessment will be performed. It usually describes in detail what analyses will be performed, how they will be performed, who will perform the work, schedules, resources, quality assurance/quality control requirements, and documentation requirements.

Animal Studies - Toxicity investigations using animals. Such studies may employ animals as surrogates for humans with the expectation that the results are pertinent to humans or for investigation of effects pertinent to animals (e.g., for ecological risk assessment).

Antagonistic Effect - The situation where exposure to two chemicals together has less effect than the sum of their independent effects.

AP-42 - A compilation of air pollutant emission factors. Volume I of the fifth edition addresses stationary point and area source emission factors. AP-42 is accessible on the Air CHIEF website (http://www.epa.gov/ttn/chief/ap42/) and is also included on the Air CHIEF CD-ROM.

Applied Dose - The amount of a substance in contact with an absorption boundary of an organism (e.g., skin, lung, gastrointestinal tract) and is available for absorption.

Area of Impact – The geographic area affected by a facility's emissions (also known as the zone of impact).

Area Source (legal sense) - A stationary source that emits less than 10 tons per year of a single hazardous air pollutant (HAP) or 25 tons per year of all HAPs combined.

Area Source (modeling sense) - An emission source in which releases are modeled as coming from a 2-dimensional surface. Emissions from the surface of a wastewater pond are, for example, often modeled as an area source.

Area Use Factor - For an animal, the ratio of its home range, breeding range, or feeding/foraging range to the area of contamination or the site area under investigation.

Assessment Endpoint - An explicit expression of the environmental value to be protected. An assessment endpoint includes both an ecological entity and specific attributes of that entity. For example, salmon are a valued ecological entity; reproduction and population maintenance (i.e., the attribute) form an assessment endpoint.

Assessment Questions - The questions asked during the planning/scoping phase of the risk assessment process to determine what the risk assessment will evaluate.

Atmospheric Stability (Stability) - the degree of resistance of a layer of air to vertical motion.

ATSDR (Agency for Toxic Substances and Disease Registry) - An Agency of the U.S. Department of Health and Human Services, whose goal is to serve the public by using the best science, taking responsive public health actions, and providing health information to prevent harmful exposures and diseases to toxic substances. Its website (www.atsdr.cdc.gov) includes information on hazardous substances [e.g., toxicological profiles, minimal risk levels (MRLs)], emergency response, measuring health effects, hazardous waste sites, education and training, publications, and special issues (e.g., Children Health).

Averaging Time - The time period over which something is averaged (e.g., exposure, measured concentration).

B

Background Levels - The concentration of a chemical already present in an environmental medium due to sources other than those under study. Two types of background levels may exist for chemical substances: (a) Naturally occurring levels of substances present in the environment, and (b) Anthropogenic concentrations of substances present in the environment due to human associated activities (e.g., automobiles, industries).

Background Source - Any source from which pollutants are released and contribute to the background level of a pollutant, such as volcano eruptions, windblown dust, or manmade source upwind of the study area.

Benchmark Dose - An exposure due to a dose of a substance associated with a specified low incidence of risk, generally in the range of 1% to 10%, of a health effect; or the dose associated with a specified measure or change of a biological effect.

Benthic Burial Rate (k_b) - Rate of the deposition of the sediment suspended in a surface water body column to the benthic sediment surface that becomes no longer available for resuspension in the water column, effectively becoming part of the sediment "sink."

Best Available Control Technology (BACT) - An emission limitation based on the maximum degree of emission reduction (considering energy, environmental, and economic impacts) achievable through application of production processes and available methods, systems, and techniques. BACT does not permit emissions in excess of those allowed under any applicable Clean Air Act provisions. Use of the BACT concept is allowable on a case by case basis for major new or modified emissions sources in attainment areas and applies to each regulated pollutant.

Best Professional Judgement - Utilizing knowledge based on education and experience to determine the best course of action during the course of performing a risk assessment project.

Bias - systematic error introduced into sampling or analysis by selecting or encouraging one outcome or answer over others.

Binational Toxics Strategy - A Canada-United States jointly-sponsored program that provides a framework for actions to reduce or eliminate persistent toxic substances, especially those which bioaccumulate, from the Great Lakes Basin.

Bioaccumulation - The net accumulation of a substance by an organism as a result of uptake from and or all routes of exposure (e.g., ingestion of food, intake of drinking water, direct contact, or inhalation).

Bioavailability - The ability to be absorbed and available to interact with the metabolic processes of an organism.

Bioaccumulation Factor (BAF) - The concentration of a substance in tissue of an organism divided by its concentration in an environmental medium in situations where the organism and its food are exposed (i.e., accounting for food chain exposure as well as direct chemical uptake). [EPA, 1999: Residual Risk Report to Congress. EPA453R99001.]

Bioassay - A test conducted in living organisms (*in vivo*) or with living cells (*in vitro*) to determine the hazard or potency of a chemical by its effect on animals, isolated tissues, or microorganisms. [Based on Air Risk Information Support Center, OAQPS, March 1989: Glossary of Terms Related to Health, Exposure, and Risk Assessment. EPA/450/3-88/016.]

Bioavailability - A measure of the degree to which a dose of a substance becomes physiologically available to the body tissues depending upon adsorption, distribution, metabolism and excretion rates. [Air Risk Information Support Center, OAQPS, March 1989: Glossary of Terms Related to Health, Exposure, and Risk Assessment. EPA/450/3-88/016.]

Bioconcentration - The net accumulation of a substance by an organism as a result of uptake directly from an environmental medium (e.g., net accumulation by an aquatic organism as a result of uptake directly from ambient water, through gill membranes or other external body surfaces).

Bioconcentration Factor (BCF) - The concentration of a substance in tissue of an organism divided by the concentration in an environmental medium (e.g., the concentration of a substance in an aquatic organism divided by the concentration in the ambient water, in situations where the organism is exposed through the water only).

Biological Medium - Any one of the major categories of material within an organism (blood, adipose tissue, breath), through which chemicals can move, be stored, or be biologically, physically, or chemically transformed.

Biological Monitoring - The measurement of chemicals in biological media (e.g., blood, urine, exhaled breath) to determine whether chemical exposure in humans, animals, or plants has occurred.

Biologically Effective Dose - The amount of chemical that reaches the cells or target site where an adverse effect may occur.

Biomagnification or Biological Magnification - The process whereby certain substances, such as pesticides or heavy metals, transfer up the food chain and increase in concentration. For example, a biomagnifying chemical deposited in rivers or lakes absorbs to algae, which are ingested by aquatic organisms, such as small fish, which are in turn eaten by larger fish, fish-

eating birds, terrestrial wildlife, or humans. The chemical tends to accumulates to higher concentration levels with each successive food chain level.

Biotic Degradation (Biodegredation) - Decomposition or metabolism of a substance into more elementary compounds by the action of organisms (e.g., bacteria, fungi).

Bounding Estimate - An estimate of exposure or risk that is higher or lower than that incurred by any person in the population. Bounding estimates are useful in developing statements that exposures or risks are within an estimated range.

Blue Book - The 1994 National Research Council (NRC) report entitled *Science and Judgement in Risk Assessment*.

Body Weight (Mass) - The weight or mass of an individual's body. It can apply to a human or an ecological receptor.

Breathing Zone - Air in the vicinity of an organism from which respired air is drawn. Personal monitors are often used to measure pollutants in the breathing zone.

Bright Line - Specific levels of risk or of exposure that are meant to provide a practical distinction between what is considered "safe" and what is not.

Building Downwash (Plume Downwash) - The interaction of a plume with a structure, such as a building, which causes the plume to fall to ground.

C

CalEPA (California Environmental Protection Agency) - An Agency within the California State government whose goal is to protect human health and the environment and to assure the coordinated deployment of State resources against the most serious environmental risks. There are six boards that address environmental issues, including air quality, pesticides, toxic substances, waste management, water control, and the Office of Environmental Health Hazard Assessment (OEHHA). Note that OEHHA is responsible for developing and providing state and local government agencies with toxicological and medical information relevant to decisions involving public health and is a good resource for such information.

Cancer - A group of related diseases characterized by group of diseases characterized by the uncontrolled growth of abnormal cells.

Cancer Incidence - The number of new cases of a disease diagnosed each year.

Cancer Risk Estimates - The probability of developing cancer from exposure to a chemical agent or a mixture of chemicals over a specified period of time. In quantitative terms, risk is expressed in values ranging from zero (representing an estimate that harm certainly will not occur) to one (representing an estimate that harm certainly will occur). The following are examples of how risk is commonly expressed: 1.E-04 or 1×10^{-4} = a risk of 1 additional cancer in an exposed population of 10,000 people (i.e., 1/10,000); 1.E-5 or 1×10^{-5} = 1/100,000; 1.E-6 or 1×10^{-6} = 1/1,000,000.

Cancer Risk Evaluation Guides (CREGs) - Developed by ATSDR, the concentration of a chemical in air, soil or water that is expected to cause no more than one excess cancer in a million persons exposed over a lifetime. The CREG is a *comparison value* used to select contaminants of potential health concern and is based on the *cancer slope factor* (CSF).

Cancer Slope Factor (CSF) - An upper bound (approximating a 95% confidence limit) on the increased cancer risk from a lifetime exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg/day, is generally reserved for use in the low-dose region of the dose-response relationship; that is, for exposures corresponding to risks less than 1 in 100. This term is usually used to refer to oral slope factors (i.e., slope factors used for assessing ingestion exposure).

Carcinogen(ic) - An agent capable of inducing cancer.

Carcinogenesis - The origin or production of a benign or malignant tumor. The carcinogenic event modifies the genome and/or other molecular control mechanisms of the target cells, giving rise to a population of altered cells.

Census Bureau (Bureau of the Census) - A Bureau within the Department of Commerce, this is the country's preeminent statistical collection and dissemination agency of national demographic information. It publishes a wide variety of statistical data about people, housing, and the economy of the nation. The Census Bureau conducts approximately 200 annual surveys and conducts the decennial census of the United States population and housing and the quinquennial economic census and census of governments.

Census Block - An area bounded by visible and/or invisible features shown on Census Bureau maps. A block is the smallest geographic entity for which the Census Bureau collects and tabulates 100-percent decennial census data.

Census Tract - A small, relatively permanent statistical subdivision of a county or statistically equivalent entity, delineated for data presentation purposes by a local group of census data users or the geographic staff of a regional census center in accordance with Census Bureau guidelines. Designed to be relatively homogeneous units with respect to population characteristics, economic status, and living conditions at the time they are established, census tracts generally contain between 1,000 and 8,000 people, with an optimum size of 4,000 people. Census tract boundaries are delineated with the intention of being stable over many decades, so they generally follow relatively permanent visible features. However, they may follow governmental unit boundaries and other invisible features in some instances; the boundary of a state or county (or statistically equivalent entity) is always a census tract boundary.

Census Tract (or Census Block) Internal Point - A set of geographic coordinates (latitude and longitude) that is located within a specified geographic entity such as a Census Tract or Census Block. For many Census Tracts or Blocks, this point represents the approximate center of the Census Tract or Block; for some, the shape of the entity or the presence of a body of water causes the central location to fall outside the Census Tract or Block or in water, in which case the point is relocated to land area within the Census Tract or Block. The geographic coordinates are shown in degrees to six decimal places in census products.

Chemical Abstracts Service Registry Number (CASRN) - A unique, chemical-specific number used in identifying a substance. The registry numbers are assigned by the Chemical Abstract Service, a division of the American Chemical Society. (Note that some mixtures of substances, such as mixtures of various forms of xylene, are also given CAS numbers.)

Chemicals of Potential Concern - Chemicals that may pose a threat to the populations within the study area. These are the chemicals which are carried through the risk assessment process.

Chemical Speciation - Detailed identification of the specific identities and forms of chemicals in a mixture.

Chemical Transformation - The change of one chemical into another.

Chronic Exposure - Continuous exposure, or multiple exposures, occurring over an extended period of time or a significant fraction of the animal's or the individual's lifetime.

Chronic Health Effects - An effect which occurs as a result of repeated or long term (chronic) exposures.

Coefficient of Variation (CV) - A dimensionless measure of dispersion, equal to the standard deviation divided by the mean, often expressed as a percentage.

Cohort - A group of people within a population that can be aggregated because the variation in a characteristic of interest (e.g., exposure, age, education level) within the group is much less than the group-to-group variation across the population.

Community - The persons associated with an area who may be directly affected by area pollution because they currently live in or near the area, or have lived in or near the area in the past (i.e., current or past residents), members of local action groups, local officials, tribal governments, health professionals, and local media. Other entities, such as local industry, may also consider themselves part of the community.

Comparative Risk Assessment - The process of comparing and ranking various types of risks to identify priorities and influence resource allocations.

Conceptual Model - A written description and/or a visual representation of actual or predicted relationships between humans or ecological entities and the chemicals or other stressors to which they may be exposed.

Conductivity (Conductance) - The ability of a material to carry and electrical current.

Confidence Interval - A range of values that has a specified probability (e.g., 95 percent) of containing the statistical parameter (i.e., a quantity such as a mean or variance that describes a statistical population) in question. The confidence limit refers to the upper or lower value of the range.

Coning - In pollution studies, emissions from a chimney stack under atmospheric conditions of near neutral stability such that concentrations of a pollutant at a given distance downwind from

the stack may be described by a normal or Gaussian distribution, being the same for both vertical and horizontal cross-sections perpendicular to the flow.

Consumption Rate - The average quantity of an item consumed or expended during a given time interval, expressed in quantities by the most appropriate unit of measurement per applicable stated basis.

Continuous Monitoring - The measurement of the air or water concentration of a specific contaminant on an uninterrupted, real-time basis by instrumental methods.

Control Technology/Measures - Equipment, processes or actions used to reduce air pollution at the source.

Convection - The transfer and mixing of heat by mass movement through a fluid (e.g., air or water). It is one of the major mechanisms for the transfer of heat within the atmosphere, together with conduction and radiation. The convection process is of major importance in the troposphere, transferring sensible heat and latent heat from the Earth's surface into the boundary layer, and by promoting the vertical exchange of air-mass properties (e.g., heat, water vapor, and momentum) throughout the depth of the troposphere. Convection is generally accepted to be vertical circulation, whereas advection is usually horizontal.

Cost-Benefit Analysis - An evaluation of the costs which would be incurred versus the overall benefits of a proposed action, such as the establishment of an acceptable exposure level of a pollutant.

Criteria Air Pollutant - One of six common air pollutants determined to be hazardous to human health and regulated under EPA's National Ambient Air Quality Standards (NAAQS). The six criteria air pollutants are carbon monoxide, lead, nitrogen dioxide, ozone, sulfur dioxide, and particulate matter. The term "criteria pollutants" derives from the requirement that EPA must describe the characteristics and potential health and welfare effects of these pollutants. It is on the basis of these criteria that standards are set or revised.

Critical Effect - The first adverse effect, or its known precursor, that occurs to the most sensitive species as the dose rate of an agent increases.

Cumulative Risk - The combined risk from aggregate exposures to multiple agents or stressors.

Cumulative Risk Assessment - An analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors.

Cumulative Distribution Function (CDF) - The CDF is alternatively referred to in the literature as the distribution function, cumulative frequency function, or the cumulative probability function. The cumulative distribution function, $F(x)$, expresses the probability the random variable X assumes a value less than or equal to some value x, $F(x) = \text{Prob}(X \leq x)$. For continuous random variables, the cumulative distribution function is obtained from the probability density function by integration, or by summation in the case of discrete random variables.

Cumulative Risk Assessment - An analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors.

D

Data Integrity - Refers to security (i.e., the protection of information from unauthorized access or revision) to ensure that the information is not compromised through corruption or falsification. Data integrity is one of the constituents of data quality.

Data Objectivity - A characteristic indicating whether information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. Data objectivity is one of the constituents of data quality.

Data Quality - The encompassing term regarding the quality of information used for analysis and/or dissemination. Utility, objectivity, and integrity are constituents of data quality.

Data Quality Objectives (DQOs) - Qualitative and quantitative statements derived from the DQO process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support the decisions.

Data Quality Objectives Process - A systematic planning tool to facilitate the planning of environmental data collection activities. Data quality objectives are the qualitative and quantitative outputs from the DQO Process.

Data Utility - Refers to the usefulness of the information to the intended users. Data utility is one of the constituents of data quality.

Delivered Dose - The amount of the chemical available for interaction by any particular organ or cell.

Deposition (Wet and Dry) - The removal of airborne substances to available surfaces that occurs as a result of gravitational settling and diffusion, as well as electrophoresis and thermophoresis in the absence of active precipitation (Dry) or in the presence of active precipitation (Wet).

Deposition (Flux) - The removal of airborne substances from the air to available surfaces that occurs as a result of gravitational settling and diffusion, as well as electrophoresis and thermophoresis.

Dermal - Referring to the skin. Dermal absorption means absorption through the skin.

Dermal Exposure - Contact between a chemical and the skin. [EPA, 1997: Terms of Environment, http://www.epa.gov/OCEPAterms/.]

Detection Limit - The lowest concentration of a chemical that can reliably with analytical methods be distinguished from a zero concentration.

Deterministic - A methodology relying on point (i.e., exact) values as inputs to estimate risk; this obviates quantitative estimates of uncertainty and variability. Results are also presented as point values. Uncertainty and variability may be discussed qualitatively, or semi-quantitatively by multiple deterministic risk estimates.

Developmental Toxicity - The potential of an agent to cause abnormal development. Developmental toxicity generally occurs in a dose-related manner, may result from short-term exposure (including single exposure situations) or from longer term low-level exposure, may be produced by various routes of exposure, and the types of effects may vary depending on the timing of exposure because of a number of critical periods of development for various organs and functional systems. The four major manifestations of developmental toxicity are death, structural abnormality, altered growth, and functional deficit.

Dietary Composition - The fractions of different foods that constitute a given diet.

Differential Heating - The property of different surfaces which causes them to heat and cool at different rates.

Direct Exposure - Contact between a receptor and a chemical where the chemical is still in the medium to which it was originally released. For example, direct exposure occurs when a pollutant is released to the air and a person breathes that air.

Direct-read Monitor - Using a pump to draw the air sample through the detector, this type of air toxics monitoring device provides a direct reading of the pollutant measurement. The monitor may be designed as a table-top unit, for example, or it may be rack-mounted such as for use in an ambient air monitoring station.

Dispersion - Pollutant or concentration mixing due to turbulent physical processes.

Disease Cluster - An unusual number, real or perceived, of health events (i.e., reports of cancer) grouped together in time and location.

Dose - The amount of substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The potential dose is the amount ingested, inhaled, or applied to the skin. The applied dose is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The absorbed does is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. Internal dose is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries. The amount of the chemical available for interaction by any particular organ or cell is termed the delivered dose for that organ or cell.

Dose-Response Assessment - A determination of the relationship between the magnitude of an administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or as the probability of occurrence within a population.

Dose-Response Curve - A graphical representation of the quantitative relationship between administered, applied, or internal dose of a chemical or agent, and a specific biological response to that chemical or agent.

Dust Resuspension - Involves the deposition of dust from the air and its subsequent resuspension or re-entrainment into the atmosphere.

E

Ecological Risk Assessment - The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

Eddy - In the atmosphere, a distinct mass within a turbulent fluid that retains its identity and behaves differently for a short period within the general larger volume flow. An eddy thus ranges in size from microscale turbulence (1 cm for example) to many hundreds of kilometers in the form of frontal cyclones and anticyclones. The smallest scale eddies are critical in the process of, for example, heat and water vapor transfer from the Earth's surface into the air, while frontal cyclones transport heat toward the poles.

Emission Factor - The relationship between the amount of pollution produced and the amount of raw material processed or product produced. For example, an emission factor for a blast furnace making iron could be the number of pounds of particulates released per ton of raw materials used.

Emission Inventory - A listing, by source, of the amount of air pollutants discharged into the atmosphere in a particular place. Two of the more important publicly available emissions inventories for air toxics studies are the National Emissions Inventory (NEI) and the Toxics Release Inventory (TRI).

Emission Rate - The amount of a given substance discharged to the air per unit time, expressed as a fixed ratio (e.g., tons/yr).

Emissions Inventory Improvement Program (EIIP) - A jointly sponsored effort of the State and Territorial Air Pollution Program Administrators/Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) and EPA, and is an outgrowth of the Standing Air Emissions Work Group (SAEWG). The goal of EIIP is to provide cost-effective, reliable inventories by: (1) Improving the quality of emissions information, and (2) Developing system(s) for collecting, calculating, and reporting emissions data. The goal is achieved by developing a set of "preferred and alternative methods" for all inventory associated tasks. This standardization improves the consistency of collected data and results in increased usefulness of emissions information.

Emissions Monitoring - The periodic or continuous physical surveillance or testing to determine the pollutant levels discharged into the atmosphere from sources such as smokestacks at industrial facilities and exhaust from motor vehicles, locomotives, or aircraft.

Emissions Tracking System (ETS) - This EPA system contains all emissions data submitted under various clean air market programs. Data from Continuous Emissions Monitoring Systems at utilities sends the emission data to the utility's computer system, which then compiles the data for submission to EPA on a quarterly basis. At the end of each calendar year, EPA compares tons of emissions emitted with the allowance holdings of the utility unit to ensure that it is in compliance with the relevant program.

Endocrine Disruptor - Substances which interfere with endocrine system function.

Environmental Data - Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. Environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

Environmental Media Evaluation Guides - Environmental Media Evaluation Guides (EMEGs) are concentrations of a contaminant in water, soil, or air that are unlikely to be associated with any appreciable risk of deleterious noncancer effects over a specified duration of exposure. EMEGs are derived from ATSDR minimal risk levels by factoring in default body weights and ingestion rates. Separate EMEGS are computed for acute (14 days), intermediate (15-364 days), and chronic (365 days) exposures.

Environmental Medium - Any one of the major categories of material found in the physical environment (e.g., surface water, ground water, soil, or air), and through which chemicals or pollutants can move.

Epidemiology - The study of disease patterns in human populations.

Epidemiologic Study, Case Study - A medical or epidemiologic evaluation of one person or a small group of people to gather information about specific health conditions and past exposures.

Epidemiologic Study, Descriptive - An evaluation of the amount and distribution of a disease in a specified population by person, place, and time.

Epidemiologic Study, Analytical - An evaluation of the association between exposure to hazardous substances and disease by testing scientific hypotheses.

Exposure - Contact made between a chemical, physical, or biological agent and the outer boundary of an organism.

Exposure Assessment - An identification and evaluation of a population exposed to a toxic agent, describing its composition and size, as well as the type, magnitude, frequency, route and duration of exposure.

Exposure Concentration - The concentration of a chemical in its transport or carrier medium (i.e., an environmental medium or contaminated food) at the point of contact.

Exposure Duration - The total time an individual is exposed to the chemical being evaluated or the length of time over which contact with the contaminant lasts.

Exposure Factors - Any of a variety of factors that relate to how an organism interacts with or is otherwise exposed to environmental pollutants (e.g., ingestion rate of contaminated fish). Such factors are used in the calculation of exposure to toxic chemicals.

Exposure Frequency - The number of occurrences in a given time frame (e.g., a lifetime) of contact or co-occurrence of a stressor with a receptor.

Exposure Investigation (in Public Health Assessment) - The collection and analysis of site-specific information and biologic tests (when appropriate) to determine whether people have been exposed to hazardous substances.

Exposure Modeling - The mathematical equations simulating how people interact with chemicals in their environment.

Exposure Pathway - The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway includes a source and release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also is included.

Exposure Profile - The exposure profile (ecological) identifies the receptors and describes the exposure pathways and intensity and spatial and temporal extent of exposure. It also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur. The profile may be a written document or a module of a larger process model.

Exposure Route - The way a chemical enters an organism after contact (e.g., by ingestion, inhalation, dermal absorption).

Exposure Scenario - A set of conditions or assumptions about sources, exposure pathways, concentrations of toxic chemicals, and populations (numbers, characteristics and habits) which aid the investigator in evaluating and quantifying exposure in a given situation.

Exposure Unit (in Geographical Information System applications) - The geographical area in which a receptor moves and contacts the contaminated medium during the period of exposure.

F

Factor Information Retrieval System (FIRE) - A database management system containing EPA's recommended emission estimation factors for criteria and hazardous air pollutants. FIRE includes information about industries and their emitting processes, the chemicals emitted, and the emission factors themselves. FIRE allows easy access to criteria and hazardous air pollutant emission factors obtained from the Compilation of Air Pollutant Emission Factors (AP-42), Locating and Estimating (L&E) documents, and the retired AFSEF and XATEF documents.

Fate and Transport - A description of how a chemical is carried through and changes in the environment.

Fate and Transport Analysis - The general process used to assess and predict the movement and behavior of chemicals in the environment.

Fate and Transport Modeling - The mathematical equations simulating a physical system which are used to assess and predict the movement and behavior of chemicals in the environment.

Fence Line - Delineated property boundary of a facility.

Field Study - Scientific study made in the ambient air to collect information that can not be obtained in a laboratory.

Food Chain - A sequence of organisms, each of which uses the next lower member of the sequence as a food source.

Forage - (1) Edible parts of plants, other than separated grain, that can provide feed for grazing animals or can be harvested for feeding, including browse, and herbage. (2) To search for or to consume forage (of animals).

Fugitive Release - Emission of a chemical to the air that does not occur from a stack, vent, duct, pipe or other confined air stream (e.g., leaks from joints).

Fumigation - (1) The use of a chemical compound in a gaseous state, often to kill pests such as insects, nematodes, arachnids, rodents, weeds, and fungi in confined or inaccessible locations or in the field. (2) a pattern of plume dispersion produced when a convective boundary layer grows upward into a plume trapped in a stable layer. The elevated plume is suddenly brought downward to the ground, producing high surface concentrations.

Future Scenario - A scenario used in risk assessment to anticipate potential future exposures of individuals (e.g., a housing development could be built on currently vacant land).

G

Geographic Information Systems (GIS) - A computer program that allows layering of different types of spatial information (i.e., on a map) to provide a better understanding of the characteristics of a certain place.

Generally Available Control Technology (GACT) Standard - These standards are less stringent standards than the Maximum Available Control Technology (MACT) standards, and are allowed at the Administrator's discretion for area sources according to the 1990 Clean Air Act Amendments for area sources.

Grab Sample -A single sample collected at a particular time and place that represents the composition of the water, air, or soil only at that time and place.

Great Waters Pollutants of Concern - The toxic pollutants of concern to the Great Waters program are mercury; cadmium and lead (and their compounds); dioxins; furans; polycyclic organic matter; polychlorinated biphenyls (PCBs); and the pesticides chlordane, DDT/DDE, dieldrin, hexachlorobenzene, alpha-hexachlorocyclohexane, lindane and toxaphene. Nitrogen compounds such as nitrogen oxides and ammonia are also pollutants of concern.

Greenhouse Effect - Trapping and build-up of heat in the atmosphere (troposphere) near the earth's surface. Some of the heat flowing back toward space from the earth's surface is absorbed by water vapor, carbon dioxide, ozone, and several other gases in the atmosphere and then re-radiated back toward the earth's surface. If the atmospheric concentrations of these greenhouse gases rise, the average temperature of the lower atmosphere will gradually increase.

Greenhouse Gas (GHG) - Any gas that absorbs infrared radiation in the atmosphere. Greenhouse gases include, but are not limited to, water vapor, carbon dioxide (CO_2), methane (CH_4), nitrous oxide (N_2O), hydrochlorofluorocarbons (HCFCs), ozone (O_3), hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), and sulfur hexafluoride (SF_6).

Guidelines (human health and ecological risk assessment) - Official documentation stating current U.S. EPA methodology in assessing risk of harm from environmental pollutants to human populations and ecological receptors.

H

Half-Life - The time required for a reaction or process to proceed such that half of the original amount of the substance of interest has reacted or undergone the process. Examples include: (1) the time required for a pollutant to degrade to one-half of its original concentration; (2) the time required for half of the atoms of a radioactive element to undergo self-transmutation or decay (half-life of radium is 1620 years); (3) the time required for elimination from the body to half a total dose.

Hazard - In a general sense, "hazard" is anything that has a potential to cause harm. In risk assessment, the likelihood of experiencing a noncancer health effect is called hazard (not risk).

Hazard Identification - The process of determining whether exposure to an agent can cause a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans at environmentally relevant doses.

Hazard Index (HI) -The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-term duration exposures.

Hazardous Air Pollutants (HAP) - Defined under the Clean Air Act as pollutants that cause or may cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental and ecological effects. Currently, the Clean Air Act regulates 188 chemicals and chemical categories as HAPs.

Hazard Quotient (HQ) - The ratio of a single substance exposure level over a specified time period (e.g., chronic) to a reference value (e.g., an RfC) for that substance derived from a similar exposure period.

Health Effects Assessment Tables (HEAST) - An older listing of (usually) interim toxicity values for chemicals of interest to Superfund, the Resource Conservation and Recovery Act (RCRA), and the EPA in general. HEAST values are generally placed low on the hierarchy of Agency recommended toxicity data sources and the compilation will eventually be phased out altogether.

Health Endpoint - An observable or measurable biological event used as an index to determine when a deviation in the normal function of the human body occurs.

Health Outcome Data (in Public Health Assessment) - Community-specific health information such as morbidity and mortality data, birth statistics, medical records, tumor and disease registries, surveillance data, and previously conducted health studies that may be collected at the local, state, and national levels by governments, private health care organizations, and professional institutions and associations.

Health Outcomes Study (in Public Health Assessment) - An investigation of exposed persons designed to assist in identifying exposure or effects on public health. Health studies also define the health problems that require further inquiry by means of, for example, a health surveillance or epidemiologic study.

Health Education (in Public Health Assessment) - Programs designed with a community to help it know about health risks and how to reduce these risks.

Health Consultation (in Public Health Assessment) - A review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical.

Henry's Law Constant - The ratio at equilibrium of the gas phase concentration to the liquid phase concentration of the gas.

High-End Exposure Estimate - A plausible estimate of individual exposure or dose for those persons at the upper end of an exposure or dose distribution, conceptually above the 90th percentile, but not higher than the individual in the population who has the highest exposure or dose.

Human Exposure Model (HEM) - An EPA model combining the Industrial Source Complex Short Term air dispersion model (ISCST) with a national set of meteorology files, U.S. census data, and a risk calculation component that can be used to estimate individual and population risks.

Hydrolysis - The decomposition of organic compounds by interaction with water.

I

Impervious Surface - A surface that cannot be penetrated by water (e.g., pavement).

Indirect Exposure Pathway - An indirect exposure pathway is one in which a receptor contacts a chemical in a medium that is different from the one to which the chemical was originally released (an example occurs with dioxin, which is emitted into the air, deposited on soil and accumulated in plants and animals which are then consumed by humans).

Individual Risk or Hazard - The risk or hazard to an individual in a population rather than to the population as a whole.

Indoor Source - Objects or places within buildings or other enclosed spaces that emit air pollutants.

Industrial Source Complex (ISC) Model - A steady-state Gaussian plume model which can be used to assess pollutant concentrations from a wide variety of sources associated with an industrial complex. This model can account for the following: settling and dry deposition of particles; downwash; point, area, line, and volume sources; plume rise as a function of downwind distance; separation of point sources; and limited terrain adjustment. ISC3 operates in both long-term (ISCLT) and short-term (ISCST) modes.

Influential Information - Scientific, financial, or statistical information that will have or does have a clear and substantial impact on important public policies or important private sector decisions.

Ingestion - Swallowing (such as eating or drinking).

Ingestion Exposure - Exposure to a chemical by swallowing it (such as eating or drinking).

Inhalation - Breathing.

Inhalation Exposure - Exposure to a chemical by breathing it in.

Inhalation Unit Risk (IUR) - The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 $\mu g/m^3$ in air. The interpretation of unit risk would be as follows: if unit risk = 2×10^{-6} $\mu g/m^3$, 2 excess tumors may develop per 1,000,000 people if exposed daily for a lifetime to a concentration of 1 µg of the chemical in 1 m^3 of air.

Intake - The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier, e.g., through ingestion or inhalation.

Intake Rate - Rate of inhalation, ingestion, and dermal contact depending on the route of exposure.

Integrated Risk Information System (IRIS) - An EPA database which contains information on human health effects that may result from exposure to various chemicals in the environment. IRIS was initially developed for EPA staff in response to a growing demand for consistent information on chemical substances for use in risk assessments, decision-making and regulatory activities. The information in IRIS is intended for those without extensive training in toxicology, but with some knowledge of health sciences.

Internal Dose - In exposure assessment, the amount of a substance penetrating the absorption barriers (e.g., skin, lung tissue, gastrointestinal tract) of an organism through either physical or biological processes.

Inversion - Subsidence Inversion - A temperature inversion that develops aloft as a result of air gradually sinking over a wide area and being warmed by adiabatic compression, usually associated with subtropical high pressure areas.

Inversion - Advection Inversion - Associated with the horizontal flow of warm air. Warm air moves over a cold surface, and the air nearest the surface cools, causing a surface-based inversion.

Inversion - Radiation Inversion - A thermally produced, surface-based inversion formed by rapid radiational cooling of the Earth's surface at night. It does not usually extend above the lower few hundred feet. Conditions which are favorable for this type of inversion are long nights, clear skies, dry air, little or no wind, and a cold or snow covered surface. It is also called a Nocturnal Inversion.

Iterative Process - Replication of a series of actions to produce successively better results, or to accommodate new and different critical information or scientific inferences.

Isopleths - A delineated line or area on a map that represent equal values of a variable.

L

Laboratory Studies - Research carried out in a laboratory (e.g., testing chemical substances, growing tissues in cultures, or performing microbiological, biochemical, hematological, microscopical, immunological, parasitological tests).

Leaching - The process by which soluble constituents are dissolved and filtered through the soil by a percolating fluid (usually rainwater).

Life Stage - A phase in the life cycle of an organism.

Line Source - A theoretical one-dimensional source from which releases may occur (e.g., roadways are often modeled as a one-dimensional line).

Lofting - In pollution studies, a pattern of flow that occurs when the top of a plume from a chimney stack disperses into slightly turbulent or neutral airflow conditions, while the lower part of the plume is prevented from dispersing down toward the surface by a stable boundary layer, especially at night. [Smith, J. [ed], 2001: The Facts on File Dictionary of Weather and Climate.]

Low-dose Extrapolation - An estimation of the dose-response relationship at doses less than the lowest dose studied experimentally.

Lowest Observed Adverse Effect Level (LOAEL) - The lowest exposure level in a study or group of studies at which there are statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group. Also referred to as lowest-effect level (LEL).

M

Major Source - Under the Clean Air Act, a stationary source that emits more than 10 tons or more per year of a single hazardous air pollutant (HAP) or 25 or more tons per year of all HAPs.

Margin of exposure (MOE) - The point of departure divided by the actual or projected environmental exposure of interest.

Mass-Balance Estimate - An estimate of release of a chemical based on, generally, a comparison of the amount of chemical in raw materials entering a process versus the amount of chemical going out in products.

Maximum Achievable Control Technology (MACT) - Under the Clean Air Act, a group of technology based standards, applicable to both major and some area sources of air toxics, that are aimed at reducing releases of air toxics to the environment. MACT standards are established on a source category by source category basis.

Maximum Exposed Individual (MEI) - The MEI represents the highest estimated risk to an exposed individual, regardless of whether people are expected to occupy that area.

Maximum Individual Risk (MIR) - An MIR represents the highest estimated risk to an exposed individual in areas that people are believed to occupy.

Metric (or Measure) of Exposure - The quantitative outcome of the exposure assessment. For air toxics risk assessments, personal air concentration (or adjusted exposure concentration) is the metric of exposure for the inhalation route of exposure and intake rate is the metric of exposure for the ingestion route of exposure.

Measurement - In air toxics assessment, a physical assessment (usually of the concentration of a pollutant) taken in an environmental or biological medium, normally with the intent of relating the measured value to the exposure of an organism.

Measurement Endpoint - A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. Also known as "measure of effect."

Mechanical Turbulence - Random irregularities of fluid motion in air caused by buildings or other nonthermal, processes.

Mechanistic Model - A model that uses information about a chemical or other agent's mechanism(s) of action – how it interacts with and harms the target organs – to predict the dose-response curve or other applications.

Media Concentrations - The amount of a given substance in a specific amount of environmental medium. For air, the concentration is usually given as micrograms (µg) of substance per cubic meter (m^3) of air; in water as µg of substance per L of water; and in soil as mg of substance per kg of soil.

Metabolism - Generally, the biochemical reactions by which energy is made available for the use of an organism. Metabolism includes all chemical transformations occurring in an organism from the time a substance enters, until it has been utilized and the waste products eliminated. In toxicology, metabolism of a toxicant consists of a series of chemical transformations that take place within an organism. A wide range of enzymes act on toxicants, that may increase water solubility, and facilitate elimination from the organism. In some cases, however, metabolites may be more toxic than their parent compound.

Meteorology - The science of the atmosphere, including weather.

Microcosm Studies - Studies of the effects of stressors on multiple species found in multiple media which are conducted in enclosed experimental systems.

Microscale Assessment - An air monitoring network designed to assess concentrations in air volumes associated with area dimensions ranging from several meters up to about 100 meters.

Microenvironment - A small 3-dimensional space (e.g., an office, a room in a home) that can be treated as homogeneous (or well characterized) with regard to exposure concentration of a chemical.

Middle Scale Assessment - An air monitoring network designed to assess concentrations typical of areas up to several city blocks in size with dimensions ranging from about 100 meters to 0.5 kilometer.

Minimal Risk Levels (MRL) - Derived by ATSDR, an MRL is defined as an estimate of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects (noncancer) over a specified duration of exposure. MRLs can be derived for acute, intermediate, and chronic duration exposures by the inhalation and oral routes.

Mixed (Mixing) Layer - In the atmosphere, that part of the turbulent boundary layer that is dominated by turbulent diffusion caused by eddies generated by friction with the surface and thermals arising from surface heat sources. Surface heating during the day and the absence of temperature inversions allow components of the air within the planetary boundary layer to exhibit mainly random vertical movements. Such movements may become more organized into gusts of wind and dust devils during the afternoon. Despite being random, the turbulent movements allow the transfer of atmospheric properties, such as heat, water vapor, momentum, and air pollutants, from the near surface up through the planetary boundary layer.

Mixing Height - The depth through which atmospheric pollutants are typically mixed by dispersive processes.

Mixtures - Any set of multiple chemical substances occurring together in an environmental medium.

Mobile Source Air Toxics - Air toxics that are emitted from non-stationary objects that release pollution. Mobile sources include cars, trucks, buses, planes, trains, motorcycles and gasoline-powered lawn mowers. Another example is a portable generator.

Model - A mathematical representation of a natural system intended to mimic the behavior of the real system, allowing description of empirical data, and predictions about untested states of the system.

Model Uncertainty - Uncertainty due to necessary simplification of real-world processes, mis-specification of the model structure, model misuse, or use of inappropriate surrogate variables or inputs.

Modeling - An investigative technique using a mathematical or physical representation of a system or theory that accounts for all or some of its known properties.

Modeling Node - In air quality modeling, the location where impacts are predicted.

Monitoring - Periodic or continuous physical surveillance or testing to determine pollutant levels in various environmental media or in humans, plants, and animals.

Monte Carlo Technique- A repeated random sampling from the distribution of values for each of the parameters in a generic exposure or risk equation to derive an estimate of the distribution of exposures or risks in the population.

Multipathway Assessment - An assessment that considers more than one exposure pathway. For example, evaluation of exposure through both inhalation and ingestion would be a multipathway assessment. Another example would be evaluation of ingestion of contaminated soil and ingestion of contaminated food.

Multipathway Exposure - When an organism is exposed to pollutants through more than one exposure pathway. One example would be exposure through both inhalation and ingestion. Another example would be ingestion of contaminated soil and ingestion of contaminated food.

Multipathway Risk - The risk resulting from exposure to pollutants through more than one pathway.

Multistage Model - A mathematical function used to extrapolate the probability of cancer from animal bioassay data, using the form:

$$P(d) = 1 - e^{-\left(q_0 + q_1 d + q_2 d^2 + \ldots + q_k d^k\right)}$$

where:

P(d)	=	probability of cancer from a continuous, lifetime exposure rate d;
q_i	=	fitted dose coefficients of model; i = 0, 1, . . ., k; and
k	=	number of stages selected through best fit of the model, no greater than one less than the number of available dose groups.

Mutagen - A chemical that causes a permanent genetic change in a cell other than that which occurs during normal growth.

Mutagenicity - The capacity of a chemical or physical agent to cause permanent genetic change in a cell other than that which occurs during normal growth.

N

National Ambient Air Quality Standards (NAAQS) - Maximum air pollutant standards that EPA has set under the Clean Air Act for attainment by each state. Standards are set for each of the criteria pollutants.

National Air Toxics Assessment (NATA) - EPA's ongoing comprehensive evaluation of air toxics in the U.S. Activities include expansion of air toxics monitoring, improving and periodically updating emission inventories, improving national- and local-scale modeling and risk characterization, continued research on health effects and exposures to both ambient and indoor air, and improvement of assessment tools.

National Emissions Inventory (NEI) - EPA's primary emissions inventory of HAPs.

National Emissions Standards for Hazardous Air Pollutants (NESHAPs) - Emissions standards set by EPA for hazardous air pollutants. Also commonly referred to as the MACT standards.

National Emissions Trends (NET) Database - The NET database is an emission inventory that contains data on stationary and mobile sources that emit criteria air pollutants and their precursors. The database also includes estimates of annual emissions of these pollutants from point, area, and mobile sources. The NET is developed every three years (e.g., 1996 and 1999) by EPA, and includes emission estimates for all 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands.

Natural Source - Non-manmade emission sources, including biological (biogenic sources such as plants) and geological sources (such as volcanoes), and windblown dust.

Neighborhood Scale Assessment - An air monitoring network designed to assess concentrations within some extended area of the city that has relatively uniform land use with dimensions in the 0.5 to 4.0 kilometers range.

Neurotoxicity - Ability to damage nervous system tissue or adversely effect nervous system function.

New Source Review - A Clean Air Act requirement that State Implementation Plans must include a permit review that applies to the construction and operation of new and modified stationary sources in nonattainment areas to ensure attainment of national ambient air quality standards.

New Source Performance Standards - Uniform national EPA air emission standards which limit the amount of pollution allowed from new sources or from modified existing sources.

Noncarcinogenic Effect - Any health effect other than cancer. Note that, while not all noncancer toxicants cause cancer, all carcinogens exhibit noncarcinogenic effects.

No Observable Adverse Effect Level (NOAEL) - An highest exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse, nor precursors to adverse effects.

Nonpoint Source (NEI sense) - Diffuse pollution sources that are not assigned a single point of origin (e.g., multiple dry cleaners in a county which are only described in an inventory in the aggregate).

Nonroad Mobile Sources - Sources such as farm and construction equipment, gasoline-powered lawn and garden equipment, and power boats and outdoor motors that emit pollutants.

Non-Threshold Effect - An effect (usually an adverse health effect) for which there is no exposure level below which the effect is not expected to occur.

Non-Threshold Toxicant - A chemical for which there is no exposure level below which an adverse health outcome is not expected to occur. Such substances are considered to pose some risk of harm at any level of exposure.

Non Steady-state Model - A dynamic model; a mathematical formulation describing and simulating the physical behavior of a system or a process and its temporal variability.

North American Industry Classification System (NAICS) - NAICS replaced the Standard Industrial Classification (SIC) beginning in 1997. This industry-wide classification system has been designed as the index for statistical reporting of all economic activities of the U.S., Canada, and Mexico. NAICS industries are identified by a 6-digit code. The international NAICS agreement fixes only the first five digits of the code. The sixth digit, where used, identifies subdivisions of NAICS industries that accommodate user needs in individual countries.

O

Octanol/Water Partition Coefficient (K_{ow}) - The ratio of a chemical's solubility in n-octanol to its solubility in water at equilibrium. This measure is often used as an indication of a chemical's ability to bioconcentrate in organisms.

Office of Air and Radiation (OAR) - EPA's Office responsible for providing information about air pollution, clean air, air quality and radiation. OAR develops national programs, technical policies, and regulations for controlling air pollution and radiation exposure. OAR is concerned with pollution prevention, indoor and outdoor air quality, industrial air pollution, pollution from vehicles and engines, radon, acid rain, stratospheric ozone depletion, and radiation protection.

Office of Air Quality, Planning, and Standards (OAQPS) - An EPA Office within OAR whose primary mission is to preserve and improve air quality in the United States. As part of this goal, OAQPS monitors and reports on air quality, air toxics, and emissions. They also respond to visibility issues, as they relate to the level of air pollution. In addition, OAQPS is tasked by the EPA with providing technical information for professionals involved with monitoring and controlling air pollution, creating governmental policies, rules, and guidance (especially for stationary sources), and educating the public about air pollution and what can be done to control and prevent it.

OAQPS Toxicity Table - The EPA Office of Air and Radiation recommended default chronic toxicity values for hazardous air pollutants. They are generally appropriate for screening-level risk assessments, including assessments of select contaminants, exposure routes, or emission sources of potential concern, or to help set priorities for further research. For more complex, refined risk assessments developed to support regulatory decisions for single sources or substances, dose-response data may be evaluated in detail for each "risk driver" to incorporate appropriate new toxicological data. (http://www.epa.gov/ttn/atw/toxsource/summary.html)

Office of Radiation and Indoor Air (ORIA) - An EPA Office within OAR whose mission is to protect the public and the environment from the risks of radiation and indoor air pollution. The Office develops protection criteria, standards, and policies; works with other programs within EPA and other agencies to control radiation and indoor air pollution exposures; provides technical assistance to states through EPA's regional offices, and to other agencies having radiation and indoor air protection programs; directs an environmental radiation monitoring program; responds to radiological emergencies; and evaluates and assesses the overall risk and impact of radiation and indoor air pollution.

Office of Transportation and Air Quality (OTAQ) - An EPA Office within OAR whose mission is to reconcile the transportation sector with the environment by advancing clean fuels and technology, and working to promote more liveable communities. OTAQ is responsible for carrying out laws to control air pollution from motor vehicles, engines, and their fuels. Mobile sources include: cars and light trucks, large trucks and buses, farm and construction equipment, lawn and garden equipment, marine engines, aircraft, and locomotives.

Onroad Mobile Source - Any mobile source of air pollution such as cars, trucks, motorcycles, and buses that travels on roads and highways.

Open Pit Source - Large, open pits, such as surface coal mines and rock quarries.

Operating Permit Program - A program required by the Clean Air Act; requires existing industrial sources to obtain an"operating permit". The operating permit program is a national permitting system that consolidates all of the air pollution control requirements into a single, comprehensive "operating permit" that covers all aspects of a source's year-to-year air pollution activities.

P

Particle-bound - Reversibly absorbed or condensed onto the surface of particles.

Particulates/Particulate Matter (PM) - Solid particles or liquid droplets suspended or carried in the air.

Partitioning - The separation or division of a substance into two or more compartments. Environmental partitioning refers to the distribution of a chemical into various media (soil, air, water, and biota).

Partitioning Model - Models consisting of mathematical equations that estimate how chemicals will divide (i.e., partition) among abiotic and biotic media in a given environment based on chemical- and site- specific characteristics.

Passive Monitor - A type of air toxics monitor that collects airborne pollutants by absorption onto a reactive material (for example, sorbent tube, filter) for subsequent laboratory analysis. No pump is used to draw the air across the reactive material. This type of monitor is usually used for personal exposure monitoring or work space monitoring.

Pathway Specific Risk - The risk associated with exposure to a chemical agent or a mixture of chemicals via a specific pathway (e.g., inhalation of outdoor air).

Persistent, Bioaccumulative, and Toxic (PBT) Chemicals - Highly toxic, long-lasting substances that can build up in the food chain to levels that are harmful to human and ecosystem health. They are associated with a range of adverse health effects, including effects on the nervous system, reproductive and developmental problems, cancer, and genetic impacts.

Percentile - Any one of the points dividing a distribution of values into parts each of which contain 1/100 of the values. For example, the 75th percentile is a value such that 75 percent of the values are less than or equal to it.

Persistence - Refers to the length of time a compound stays in the environment, once introduced. A compound may persist for very short amounts of time (e.g., fractions of a second) or for long periods of time (e.g., hundreds of years).

Persistent Organic Pollutants (POPs) - Highly stable organic compounds used as pesticides or in industry. They are also generated unintentionally as the byproduct of combustion and industrial processes. POPs are a special problem because they persist in the environment, accumulate in the tissues of living organisms, and are toxic to humans and wildlife. POPs with these characteristics are typically semi-volatile, enabling them to move long distances and condense over colder regions of the earth. These properties lead to increased concern for the toxic effects that they can exert on a range of biota, in particular on top-of-the-food chain species, even at extremely low levels in the ambient environment.

Personal Air Monitoring Device - Unlike a passive air toxics monitor, this device uses a pump to draw the air sample through to measure exposure in the immediate vicinity of an individual. The air sample can be drawn across a reactive material (to be analayzed in a laboratory), or it can be drawn through a direct-read detector.

Personal Monitoring - A measurement collected from an individual's immediate environment using active or passive devices to collect the samples.

Pervious Surface - A surface that can be penetrated (usually in reference to water; e.g., crop land).

Pharmacodynamics - Process of interaction of pharmacologically active substances with target sites, and the biochemical and physiological consequences leading to therapeutic or adverse effects.

Pharmacokinetics - The study of the absorption, distribution, metabolism, and excretion of chemicals in living organisms and the genetic, nutritional, behavioral, and environmental factors that modify these parameters.

Photolysis - The breakdown of a material by sunlight; an important mechanism for the degradation of contaminants in air, surface water, and the terrestrial environment.

Physical Factors - Manmade and/or natural characteristics or features that influence the movement of pollutants in the environment (e.g., settling velocity, terrain effects).

Physiologically Based Pharmacokinetic (PBPK) Model - A computer model that describes what happens to a chemical in the body of a human or laboratory animal. It describes how the chemical gets into the body, where it goes in the body, how it is changed by the body, and how it leaves the body.

Piscivorous - A species feeding preferably on fish.

Planning and Scoping - The process of determining the purpose, scope, players, expected outcomes, analytical approach, schedule, deliverables, QA/QC, resources, and document requirements for the risk assessment.

Plume - The visible or measurable presence of a contaminant in the atmosphere, once released from a given point of origin (e.g., a plume of smoke from a forest fire).

Plume Height - The elevation to which a plume travels (i.e., the sum of the release height and plume rise).

Plume Rise - The height to which a plume rises in the atmosphere from the point of release.

Plume Transport - The movement of a plume through the atmosphere and across land and water features.

Plume Washout - The removal of a substance from the atmosphere via a precipitation event.

PM-10/PM-2.5. PM-10 or PM_{10} refers to particles in the atmosphere with a diameter of less than ten or equal to 10 micrometers. PM-2.5 or $PM_{2.5}$ refers to smaller particles in the air (i.e., less than or equal to 2.5 micrometers in diameter).

Point of Departure (PoD) - The dose-response point that marks the beginning of a low-dose extrapolation. This point can be the lower bound on dose for an estimated incidence or a change in response level from a dose-response model (BMD), or a NOAEL or LOAEL for an observed incidence, or change in level of response.

Point of Exposure - The location of potential contact between an organism and a chemical or physical agent.

Point of Release - Location of release to the environment.

Point Source (NEI sense) - A source of air pollution which can be physically located on a map.

Point Source (non-NEI sense) - A stack, vent, duct, pipe or other confined air stream from which chemicals may be released to the air.

Pollutant Release and Transfer Registries (PRTRs) - The international equivalent to the Toxics Release Inventory (TRI). PRTRs are data banks of recorded information of the releases

and transfers of toxic chemicals from industries, such as manufacturers, mining facilities, processors, or government-owned and operated facilities.

Population Risk or Hazard - Population risk refers to an estimate of the extent of harm for the population or population segment being addressed. It often refers to an analysis of the number of people living at a particular risk or hazard level.

Potential Risk - Estimated likelihood, or probability, of injury, disease, or death resulting from exposure to a potential environmental hazard.

Potential Dose - The amount of a compound contained in material swallowed, breathed, or applied to the skin.

Practical Quantitation Limit - The lowest level of quantitation that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions.

Precision - A measure of the reproducibility of a measured value under a given set of circumstances.

Present Scenario - Risk characterizations using present scenarios to estimate risks to individuals (or populations) that currently reside in areas where potential exposures may occur (e.g., using an existing population within some specified area).

Prevailing Wind - Direction from which the wind blows most frequently.

Prevention of Significant Deterioration (PSD) - An EPA program in which state and/or federal permits are required in order to restrict emissions from new or modified sources in places where air quality already meets or exceeds primary and secondary ambient air quality standards.

Primary Standard - A pollution limit based on health effects. Primary standards are set for criteria air pollutants.

Probabilistic - A type of statistical modeling approach used to assess the expected frequency and magnitude of a parameter by running repetitive simulations using statistically selected inputs for the determinants of that parameter (e.g., rainfall, pollutants, flows, temperature).

Probabilistic Risk Assessment/Analysis - Calculation and expression of health risks using multiple risk descriptors to provide the likelihood of various risk levels. Probabilistic risk results approximate a full range of possible outcomes and the likelihood of each, which often is presented as a frequency distribution graph, thus allowing uncertainty or variability to be expressed quantitatively.

Probability Density Function (PDF) - The PDF is alternatively referred to in the literature as the probability function or the frequency function. For continuous random variables, that is, the random variables which can assume any value within some defined range (either finite or infinite), the probability density function expresses the probability that the random variable falls within some very small interval. For discrete random variables, that is, random variables which can only assume certain isolated or fixed values, the term probability mass function (PMF) is preferred over the term probability density function. PMF expresses the probability that the random variable takes on a specific value.

Problem Formulation (in Ecological Risk Assessment) - The initial stage of a risk assessment where the purpose of the assessment is articulated, assessment endpoints and a conceptual model are developed, and a plan for analyzing and characterizing risk is determined.

Problem Statement - A statement of the perceived problem to be studied by the risk assessment. Problem statements often also include statements about how the problem is going to be studied.

Public Health Consultation (Public Health Assessment) - See health consultation.

Public Health Assessment (PHA) - An evaluation of hazardous substances, health outcomes, and community concerns at a hazardous waste site or other potential source of pollutants to determine whether people could be harmed from coming into contact with those substances. The PHA also lists actions that need to be taken to protect public health.

Public Health Advisory (in Public Health Assessment) - A statement made by a regulatory agency that a release of hazardous substances or contamination by microbial pathogens poses an immediate threat to human health. The advisory includes recommended measures to reduce exposure and reduce the threat to human health.

Public Health Hazard Category (in Public Health Assessment) - Statements about whether people could be harmed by conditions present at the site in the past, present, or future. One or more hazard categories might be appropriate for each site. ATSDR's five public health hazard categories are no public health hazard, no apparent public health hazard, indeterminate public health hazard, public health hazard, and urgent public health hazard.

Q

Qualitative Uncertainty Estimate - A detailed examination, using qualitative information, of the systematic and random errors of a measurement or estimate.

Quality Assurance Project Plan - A document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Quality Assurance - An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality Control - The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of its users. The aim is to provide data quality that is satisfactory, adequate, and dependable.

R

Random Variable - A quantity which can take on any number of values but whose exact value cannot be known before a direct observation is made. For example, the outcome of the toss of a pair of dice is a random variable, as is the height or weight of a person selected at random from a city phone book.

Receptor (modeling sense) - In fate/transport modeling, the location where impacts are predicted.

Receptor (non-modeling sense) - The entity which is exposed to an environmental stressor.

Red Book - 1983 NRC publication entitled *Risk Assessment in the Federal Government: Managing the Process*.

Reference Concentration (RfC) - An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Reference Dose (RfD) - An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Reference Media Evaluation Guides (RMEG) - A type of comparison value derived by ATSDR to protect the most sensitive populations. They do not consider carcinogenic effects, chemical interactions, multiple route exposure, or other media-specific routes of exposure, and are very conservative concentration values designed to protect sensitive members of the population.

Regional/National Scale Assessment - An air monitoring network designed to assess from tens to hundreds of kilometers, up to the entire nation.

Relative Potency Factor - The ratio of the toxic potency of a given chemical to that of an index chemical.

Release Parameters - The specific physical characteristics of the release (e.g., stack diameter, stack height, release flow rate, temperature).

Representativeness - The degree to which one or a few samples are characteristic of a larger population about which the analyst is attempting to make an inference.

Reproductive Toxicity - The occurrence of biologically adverse effects on the reproductive systems of females or males that may result from exposure to environmental agents. The toxicity may be expressed as alterations to the female or male reproductive organs, the related endocrine system, or pregnancy outcomes. The manifestation of such toxicity may include, but not be limited to, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behavior, fertility, gestation, parturition, lactation, developmental toxicity, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

Residual Risk - The extent of health risk from air pollutants remaining after application of the Maximum Achievable Control Technology (MACT).

Resources - Money, time, equipment, and personnel available to perform the assessment.

Risk (in the context of human health) - The probability of injury, disease, or death from exposure to a chemical agent or a mixture of chemicals. In quantitative terms, risk is expressed in values ranging from zero (representing the certainty that harm will not occur) to one (representing the certainty that harm will occur). (Compare with hazard.)

Risk Assessor(s) - The person or group of people responsible for conducting a qualitative and quantitative evaluation of the risk posed to human health and/or the environment by environmental pollutants.

Risk Assessment - For air toxics, the scientific activity of evaluating the toxic properties of a chemical and the conditions of human or ecological exposure to it in order both to ascertain the likelihood that exposed humans or ecological receptors will be adversely affected, and to characterize the nature of the effects they may experience.

Risk Assessment Forum - A standing committee of senior EPA scientists which was established to promote Agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate Agency risk assessment guidance.

Risk Assessment Work Plan - A document that outlines the specific methods to be used to assess risk, and the protocol for presenting risk results. The risk assessment workplan may consist of one document or the compilation of several workplans that, together, constitute the overall risk assessment workplan.

Risk Characterization - The last phase of the risk assessment process in which the information from the toxicity and exposure assessment steps are integrated and an overall conclusion about risk is synthesized that is complete, informative and useful for decision-makers. In all cases, major issues and uncertainty and variability associated with determining the nature and extent of the risk should be identified and discussed. The risk characterization should be prepared in a manner that is clear, transparent, reasonable and consistent.

Risk Communication - The exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, and other stakeholders.

Risk Management - The decision-making process that uses the results of risk assessment to produce a decision about environmental action. Risk management includes consideration of technical, scientific, social, economic, and political information.

Risk Manager(s) - The person or group responsible for evaluating and selecting alternative regulatory and non-regulatory responses to risk.

Root Uptake - The uptake of compounds available in the soil and their transfer to the above ground portions of the plant.

Route-to-Route Extrapolation - Calculations to estimate the dose-response relationship of an exposure route for which experimental data do not exist or are inadequate, and which are based on existing experimental data for other route(s) of exposure.

Runoff - That part of precipitation, snow melt, or irrigation water that runs off the land into streams or other surface water. It can carry pollutants from the air and land into receiving waters.

S

Sample - A small portion of something designed to evaluate the nature or quality of the whole (for example, one or several samples of air used to evaluate air quality generally).

Sampling and Analysis Plan - An established set of procedures specifying how a sample is to be collected, handled, analyzed, and the data validated and reported.

Sampling Frequency - The time interval between the collection of successive samples.

Science Advisory Board (SAB) - A group of recognized, non-EPA experts who advise EPA on science and science policy.

Scenario Uncertainty - Uncertainty due to descriptive errors, aggregation errors, errors in professional judgment, or incomplete analysis.

SCREEN3 - An air dispersion model developed to obtain conservative estimates of air concentration for use in screening level assessments through the use of conservative algorithms and meteorology.

Screening-level Risk Assessment - A risk assessment performed with few data and many conservative assumptions to identify exposures that should be evaluated more carefully for potential risk.

Secondary Production/Pollutant - Formation of pollutants in the atmosphere by chemical transformation of precursor compounds.

Secondary Standard - A pollution limit based on environmental effects (e.g., damage to property, plants, visibility). Secondary standards are set for criteria air pollutants.

Sensitive Subgroups - Identifiable subsets of the general population that, due to differential exposure or susceptibility, are at greater risk than the general population to the toxic effects of a specific air pollutant (e.g., depending on the pollutant and the exposure circumstances, these may be groups such as subsistence fishers, infants, asthmatics, or the elderly).

Settling Velocity/Rate - The maximum speed at which a particle will fall in still air. It is a function of its size, density, and shape.

Silage - Stored vegetation used as feed for cattle.

Simulation - A representation of a problem, situation in mathematical terms, especially using a computer.

Soil Volumetric Water Content - The soil-water content expressed as the volume of water per unit bulk volume of soil.

Soil Dry Bulk Density - The mass of dry soil per unit bulk volume.

Soil Erosion - Detachment and movement of topsoil or soil material from the upper part of the soil profile, by the action of wind or running water, especially as a result of changes brought about by human activity, such as unsuitable or mismanaged agriculture.

Solar Radiation - Energy from the sun. Of importance to the climate system, solar radiation includes ultra-violet radiation, visible radiation, and infrared radiation.

Solubility - The amount of mass of a compound that will dissolve in a unit volume of solution. Aqueous solubility is the maximum concentration of a chemical that will dissolve in pure water at a reference temperature.

Source - Any place or object from which pollutants are released.

Source Category - A group of similar industrial processes or industries that are contributors to releases of hazardous air pollutants. The 1990 amendments to the Clean Air Act (CAA) requires that the EPA publish and regularly update a listing of all categories and subcategories of major and area sources that emit hazardous air pollutants.

Source Characterization - The detailed description of the source (e.g., location, source of pollutant releases, pollutants released, release parameters).

Spatial Variability - The magnitude of difference in contaminant concentrations in samples separated by a known distance.

SPECIATE - EPA's repository of Total Organic Compound (TOC) and Particulate Matter (PM) speciated profiles for a variety of sources for use in source apportionment studies. The profiles in the system are provided as a library of available profiles for source-receptor and source apportionment type models, such as Chemical Mass Balance 8 (CMB8).

Stable Conditions (in the Atmosphere) - Air with little or no tendency to rise, that is usually accompanied by clear dry weather. Stable air holds, instead of dispersing, pollutants. [National Weather Service, Southern Region Headquarters' Jetstream Weather School, http://www.srh.weather.gov/jetstream/append/glossary.htm and EPA, 1997: Terms of Environment, http://www.epa.gov/OCEPAterms/.]

Stack - A chimney, smokestack, or vertical pipe that discharges used air.

Stack Release - The release of a chemical through a stack.

Stack Testing - The monitoring, by testing, of chemicals released from a stack.

Stakeholder(s) - Any organization, governmental entity, or individual that has a stake in or may be impacted by a given approach to environmental regulation, pollution prevention, energy conservation, etc.

Standard Industrial Classification (SIC) - A method of grouping industries with similar products or services and assigning codes to these groups.

Standard Operating Procedure (SOP) - A established set of written procedures adopted and used to guide the work of for a specific project. For example, an air monitoring study would include SOPs on sample collection and handling and SOPs on analytical requirements and data validation and reporting.

Standing Crop - The quantity of plant biomass in a given area, usually expressed as density (dry mass per unit area) or energy content per unit area.

Stationary Source - A source of pollution that is fixed in space.

Steady-state Model - Mathematical model of fate and transport that uses constant values of input variables to predict constant values of receiving media concentrations.

Stochastic - Involving or containing a random variable; involving probability or chance.

Stressor - Any physical, chemical, or biological entity that can induce adverse effects on ecosystems or human health.

Stressor-response Profile or Relationship (in Ecological Risk Assessment] - The product of characterization of ecological effects in the analysis phase of ecological risk assessment. The stressor-response profile/relationship summarizes the data on the effects of a stressor and the relationship of the data to the assessment endpoint.

Structure-activity Relationship (SAR) - Mathematical or qualitative expression of the relationships between biological activity or toxicity of a chemical to its chemical structure or substructure. Ideally, such relationships can be formulated as Quantitative Structure Activity Relationships (QSARs), in which some degree of predictive capability is present. [Air Risk Information Support Center, OAQPS, March 1989: Glossary of Terms Related to Health, Exposure, and Risk Assessment. EPA/450/3-88/016.]

Support Center for Regulatory Models (SCRAM) - An EPA website that is a source of information on atmospheric dispersion models (e.g., ISCST3, SCREEN 3, and ASPEN) that support regulatory programs required by the Clean Air Act. Documentation and guidance for these computerized models are a major feature of this website. This site also contains computer code, data, and technical documents that deal with mathematical modeling for the dispersion of air pollutants.

Synergistic Effect - A situation in which the overall effect of two chemicals acting together is greater than the simple sum of their individual effects.

T

Target Organ - The biological organ(s) most adversely affected by exposure to a chemical substance (e.g., the site of the critical effect).

Target Organ Specific Hazard Index (TOSHI) - The sum of hazard quotients for individual air toxics that affect the same organ/organ system or act by similar toxicologic processes

Temporal Variability - The difference in contaminant concentrations observed in samples taken at different times.

Teratogenesis - The introduction of nonhereditary birth defects in a developing fetus by exogenous factors such as physical or chemical agents acting in the womb to interfere with normal embryonic development.

Terrain Effects - The impact on the airflow as it passes over complex land features such as mountains.

Terrestrial Radiation - The total infrared radiation emitted by the earth and its atmosphere in the temperature range of approximately 200 to 300 Kelvin. Terrestrial radiation provides a major part of the potential energy changes necessary to drive the atmospheric wind system and is responsible for maintaining the surface air temperature within limits of livability.

Thermal Turbulence - Turbulent vertical motions that result from surface heating and the subsequent rising and sinking of air.

Threshold Dose/Threshold - The lowest dose of a chemical at which a specified measurable effect is observed and below which it is not observed.

Threshold Effect - An effect (usually an adverse health effect) for which there is an exposure level below which the effect is not expected to occur.

Threshold Toxicant - A chemical for which there is an exposure level below which an adverse health outcome is not expected to occur.

Tiered Analysis - An analysis arranged in layers/steps. Risk assessments/analyses are often conducted in consecutive layers/steps that begin with a reliance on conservative assumptions and little data (resulting in less certain, but generally conservative answers) and move to more study-area specific data and less reliance on assumptions (resulting in more realistic answers). The level of effort and resources also increases with the development of more realistic data.

Time-integrated Sample - Samples are collected over a period of time. Only the total pollutant collected is measured, and so only the average concentration during the sampling period can be determined.

Time-trend Study - Samples spaced in time to capture systematic temporal trends (e.g., a facility might change its production methods or products over time).

Time-weighted Sum of Exposures - Used in inhalation exposure modeling. Provides a total exposure from all different microenvironments in which a person spends time.

Toxic Air Pollutants - see hazardous air pollutant.

Toxicity - The degree to which a substance or mixture of substances can harm humans or environmental receptors.

Toxicity Assessment - Characterization of the toxicological properties and effects of a chemical, with special emphasis on establishment of dose-response characteristics.

Toxicity Test - Biological testing (usually with an cell system, invertebrate, fish, or small mammal) to determine the adverse effects of a compound.

Toxicology - The study of harmful interactions between chemicals and biological systems.

Toxic Release Inventory (TRI) - Annual database of releases to air, land, and water, and information on waste management in the United States of over 650 chemicals and chemical compounds. This data is collected under Section 313 of the Emergency Planning and Community Right to Know Act.

Trajectory - The track taken by a parcel of air as it moves within the atmosphere over a given period.

Transformation - The change of a chemical from one form to another.

Transparency - Conducting a risk assessment in such a manner that all of the scientific analyses, uncertainties, assumptions, and science policies which underlie the decisions made throughout the risk assessment are clearly stated (i.e., made readily apparent).

Turbulence - Irregular motion of the atmosphere, as indicated by gusts and lulls in the wind.

U

Uncertainty - Uncertainty represents a lack of knowledge about factors affecting exposure/toxicity assessments and risk characterization and can lead to inaccurate or biased estimates of risk and hazard. Some of the types of uncertainty include scenario uncertainty, parameter uncertainty, and model uncertainty.

Uncertainty analysis - A detailed examination of the systematic and random errors of a measurement or estimate (in this case a risk or hazard estimate); an analytical process to provide information regarding the uncertainty.

Uncertainty Factor (UF) - One of several, generally 10-fold factors, used in operationally deriving the RfD and RfC from experimental data. UFs are intended to account for (1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to humans, i.e., interspecies variability; (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure, i.e., extrapolating from subchronic to chronic exposure; (4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and (5) the uncertainty associated with extrapolation from animal data when the data base is incomplete.

Universal Soil Loss Equation - An equation used to predict the average annual soil loss per unit area per year.

Unit Risk Estimate (URE) - The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1µ g/L in water, or 1 $\mu g/m^3$ in air. The interpretation of unit risk would be as follows: if the water unit risk = 2×10^{-6} µg/L, 2 excess tumors may develop per 1,000,000 people if exposed daily for a lifetime to 1 µg of the chemical in 1 liter of drinking water.

Unstable Conditions (in the Atmosphere) - An atmospheric state in which warm air is below cold air. Since warm air naturally rises above cold air (due to warm air being less dense than cold air), vertical movement and mixing of air layers can occur.

Uptake - The process by which a substance crosses an absorption barrier and is absorbed into the body.

Urban Scale Assessment - An air monitoring network designed to assess the overall, citywide conditions with dimensions on the order of 4 to 50 kilometers. This scale would usually require more than one site for definition.

V

Vapor - The gas given off by substances that are solids or liquids at ordinary atmospheric pressure and temperatures.

Variability - Refers to the observed differences attributable to true heterogeneity or diversity in a population or exposure parameter. Examples include human physiological variation (e.g., natural variation in body weight, height, breathing rate, drinking water intake rate), weather variability, variation in soil types and differences in contaminant concentrations in the environment. Variability is usually not reducible by further measurement of study, but it can be better characterized.

Volatilization/Vapor Release - The conversion of a liquid or solid into vapors.

Volume Source - In air dispersion modeling, a three dimensional volume from which a release may occur (e.g., a gas station modeled as a box from which chemicals are emitted).

W

Watershed - The land area that drains into a stream; the watershed for a major river may encompass a number of smaller watersheds that ultimately combine at a common point.

Weight-of-Evidence (WOE) - A system for characterizing the extent to which the available data support the hypothesis that an agent causes an adverse health effect in humans. For example, under EPA's 1986 cancer risk assessment guidelines, the WOE was described by categories "A through E," Group A for known human carcinogens through Group E for agents with evidence of noncarcinogenicity. The approach outlined in EPA's proposed guidelines for carcinogen risk assessment (1996 and updates) considers all scientific information in determining whether and under what conditions an agent may cause cancer in humans, and provides a narrative approach to characterize carcinogenicity rather than categories.

White Book - 1996 Presidential Commission on Risk Assessment and Risk Management (CRARM) publication entitled *Risk Assessment and Risk Management in Regulatory Decision-Making*.

Wind Rose - A graphical display showing the frequency and strength of winds from different directions over some period of time.

Appendix A Listing of All HAPs

Appendix A. Listing of HAPs

CAS Number	Chemical Name	Common Name	CAA HAP	TRI Chemical	Urban HAP	Mobile Source Air Toxic
75-07-0	Acetaldehyde		X	X	X	X
60-35-5	Acetamide		X	X		
75-05-8	Acetonitrile		X	X		
98-86-2	Acetophenone		X	X		
53-96-3	2-Acetylaminofluorene		X	X		
107-02-8	Acrolein		X	X	X	X
79-06-1	Acrylamide		X	X		
79-10-7	Acrylic acid		X	X		
107-13-1	Acrylonitrile		X	X	X	
107-05-1	Allyl chloride		X	X		
92-67-1	4-Aminobiphenyl		X	X		
62-53-3	Aniline		X	X		
90-04-0	o-Anisidine		X	X		
1332-21-4	Asbestos		X	X		
71-43-2	Benzene (including benzene from gasoline)		X	X	X	X
92-87-5	Benzidine		X	X		
98-07-7	Benzotrichloride		X	X		
100-44-7	Benzylchloride		X	X		
92-52-4	Biphenyl		X	X		
117-81-7	Bis (2-ethylhexyl) phthalate	DEHP	X	X		
542-88-1	Bis(chloromethyl)ether		X	X		
75-25-2	Bromoform		X	X		
106-99-0	1,3-Butadiene		X	X	X	X
156-62-7	Calcium cyanamide		X	X		
133-06-2	Captan		X	X		
63-25-2	Carbaryl		X	X		
75-15-0	Carbon disulfide		X	X		
56-23-5	Carbon tetrachloride		X	X	X	
463-58-1	Carbonyl sulfide		X	X		
120-80-9	Catechol		X	X		
133-90-4	Chloramben		X	X		
57-74-9	Chlordane		X	X		
7782-50-5	Chlorine		X	X		
79-11-8	Chloroacetic acid		X	X		
532-27-4	2-Chloroacetophenone		X	X		
108-90-7	Chlorobenzene		X	X		
510-15-6	Chlorobenzilate		X	X		
67-66-3	Chloroform		X	X	X	
107-30-2	Chloromethyl methyl ether		X	X		
126-99-8	Chloroprene		X	X		
1319-77-3	Cresol/Cresylic acid (mixed isomers)		X	X		

Appendix A. Listing of HAPs

CAS Number	Chemical Name	Common Name	CAA HAP	TRI Chemical	Urban HAP	Mobile Source Air Toxic
95-48-7	o-Cresol		X	X		
108-39-4	m-Cresol		X	X		
106-44-5	p-Cresol		X	X		
98-82-8	Cumene		X	X		
N/A	2,4-Dichlorophenoxyacetic Acid (including salts and esters)	2-4-D	X			
72-55-9	1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene	DDE	X			
334-88-3	Diazomethane		X	X		
132-64-9	Dibenzofuran		X	X		
96-12-8	1,2-Dibromo-3-chloropropane		X	X		
84-74-2	Dibutyl phthalate		X	X		
106-46-7	1,4-Dichlorobenzene		X	X		
91-94-1	3,3'-Dichlorobenzidine		X	X		
111-44-4	Dichloroethylether	Bis[2-chloroethyl]ether	X	X		
542-75-6	1,3-Dichloropropene		X	X	X	
62-73-7	Dichlorvos		X	X		
111-42-2	Diethanolamine		X	X		
64-67-5	Diethyl sulfate		X	X		
119-90-4	3,3'-Dimethoxybenzidine		X	X		
60-11-7	4-Dimethylaminoazobenzene		X	X		
121-69-7	N,N-Dimethylaniline		X	X		
119-93-7	3,3'-Dimethylbenzidine		X	X		
79-44-7	Dimethylcarbamoyl chloride		X	X		
68-12-2	N,N-Dimethylformamide		X	X		
57-14-7	1,1-Dimethylhydrazine		X	X		
131-11-3	Dimethyl phthalate		X	X		
77-78-1	Dimethyl sulfate		X	X		
N/A	4,6-Dinitro-o-cresol (including salts)		X			
51-28-5	2,4-Dinitrophenol		X	X		
121-14-2	2-4-Dinitrotoluene		X	X		
123-91-1	1,4-Dioxane	1,4-Diethyleneoxide	X	X		
122-66-7	1,2-Diphenylhydrazine		X	X		
106-89-8	Epichlorohydrin	l-Chloro-2,3-epoxypropane	X	X		
106-88-7	1,2-Epoxybutane		X	X		
140-88-5	Ethyl acrylate		X	X		
100-41-4	Ethylbenzene		X	X		X
51-79-6	Ethyl carbamate	Urethane	X	X		
75-00-3	Ethyl chloride	Chloroethane	X	X		
106-93-4	Ethylene dibromide	Dibromoethane	X	X	X	
107-06-2	Ethylene dichloride	1,2-Dichloroethane	X	X	X	
107-21-1	Ethylene glycol		X	X		
151-56-4	Ethyleneimine	Aziridine	X	X		

Appendix A. Listing of HAPs

CAS Number	Chemical Name	Common Name	CAA HAP	TRI Chemical	Urban HAP	Mobile Source Air Toxic
75-21-8	Ethylene oxide		X	X	X	
96-45-7	Ethylene thiourea		X	X		
75-34-3	Ethylidene dichloride	1-1-Dichloroethane	X	X		
50-00-0	Formaldehyde		X	X	X	X
76-44-8	Heptachlor		X	X		
118-74-1	Hexachlorobenzene		X	X	X	
87-68-3	Hexachlorobutadiene		X	X		
N/A	1,2,3,4,5,6-Hexachlorocyclohexane (all stereoisomers-including lindane)		X			
77-47-4	Hexachlorocyclopentadiene		X	X		
67-72-1	Hexachloroethane		X	X		
822-06-0	Hexamethylene diisocyanate		X			
680-31-9	Hexamethylphosphoramide		X	X		
110-54-3	Hexane		X	X		X
302-01-2	Hydrazine		X	X	X	
7647-01-0	Hydrochloric acid	Hydrogen Chloride	X	X		
7664-39-3	Hydrogen fluoride	Hydrofluoric acid	X	X		
123-31-9	Hydroquinone		X	X		
78-59-1	Isophorone		X			
108-31-6	Maleic anhydride		X	X		
67-56-1	Methanol		X	X		
72-43-5	Methoxychlor		X	X		
74-83-9	Methyl bromide	Bromomethane	X	X		
74-87-3	Methyl chloride	Chloromethane	X	X		
71-55-6	Methyl chloroform	1-1-1-Trichloroethane	X	X		
78-93-3	Methyl ethyl ketone	2-Butanone	X	X		
60-34-4	Methyl hydrazine		X	X		
74-88-4	Methyl iodide	Iodomethane	X	X		
108-10-1	Methyl isobutyl ketone	Hexone	X	X		
624-83-9	Methyl isocyanate		X	X		
80-62-6	Methyl methacrylate		X	X		
1634-04-4	Methyl tert-butyl ether	MTBE	X	X		X
101-14-4	4,4'-Methylenebis	2-chloroaniline	X	X		
75-09-2	Methylene chloride	Dichloromethane	X	X	X	
101-68-8	4-4'-Methylenediphenyl diisocyanate	MDI	X			
101-77-9	4-4'-Methylenedianiline		X	X		
91-20-3	Naphthalene		X	X		X
98-95-3	Nitrobenzene		X	X		
92-93-3	4-Nitrobiphenyl		X	X		
100-02-7	4-Nitrophenol		X	X		
79-46-9	2-Nitropropane		X	X		
684-93-5	N-Nitroso-N-methylurea		X	X		

Appendix A. Listing of HAPs

CAS Number	Chemical Name	Common Name	CAA HAP	TRI Chemical	Urban HAP	Mobile Source Air Toxic
62-75-9	N-Nitrosodimethylamine		X	X		
59-89-2	N-Nitrosomorpholine		X	X		
56-38-2	Parathion		X	X		
82-68-8	Pentachloronitrobenzene	Quintobenzene	X	X		
87-86-5	Pentachlorophenol		X	X		
108-95-2	Phenol		X	X		
106-50-3	p-Phenylenediamine		X	X		
75-44-5	Phosgene		X	X		
7803-51-2	Phosphine		X	X		
7723-14-0	Phosphorus		X	X		
85-44-9	Phthalic anhydride		X	X		
1336-36-3	Polychlorinated biphenyls	Aroclors	X	X	X	
1120-71-4	1-3-Propane sultone		X	X		
57-57-8	beta-Propiolactone		X	X		
123-38-6	Propionaldehyde		X	X		
114-26-1	Propoxur	Baygon	X	X		
78-87-5	Propylene dichloride	1,2-Dichloropropane	X	X	X	
75-56-9	Propylene oxide		X	X		
75-55-8	1-2-Propylenimine	2-Methylaziridine	X	X		
91-22-5	Quinoline		X	X	X	
106-51-4	Quinone	p-Benzoquinone	X	X		
100-42-5	Styrene		X	X		X
96-09-3	Styrene oxide		X	X		
1746-01-6	2,3,7,8-Tetrachlorodibenzo-p-dioxin		X		X	X
79-34-5	1,1,2,2-Tetrachloroethane		X	X	X	
127-18-4	Tetrachloroethylene	Perchloroethylene	X	X	X	
7550-45-0	Titanium tetrachloride		X	X		
108-88-3	Toluene		X	X		X
95-80-7	Toluene-2,4-diamine		X	X		
584-84-9	2,4-Toluene diisocyanate		X	X		
95-53-4	o-Toluidine		X	X		
8001-35-2	Toxaphene	chlorinated camphene	X	X		
120-82-1	1,2,4-Trichlorobenzene		X	X		
79-00-5	1,1,2-Trichloroethane		X	X		
79-01-6	Trichloroethylene		X	X	X	
95-95-4	2-4-5-Trichlorophenol		X	X		
88-06-2	2-4-6-Trichlorophenol		X	X		
121-44-8	Triethylamine		X	X		
1582-09-8	Trifluralin		X	X		
540-84-1	2,2,4-Trimethylpentane		X			
108-05-4	Vinyl acetate		X	X		

Appendix A. Listing of HAPs

CAS Number	Chemical Name	Common Name	CAA HAP	TRI Chemical	Urban HAP	Mobile Source Air Toxic
593-60-2	Vinyl bromide		X	X		
75-01-4	Vinyl chloride		X	X	X	
75-35-4	Vinylidene chloride	1,1-Dichloroethylene	X	X		
1330-20-7	Xylenes (mixed isomers)		X	X		X
95-47-6	o-Xylene		X	X		
108-38-3	m-Xylene		X	X		
106-42-3	p-Xylene		X	X		
	Antimony Compounds		X	X		
	Arsenic Compounds (inorganic including arsine)		X	X	X	X
	Beryllium Compounds		X	X	X	
	Cadmium Compounds		X	X	X	
	Chromium Compounds		X	X	X	X
	Cobalt Compounds		X	X		
	Coke Oven Emissions		X		X	
	Cyanide Compounds **1**		X	X		
	Glycol ethers **2**		X			
	Lead Compounds		X	X	X	X
	Manganese Compounds		X	X	X	X
	Mercury Compounds		X	X	X	X
	Fine mineral fibers **3**		X			
	Nickel Compounds		X	X	X	X
	Polycyclic Organic Matter **4**		X	X	X	X
	Radionuclides (including radon) **5**		X			
	Selenium Compounds		X	X		

1 X'CN where X=H or any other group where a formal dissociation may occur. For example KCN or CA(CN)2.

2 Includes mono- and di- ethers of ethylene glycol, diethylene glycol, triethylene glycol R-(OCH2CH2)n-OR where n= 1,2, or 3; R= alkyl or aryl groups; R' = R, H or groups which, when removed, yield glycol ethers with the structure: R-(OCH2CH)n-OH. Polymers are excluded from the glycol category.

3 Includes mineral fiber emissions from facilities manufacturing or processing glass, rock or slag fibers (or other mineral derived fibers) or average diameter 1micrometer or less.

4 Includes organic compounds with more than one benzene ring, and which have a boiling point greater than or equal to 100 degrees C.

5 A type of atom which spontaneously undergoes radioactive decay.

Appendix B Guide to Federal Agencies that Oversee Air Toxics

This appendix contains descriptions and contacts of the primary EPA organizations that routinely deal with air toxics risk related regulations and information. Additional governmental offices that also deal with air toxics information are also listed. This listing is not meant to be either comprehensive or static and updates and suggestions for additions are welcome (email to mitchell.ken@epa.gov).

The listing is arranged first by EPA headquarters offices and contacts that deal specifically with air toxics risk related issues. EPA Regional air toxics contacts and other governmental agencies that provide health and risk assessment information complete the listing.

1. EPA Headquarters Offices that Work Directly on Air Toxics Issues

a. **Office of Air and Radiation.** The Office of Air and Radiation (OAR) develops national programs, technical policies, and regulations for controlling air pollution and radiation exposure. OAR is concerned with energy conservation and pollution prevention, indoor and outdoor air quality, industrial air pollution, pollution from vehicles and engines, radon, acid rain, stratospheric ozone depletion, and radiation protection. http://www.epa.gov/air

There are three main offices within OAR that work on air toxics issues - OAQPS, OTAQ, and ORIA.

i. **Office of Air Quality Planning and Standards (OAQPS).** OAQPS primary mission is to preserve and improve air quality in the United States. OAQPS, as part of this goal, monitors and reports on air quality, air toxics, and emissions. They also watch for visibility issues, as they relate to the level of air pollution. In addition, OAQPS is tasked by the EPA with providing technical information for professionals involved with monitoring and controlling air pollution, creating governmental policies, rules, and guidance for professionals and government, and educating the public about air pollution and what can be done to control and prevent it. http://www.epa.gov/air/oaqps/index.html

ii. **Office of Transportation and Air Quality (OTAQ).** OTAQ protects public health and the environment by controlling air pollution from motor vehicles, engines, and the fuels used to operate them, and by encouraging travel choices that minimize emissions. These "mobile sources" include cars and light trucks, large trucks and buses, nonroad recreational vehicles (such as dirt bikes and snowmobiles), farm and construction equipment, lawn and garden equipment, marine engines, aircraft, and locomotives. http://www.epa.gov/otaq/

iii. **Office of Radiation and Indoor Air (ORIA).** The mission of ORIA is to protect the public and the environment from the risks of radiation and indoor air pollution. The

programs within EPA and other agencies to control radiation and indoor air pollution exposures; provides technical assistance to states through EPA's regional offices, and to other agencies having radiation and indoor air protection programs; directs an environmental radiation monitoring program; responds to radiological emergencies; and evaluates and assesses the overall risk and impact of radiation and indoor air pollution. http://www.epa.gov/air/oria.html

b. **Office of Pollution Prevention and Toxics (OPPT).** OPPT has the primary responsibility for administering the Toxic Substances Control Act (TSCA) and the Pollution Prevention Act of 1990. It also manages the Chemical Right-to-Know Initiative and the New and Existing Chemicals programs; the Design for the Environment (DFE), Green Chemistry, and Environmentally Preferable Products (EPP) programs; and the Lead, Asbestos, and Polychlorinated Biphenyls (PCBs) program. http://www.epa.gov/opptintr/.

c. **Office of Research and Development (ORD).** The U.S. Environmental Protection Agency (EPA) relies on sound science to safeguard both human health and the environment. The Office of Research and Development (ORD) is the scientific research arm of EPA. ORD's leading-edge research helps provide the solid underpinning of science and technology for the Agency. ORD conducts research on ways to prevent pollution, protect human health, and reduce risk. The work at ORD laboratories, research centers, and offices across the country helps improve the quality of air, water, soil, and the way we use resources. Applied science at ORD builds our understanding of how to protect and enhance the relationship between humans and the ecosystems of Earth. www.epa.gov/ord

i. **Office of Science Policy (OSP)**. The OSP integrates and communicates scientific information generated by or for ORD's laboratories and centers, as well as ORD's expert advice on the use of scientific information. EPA and the scientific community at large use this information to ensure that EPA's decisions and environmental policies are informed by sound science. http://www.epa.gov/osp/

ii. **The National Center for Environmental Assessment (NCEA).** NCEA is EPA's national resource center for human health and ecological risk assessment. NCEA conducts risk assessments, carries out research to improve the state-of-the-science of risk assessment, and provides guidance and support to risk assessors. www.epa.gov/ncea

iii. **National Exposure Research Laboratory (NERL).** NERL is comprised of several divisions with diversified research specialties. NERL conducts research and development that leads to improved methods, measurements and models to assess and predict exposures of humans and ecosystems to harmful pollutants and other conditions in air, water, soil, and food. www.epa.gov/nerl/

iv. **National Health and Environmental Effects Research Laboratory (NHEERL).** NHEERL is the Agency's focal point for scientific research on the effects of contaminants and environmental stressors on human health and ecosystem integrity. Its research mission and goals help the Agency to identify and understand the

processes that affect our health and environment, and helps the Agency to evaluate the risks that pollution poses to humans and ecosystems. The impact of NHEERL's efforts can be felt far beyond the EPA, by enabling state and local governments to implement effective environmental programs, assisting industry in setting and achieving environmental goals, and collaborating with international governments and organizations on issues of environmental importance. http://www.epa.gov/nheerl/

v. **National Risk Management Research Laboratory (NRMRL).** NRMRL conducts research into ways to prevent and reduce pollution risks that threaten human health and the environment. The laboratory investigates methods to prevent and control pollution of air, land, and water, and to restore ecosystems. The goals of this research are to develop and promote technologies that protect and improve the environment; develop scientific and engineering information to support regulatory and policy decisions; and provide technical support and information transfer to ensure implementation of environmental regulations and strategies at the national and community levels. In addition, NRMRL collaborates with both public and private sector partners to anticipate emerging problems and to foster technologies that reduce the cost of compliance. http://www.epa.gov/ORD/NRMRL/

2. EPA Headquarters Offices that Work on Specific Air Toxics Risk Issues

a. OAQPS Risk and Exposure Assessment Group (REAG). The REAG maintains the scientific and analytical expertise necessary to conduct human and ecological air toxics risk assessments and develop new assessment methodologies, guidelines, and policies for air toxics risk assessments, risk characteristics, and risk communication. The Group also serves as a center of air toxics health risk information for Regional, State, and local agencies. http://www.epa.gov/oar/oaqps/organization/esd/reag.html

b. OAQPS Air Quality Modeling Group (AQMG). The Air Quality Modeling Group is responsible for providing leadership and direction on the full range of atmospheric dispersion models and other mathematical simulation techniques used in assessing source impacts and control strategies. The Group serves as the focal point on modeling techniques for other EPA headquarters staff, Regional Offices, and State and local agencies. It coordinates with ORD on the development of new models and techniques, as well as wider issues of atmospheric research. Finally, the Group conducts modeling analyses to support policy/regulatory decisions in OAQPS. http://www.epa.gov/air/oaqps/organization/emad/aqmg.html

c. OAQPS Emission Factors and Inventories Group (EFIG). Emission inventories are the basis for numerous efforts including trends analysis, regional, and local scale air quality modeling, regulatory impact assessments, and human exposure modeling. These inventories are used in analyses by EPA, State and local agencies, as well as the public. As a central depository for emission facts, inventory data and factor and inventory development references, the EFIG is responsible for providing technical assistance to Regional, State, and local clients. Through this working relationship, inventories are

developed to meet the emerging needs of all their users.
http://www.epa.gov/air/oaqps/organization/emad/efig.html

d. OAQPS Monitoring and Quality Assurance Group (MQAG). MQAG is responsible for identifying ambient monitoring needs based on OAQPS' data requirements, and for developing the monitoring program and quality assurance infrastructure to support these requirements with the highest quality ambient air data.
http://www.epa.gov/air/oaqps/organization/emad/mqag.html

e. **OAQPS Policy, Planning, and Standards Group (PPSG).** The PPSG, which is in the Emissions Standards Division of OAQPS, facilitates planning and development of Division activities and integration of Division programs with other OAQPS and EPA programs. The group is responsible for developing and implementing national emission standards, new source performance standards, control techniques guidelines, regulatory review programs, and other technical documents for specific categories of stationary sources of hazardous and criteria air pollutants. Finally, the Group performs comprehensive analyses of hazardous and criteria air pollutant emissions and control measures for the specified categories of stationary sources. Such analyses typically form the basis for national emission standards or technical guidance documents.
http://www.epa.gov/oar/oaqps/organization/esd/ppsg.html

f. **OTAQ Air Toxics Center.** The Air Toxics Center is OTAQ's resource on mobile source air toxics and other mobile source-related human health and welfare issues. The Center provides expertise on mobile source air toxic emissions, exposure and risk to the Agency. It helps regulators and the public understand the risk from mobile source air toxics to human health and welfare. It also develops mobile source-related air toxics regulations, and addresses air toxics impacts of all mobile source control programs. In addition, it develops information, tools and resources to empower states, communities and individuals to make and implement their own decisions about air toxics. Finally, the Center works to influence the toxics research agenda and strategies of parties internal and external to EPA in order to advance OTAQ's mission. www.epa.gov/otaq/toxics.htm

3. EPA Regional Air Toxics Contacts

Region 1		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Susan Lancey	617-918-1656
Toxics Emissions Inventory	Bob McConnell	617-918-1046
Air Deposition	Ian Cohen	617-918-1655
Air Dispersion/ Deposition Modeling	Brian Hennessey	617-918-1654
Monitoring	Peter Kahn	781-860-4392
Community Assessments	Marybeth Smuts	617-918-1512
Risk Assessment	Marybeth Smuts	617-918-1512
Mobile Sources	Robert Judge	617-918-1045
Indoor Air	Eugene Benoit	617-918-1639

Region 2		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Umesh Dholakia	212-637-4023
Toxics Emissions Inventory	Raymond Forde	212-637-3716
Air Deposition	Bob Kelly	212-637-3709
Air Dispersion/ Deposition Modeling	Bob Kelly	212-637-3709
Monitoring	Mazeeda Khan Avi Teitz	212-637-3715 732-906-6160
Community Assessments	Carol Bellizzi Marlon Gonzales	212-637-3712 212-637-3769
Risk Assessment	Gina Ferreira Carol Bellizzi	212-637-3768 212-637-3712
Mobile Sources	Reema Persaud	212-637-3760
Indoor Air	Larainne Koehler	212-637-4005

Region 3		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Ray Chalmers	215-814-2061
Air Deposition	Al Cimorelli	215-814-2189
Air Dispersion/Deposition Modeling	Al Cimorelli	215-814-2189
Monitoring	Ted Erdman	215-814-2766
Community Assessments	Helene Drago	215-814-5796
Risk Assessment	Alvaro Alvarado	215-814-2109
Mobile Sources	Brian Rehn	215-814-2176
Indoor Air	Fran Dougherty Cristina Schulingkamp	215-814-2083 215-814-2086

Region 4		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Lee Page	404-562-9131
Toxics Emissions Inventory	Leonardo Ceron	404-562-9129
Air Deposition	Dr. John Ackermann Latoya Miller	404-562-9063 404-562-9885
Air Dispersion/Deposition Modeling	Stan Krivo Rick Gillam	404-562-9123 404-562-9049
Monitoring	Van Shrieves Danny France	404-562-9089 706-355-8738
Community Assessments	Paul Wagner	404-562-9100
Risk Assessment	Dr. Kenneth Mitchell (human health/ecological) Dr. Solomon Pollard (human health) Ofia Hodoh (human health) Dr. John Ackermann (ecological) Latoya Miller (ecological)	404-562-9065 404-562-9180 404-562-9176 404-562-9063 404-562-9885
Mobile Sources	Dale Aspy	404-562-9041
Indoor Air	Henry Slack	404-562-9143

Region 5		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Bruce Varner	312-886-6793
Toxics Emissions Inventory	Suzanne King	312-886-6054
Air Deposition	Erin Newman	312-886-4587
Air Dispersion/ Deposition Modeling	Randy Robinson Phuong Nguyen	312-353-6713 312-886-6701
Monitoring	Motria Caudill	312-886-0267
Community Assessments	Jackie Nwia Michele Palmer	312-886-6081 312-886-0387
Risk Assessment	George Bollweg Margaret Sieffert Jaime Julian	312-353-5598 312-353-1151 312-886-9402
Mobile Sources	Suzanne King	312-886-6054
Indoor Air	Jack Barnette Sheila Batka	312-886-6175 312-886-6053

Region 6		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Jeff Robinson	214-665-6435
Toxics Emissions Inventory	Herb Sherrow	214-665-7237
Air Deposition	Phil Crocker	214-665-7373
Air Dispersion/ Deposition Modeling	Quang Nguyen	214-665-7238
Monitoring	Kuenja Chung	214-665-8345
Community Assessments	Ruben Casso	214-665-6763
Risk Assessment	Jeff Yurk	214-665-8309
Mobile Sources	Sandra Rennie	214-665-7367
Indoor Air	Mike Miller	214-665-7550

Region 7		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Richard Tripp	913-551-7566
Toxics Emissions Inventory	Michael Jay	913-551-7460
Air Deposition	Michael Jay	913-551-7460
Air Dispersion/ Deposition Modeling	Richard Daye	913-551-7619
Monitoring	Michael Davis	913-551-7096
Community Assessments	Marcus Rivas	913-551-7669
Risk Assessment	James Hirtz	913-551-7472
Mobile Sources	James Hirtz	913-551-7472
Indoor Air	Robert Dye	913-551-7605

Region 8		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Deldi Reyes	303-312-6055
Toxics Emissions Inventory	Daniel Webster	303-312-6446
Air Deposition	Anne-Marie Patrie	303-312-6524
Air Dispersion/ Deposition Modeling	Victoria Parker-Christensen	303-312-6441
Monitoring	Michael Copeland	303-312-6010
Community Assessments	Victoria Parker-Christensen Anne-Marie Patrie	303-312-6441 303-312-6524
Risk Assessment	Victoria Parker-Christensen Anne-Marie Patrie	303-312-6441 303-312-6524
Mobile Sources	Jeff Kimes	303-312-6445
Indoor Air	Ron Schiller	303-312-6017

Region 9		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Mae Wang John Brock	415-947-4124 415-947-3999
Toxics Emissions Inventory	Larry Biland	415-947-4132
Air Deposition	Pam Tsai Barbara Toole-O'Neil	415-947-4196 415-972-3991
Air Dispersion/ Deposition Modeling	Carol Bohnenkamp Scott Bohning	415-947-4130 415-947-4127
Monitoring	Catherine Brown	415-947-4137
Community Assessments	Mike Bandrowski	415-947-4194
Risk Assessment	Pam Tsai Arnold Den	415-947-4196 415-947-4191
Indoor Air	Barbara Spark	415-947-4189
Mobile Sources	Sylvia Dugre David Jesson	415-947-4149 415-947-4150

Region 10		
FUNCTION	**NAME**	**TELEPHONE**
Maximum Achievable Control Technology (MACT)	Lucita Valiere	206-553-8087
Toxics Emissions Inventory	Madonna Narvaez	206-553-2117
Air Deposition	Madonna Narvaez	206-553-2117
Air Dispersion/ Deposition Modeling	Mahbubul Islam	206-553-6985
Monitoring	Keith Rose	206-553-1949
Community Assessments	Peter Murchie Lisa McArthur	503-326-6554 206-553-1814
Risk Assessment	Julie Wroble	206-553-1079
Mobile Sources	Wayne Elson	206-553-1463
Indoor Air	Ann Wawrukiewicz	206-553-2589

4. Other Federal Agencies

a. **Agency for Toxics Substances and Disease Registry (ATSDR).** The mission of the Agency for Toxic Substances and Disease Registry (ATSDR), as an agency of the U.S. Department of Health and Human Services, is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances. ATSDR is directed by congressional mandate to perform specific functions concerning the effect on public health of hazardous substances in the environment. These functions include public health assessments of waste sites, health consultations concerning specific hazardous substances, health surveillance and registries, response to emergency releases of hazardous substances, applied research in support of public health assessments, information development and dissemination, and education and training concerning hazardous substances. http://www.atsdr.cdc.gov/about.html

b. **National Center for Environmental Health (NCEH).** CDC's National Center for Environmental Health (NCEH) strives to promote health and quality of life by preventing or controlling those diseases or deaths that result from interactions between people and their environment. http://www.cdc.gov/nceh/

c. **National Cancer Institute (NCI).** The NCI is a component of the National Institutes of Health (NIH), one of eight agencies that compose the Public Health Service (PHS) in the Department of Health and Human Services (DHHS). The NCI, established under the National Cancer Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program. Over the years, legislative amendments have maintained the NCI authorities and responsibilities and added new information dissemination mandates as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice. The National Cancer Institute coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients. www.cancer.gov

d. **National Library of Medicine (NLM).** The National Library of Medicine (NLM), on the campus of the National Institutes of Health in Bethesda, Maryland, is the world's largest medical library. The Library collects materials in all areas of biomedicine and health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences. The collections stand at more than 6 million items--books, journals, technical reports, manuscripts, microfilms, photographs and images. Housed within the Library is one of the world's finest medical history collections of old and rare medical works. The Library's collection may be consulted in the reading room or requested on interlibrary loan. NLM is a national resource for all U.S. health science libraries through a National Network of Libraries of Medicine®. http://www.nlm.nih.gov/nlmhome.html

e. **National Institute of Environmental Health Sciences (NIEHS).** Human health and human disease result from three interactive elements: environmental factors, individual susceptibility and age. The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by understanding each of these elements and how they interrelate. The NIEHS achieves its mission through multidisciplinary biomedical research programs, prevention and intervention efforts, and communication strategies that encompass training, education, technology transfer, and community outreach. http://www.niehs.nih.gov/external/welcome.htm

Appendix C Recommended Dose-Response Values for HAPs

This appendix presents tabulated dose-response assessments that the Office of Air Quality Planning and Standards (OAQPS) uses for risk assessments of hazardous air pollutants. A description of the derivation of these values, along with any updates can be found at the following website: http://www.epa.gov/ttn/atw/toxsource/summary.html.

Table 1. Prioritized Dose-Response Values (10/28/03)			WOE[3] for Cancer		CHRONIC INHALATION				CHRONIC ORAL			
					NONCANCER		CANCER		NONCANCER		CANCER	
CHEMICAL NAME	CAS NO.[1]	HAP NO.[2]	EPA	IARC	mg/m3	SOURCE	1/(ug/m3)	SOURCE	mg/kg/d	SOURCE	1/(mg/kg/d)	SOURCE
Acetaldehyde	75-07-0	1	B2	2B	0.009	IRIS	2.2E-06	IRIS				
Acetamide	60-35-5	2		2B			2.0E-05	CAL				
Acetonitrile	75-05-8	3	D		0.06	IRIS						
Acetophenone	98-86-2	4	D									
Acrolein	107-02-8	6		3	0.00002	IRIS						
Acrylamide	79-06-1	7	B2	2A	0.0007	P-CAL	1.3E-03	IRIS				
Acrylic acid	79-10-7	8			0.001	IRIS						
Acrylonitrile	107-13-1	9	B1	2A	0.002	IRIS	6.8E-05	IRIS				
Allyl chloride	107-05-1	10	C	3	0.001	IRIS	6.0E-06	CAL				
Aniline	62-53-3	12	B2	3	0.001	IRIS	1.6E-06	CAL				
Antimony compounds	7440-36-0	173										
Antimony pentoxide	1314-60-9	173										
Antimony potassium tartrate	304-61-0	173										
Antimony tetroxide	1332-81-6	173										
Antimony trioxide	1309-64-4	173		2B	0.0002	IRIS						
Arsenic compounds	7440-38-2	174	A	1	0.00003	CAL	4.3E-03	IRIS				
Arsine	7784-42-1	174			0.00005	IRIS						
Benzene	71-43-2	15	A	1	0.03	IRIS	7.8E-06	IRIS				
Benzidine	92-87-5	16	A		0.01	P-CAL	6.7E-02	IRIS				
Benzotrichloride	98-07-7	17	B2	2B			3.7E-03	Conv. Oral				
Benzyl chloride	100-44-7	18	B2	2B			4.9E-05	CAL				
Beryllium compounds	7440-41-7	175	B1	1	0.00002	IRIS	2.4E-03	IRIS				
Biphenyl	92-52-4	19	D									
Bis(2-ethylhexyl)phthalate	117-81-7	20	B2	2B	0.01	CAL	2.4E-06	CAL				
Bis(chloromethyl)ether	542-88-1	21	A	1			6.2E-02	IRIS				
Bromoform	75-25-2	22	B2	3			1.1E-06	IRIS				
1,3-Butadiene	106-99-0	23	A	2A	0.002	IRIS	3.0E-05	IRIS				
Cadmium compounds	7440-43-9	176	B1	1	0.00002	CAL	1.8E-03	IRIS	0.0005	IRIS		
Captan	133-06-2	26	B2	3			1.0E-06	Conv. Oral				
Carbaryl	63-25-2	27										
Carbon disulfide	75-15-0	28			0.7	IRIS						
Carbon tetrachloride	56-23-5	29	B2	2B	0.04	CAL	1.5E-05	IRIS				
Chloramben	133-90-4	32										
Chlordane	57-74-9	33	B2	2B	0.0007	IRIS	1.0E-04	IRIS	0.0005	IRIS	3.5E-01	IRIS
Chlorine	7782-50-5	34			0.0002	CAL						
Chloroacetic acid	79-11-8	35										
2-Chloroacetophenone	532-27-4	36			0.00003	IRIS						
Chlorobenzene	108-90-7	37	D		1	CAL						
Chlorobenzilate	510-15-6	38	B2				7.8E-05	HEAST				
Chloroform	67-66-3	39	B2	2B	0.098	ATSDR						
Chloroprene	126-99-8	41			0.007	HEAST						
Chromium (III) compounds	16065-83-1	177	D									
Chromium (VI) compounds	18540-29-9	177	A	1	0.0001	IRIS	1.2E-02	IRIS				

Table 1. Prioritized Dose-Response Values (10/28/03)			WOE[3] for Cancer		CHRONIC INHALATION				CHRONIC ORAL			
					NONCANCER		CANCER		NONCANCER		CANCER	
CHEMICAL NAME	CAS NO.[1]	HAP NO.[2]	EPA	IARC	mg/m3	SOURCE	1/(ug/m3)	SOURCE	mg/kg/d	SOURCE	1/(mg/kg/d)	SOURCE
Chromium (VI) trioxide, chromic acid mist	11115-74-5	177	A	1	0.000008	IRIS						
Cobalt compounds	7440-48-4	178			0.0001	ATSDR						
Coke Oven Emissions	8007-45-2	179	A				6.2E-04	IRIS				
m-Cresol	108-39-4	44	C									
o-Cresol	95-48-7	43	C									
p-Cresol	106-44-5	45	C									
Cresols (mixed)	1319-77-3	42	C		0.6	CAL						
Cumene	98-82-8	46	D		0.4	IRIS						
Cyanazine	21725-46-2	180	C				2.4E-04	Conv. Oral				
Cyanide compounds	57-12-5	180	D									
Acetone cyanohydrin	75-86-5	180			0.01	HEAST						
Calcium cyanide	592-01-8	180										
Copper cyanide	544-92-3	180										
Cyanogen	460-19-5	180										
Cyanogen bromide	506-68-3	180										
Cyanogen chloride	506-77-4	180										
Ethylene cyanohydrin	109-78-4	180										
Hydrogen cyanide	74-90-8	180			0.003	IRIS						
Potassium cyanide	151-50-8	180										
Potassium silver cyanide	506-61-6	180										
Silver cyanide	506-64-9	180										
Sodium cyanide	143-33-9	180										
Thiocyanic acid, 2-(benzothiazolylthio) methyl est	21564-17-0	180										
Zinc cyanide	557-21-1	180										
2,4-D, salts and esters	94-75-7	47										
DDE	72-55-9	48	B2				9.7E-05	Conv. Oral			3.4E-01	IRIS
1,2-Dibromo-3-chloropropane	96-12-8	51	B2		0.0002	IRIS	2.0E-03	CAL				
Dibutylphthalate	84-74-2	52	D									
p-Dichlorobenzene	106-46-7	53	C	2B	0.8	IRIS	1.1E-05	CAL				
3,3'-Dichlorobenzidine	91-94-1	54	B2	2B			3.4E-04	CAL				
Dichloroethyl ether	111-44-4	55	B2				3.3E-04	IRIS				
1,3-dichloropropene	542-75-6	56	B2	2B	0.02	IRIS	4.0E-06	IRIS				
Dichlorvos	62-73-7	57	B2	2B	0.0005	IRIS	8.3E-05	Conv. Oral				
Diesel engine emissions	DIESEL EMIS.	190	B1		0.005	IRIS						
Diethanolamine	111-42-2	58			0.003	CAL						
3,3'-Dimethoxybenzidine	119-90-4	61	B2	2B			4.0E-06	Conv. Oral				
p-Dimethylaminoazobenzene	60-11-7	62		2B			1.3E-03	CAL				
3,3'-Dimethylbenzidine	119-93-7	63	B2				2.6E-03	Conv. Oral				
Dimethyl formamide	68-12-2	65		2B	0.03	IRIS						
N,N-dimethylaniline	121-69-7	59		3								
1,1-Dimethylhydrazine	57-14-7	66	B2	2B								
2,4-dinitrophenol	51-28-5	70										
2,4-Dinitrotoluene	121-14-2	71	B2	2B	0.007	P-CAL	8.9E-05	CAL				

Table 1. Prioritized Dose-Response Values (10/28/03)			WOE[3] for Cancer		CHRONIC INHALATION				CHRONIC ORAL			
					NONCANCER		CANCER		NONCANCER		CANCER	
CHEMICAL NAME	CAS NO.[1]	HAP NO.[2]	EPA	IARC	mg/m3	SOURCE	1/(ug/m3)	SOURCE	mg/kg/d	SOURCE	1/(mg/kg/d)	SOURCE
2,4/2,6-Dinitrotoluene (mixture)	25321-14-6	71	B2	2B			1.9E-04	Conv. Oral				
1,4-Dioxane	123-91-1	72	B2	2B	3	CAL	3.1E-06	Conv. Oral				
1,2-Diphenylhydrazine	122-66-7	73	B2				2.2E-04	IRIS				
Epichlorohydrin	106-89-8	74	B2	2A	0.001	IRIS	1.2E-06	IRIS				
1,2-Epoxybutane	106-88-7	75			0.02	IRIS						
Ethyl acrylate	140-88-5	76	B2	2B			1.4E-05	Conv. Oral				
Ethyl benzene	100-41-4	77	D		1	IRIS						
Ethyl carbamate	51-79-6	78		2B			2.9E-04	CAL				
Ethyl chloride	75-00-3	79			10	IRIS						
Ethylene dibromide	106-93-4	80	B2	2A	0.0008	CAL	2.2E-04	IRIS				
Ethylene dichloride	107-06-2	81	B2	2B	2.4	ATSDR	2.6E-05	IRIS				
Ethylene glycol	107-21-1	82			0.4	CAL						
Ethylene oxide	75-21-8	84	B1	1	0.03	CAL	8.8E-05	CAL				
Ethylene thiourea	96-45-7	85	B2	2B	0.003	P-CAL	1.3E-05	CAL				
Ethylidene dichloride	75-34-3	86	C		0.5	HEAST	1.6E-06	CAL				
Formaldehyde	50-00-0	87	B1	2A	0.0098	ATSDR	5.5E-09	EPA OAQPS				
Diethylene glycol monobutyl ether	112-34-5	181			0.02	HEAST						
Diethylene glycol monoethyl ether	111-90-0	181										
Ethylene glycol butyl ether	111-76-2	181	C		13	IRIS						
Ethylene glycol ethyl ether	110-80-5	181			0.2	IRIS						
Ethylene glycol ethyl ether acetate	111-15-9	181			0.3	CAL						
Ethylene glycol methyl ether	109-86-4	181			0.02	IRIS						
Ethylene glycol methyl ether acetate	110-49-6	181			0.09	CAL						
Heptachlor	76-44-8	88	B2	2B			1.3E-03	IRIS	0.0005	IRIS	4.5E+00	IRIS
Hexachlorobenzene	118-74-1	89	B2	2B	0.003	P-CAL	4.6E-04	IRIS	0.0008	IRIS	1.6E+00	IRIS
Hexachlorobutadiene	87-68-3	90	C	3	0.09	P-CAL	2.2E-05	IRIS				
Hexachlorocyclopentadiene	77-47-4	91	E		0.0002	IRIS						
Hexachlorodibenzo-p-dioxin, mixture	19408-74-3	187	B2				1.3E+00	IRIS			6.2E+03	IRIS
Hexachloroethane	67-72-1	92	C	3	0.08	P-CAL	4.0E-06	IRIS				
Hexamethylene-1,6-diisocyanate	822-06-0	93			0.00001	IRIS						
n-Hexane	110-54-3	95			0.2	IRIS						
Hydrazine	302-01-2	96	B2	2B	0.0002	CAL	4.9E-03	IRIS				
Hydrochloric acid	7647-01-0	97			0.02	IRIS						
Hydrofluoric acid	7664-39-3	98			0.03	CAL						
Hydroquinone	123-31-9	99										
Isophorone	78-59-1	100	C		2	CAL	2.7E-07	Conv. Oral				
Lead compounds	7439-92-1	182	B2	2B	0.0015	EPA OAQPS						
Tetraethyl lead	78-00-2	182							0.0000001	IRIS		
Lindane (gamma-HCH)	58-89-9	101		2B	0.0003	P-CAL	3.1E-04	CAL	0.0003	IRIS	1.1E+00	CAL
alpha-Hexachlorocyclohexane (a-HCH)	319-84-6	101	B2	2B	0.02	P-CAL	1.8E-03	IRIS	0.008	ATSDR	6.3E+00	IRIS
beta-Hexachlorocyclohexane (b-HCH)	319-85-7	101	C	2B	0.002	P-CAL	5.3E-04	IRIS			1.8E+00	IRIS
technical Hexachlorocyclohexane (HCH)	608-73-1	101	B2	2B			5.1E-04	IRIS			1.8E+00	IRIS
Maleic anhydride	108-31-6	102			0.0007	CAL						

Table 1. Prioritized Dose-Response Values (10/28/03)			WOE[3] for Cancer		CHRONIC INHALATION				CHRONIC ORAL			
					NONCANCER		CANCER		NONCANCER		CANCER	
CHEMICAL NAME	CAS NO.[1]	HAP NO.[2]	EPA	IARC	mg/m3	SOURCE	1/(ug/m3)	SOURCE	mg/kg/d	SOURCE	1/(mg/kg/d)	SOURCE
Manganese compounds	7439-96-5	183	D		0.00005	IRIS						
Mercuric chloride	7487-94-7	184	C		0.00009	CAL			0.0003	IRIS		
Mercury (elemental)	7439-97-6	184	D		0.0003	IRIS						
Methyl mercury	22967-92-6	184	C						0.0001	IRIS		
Phenylmercuric acetate	62-38-4	184							0.00008	IRIS		
Methanol	67-56-1	103			4	CAL						
Methoxychlor	72-43-5	104	D	3					0.005	IRIS		
Methyl bromide	74-83-9	105	D		0.005	IRIS						
Methyl chloride	74-87-3	106	D		0.09	IRIS						
Methyl ethyl ketone	78-93-3	108			5	IRIS						
Methyl isobutyl ketone	108-10-1	111			3	IRIS						
Methyl isocyanate	624-83-9	112			0.001	CAL						
Methyl methacrylate	80-62-6	113	E		0.7	IRIS						
Methyl tert-butyl ether	1634-04-4	114			3	IRIS						
4,4'-Methylene bis(2-chloroaniline)	101-14-4	115	B2	2A			4.3E-04	CAL				
Methylene chloride	75-09-2	116	B2	2B	1	ATSDR	4.7E-07	IRIS				
Methylene diphenyl diisocyanate	101-68-8	117	D		0.0006	IRIS						
4,4'-Methylenedianiline	101-77-9	118		2B	0.02	CAL	4.6E-04	CAL				
Naphthalene	91-20-3	119	C		0.003	IRIS						
Nickel compounds	7440-02-0	186	A	2B	0.0002	ATSDR						
Nickel oxide	1313-99-1	186			0.0001	CAL						
Nickel refinery dust	NI_DUST	186	A				2.4E-04	IRIS				
Nickel subsulfide	12035-72-2	186	A				4.8E-04	IRIS				
Nitrobenzene	98-95-3	120	D	2B	0.03	P-CAL						
2-Nitropropane	79-46-9	123	B2	2B	0.02	IRIS	5.6E-06	EPA OAQPS				
Nitrosodimethylamine	62-75-9	125	B2	2A			1.4E-02	IRIS				
N-Nitrosomorpholine	59-89-2	126		2B			1.9E-03	CAL				
Parathion	56-38-2	127	C	3								
Polychlorinated biphenyls	1336-36-3	136	B2	2A			1.0E-04	IRIS			2.0E+00	IRIS
Aroclor 1016	12674-11-2	136							0.00007	IRIS		
Aroclor 1254	11097-69-1	136							0.00002	IRIS		
Pentachloronitrobenzene	82-68-8	128	C	3			7.4E-05	Conv. Oral				
Pentachlorophenol	87-86-5	129	B2	2B	0.1	P-CAL	5.1E-06	CAL				
Phenol	108-95-2	130	D	3	0.2	CAL						
p-Phenylenediamine	106-50-3	131										
Phosgene	75-44-5	132			0.0003	P-CAL						
Phosphine	7803-51-2	133	D		0.0003	IRIS						
Phosphorus, white	7723-14-0	134	D		0.00007	P-CAL						
Phthalic anhydride	85-44-9	135			0.02	CAL						
Polybrominated Diphenyl Ethers	PBDE	187							0.007	ATSDR		
Acenaphthene	83-32-9	187	D						0.06	IRIS		
Acenaphthylene	206-96-8	187	D									
Anthracene	120-12-7	187	D	3					0.3	IRIS		

Table 1. Prioritized Dose-Response Values (10/28/03)			WOE[3] for Cancer		CHRONIC INHALATION				CHRONIC ORAL			
					NONCANCER		CANCER		NONCANCER		CANCER	
CHEMICAL NAME	CAS NO.[1]	HAP NO.[2]	EPA	IARC	mg/m3	SOURCE	1/(ug/m3)	SOURCE	mg/kg/d	SOURCE	1/(mg/kg/d)	SOURCE
Benzo(a)anthracene	56-55-3	187	B2	2A			1.1E-04	CAL			1.2E+00	CAL
Benzo(b)fluoranthene	205-99-2	187	B2	2B			1.1E-04	CAL			1.2E+00	CAL
Benzo[j]fluoranthene	205-82-3	187		2B			1.1E-04	CAL			1.2E+00	CAL
Benzo(k)fluoranthene	207-08-9	187	B2	2B			1.1E-04	CAL			1.2E+00	CAL
Benzo(g,h,i)perylene	191-24-2	187	D	3								
Benzo(a)pyrene	50-32-8	187	B2	2A			1.1E-03	CAL			7.3E+00	IRIS
Benzo(e)pyrene	192-97-2	187		3								
Carbazole	86-74-8	187	B2	3			5.7E-06	Conv. Oral			2.0E-02	HEAST
beta-Chloronaphthalene	91-58-7	187							0.08	IRIS		
Chrysene	218-01-9	187	B2	3			1.1E-05	CAL			1.2E-01	CAL
Dibenz[a,h]acridine	226-36-8	187		2B			1.1E-04	CAL			1.2E+00	CAL
Dibenz[a,j]acridine	224-42-0	187		2B			1.1E-04	CAL			1.2E+00	CAL
Dibenz(a,h)anthracene	53-70-3	187	B2	2A			1.2E-03	CAL			4.1E+00	CAL
7H-Dibenzo[c,g]carbazole	194-59-2	187		2B			1.1E-03	CAL			1.2E+01	CAL
Dibenzo[a,e]pyrene	192-65-4	187		2B			1.1E-03	CAL			1.2E+01	CAL
Dibenzo[a,h]pyrene	189-64-0	187		2B			1.1E-02	CAL			1.2E+02	CAL
Dibenzo[a,i]pyrene	189-55-9	187		2B			1.1E-02	CAL			1.2E+02	CAL
Dibenzo[a,l]pyrene	191-30-0	187		2B			1.1E-02	CAL			1.2E+02	CAL
7,12-Dimethylbenz(a)anthracene	57-97-6	187					7.1E-02	CAL			2.5E+02	CAL
1,6-Dinitropyrene	42397-64-8	187		2B			1.1E-02	CAL			1.2E+02	CAL
1,8-Dinitropyrene	42397-65-9	187		2B			1.1E-03	CAL			1.2E+01	CAL
Fluoranthene	206-44-0	187	D	3					0.04	IRIS		
Fluorene	86-73-7	187	D	3					0.04	IRIS		
Indeno(1,2,3-cd)pyrene	193-39-5	187	B2	2B			1.1E-04	CAL			1.2E+00	CAL
3-Methylcholanthrene	56-49-5	187					6.3E-03	CAL			2.2E+01	CAL
5-Methylchrysene	3697-24-3	187		2B			1.1E-03	CAL			1.2E+01	CAL
1-Methylnaphthalene	90-12-0	187							0.07	ATSDR		
5-Nitroacenaphthene	602-87-9	187		2B			3.7E-05	CAL			1.3E-01	CAL
6-Nitrochrysene	7496-02-8	187		2B			1.1E-02	CAL			1.2E+02	CAL
2-Nitrofluorene	607-57-8	187		2B			1.1E-05	CAL			1.2E-01	CAL
1-Nitropyrene	5522-43-0	187		2B			1.1E-04	CAL			1.2E+00	CAL
4-Nitropyrene	57835-92-4	187		2B			1.1E-04	CAL			1.2E+00	CAL
Phenanthrene	85-01-8	187	D									
Pyrene	129-00-0	187	D						0.03	IRIS		
1,3-Propane sultone	1120-71-4	137		2B			6.9E-04	CAL				
Propoxur	114-26-1	140	B2									
Propylene dichloride	78-87-5	141	B2		0.004	IRIS	1.9E-05	Conv. Oral				
Propylene oxide	75-56-9	142	B2	2B	0.03	IRIS	3.7E-06	IRIS				
Quinoline	91-22-5	144	B2									
Selenium compounds	7782-49-2	189	D		0.02	CAL						
Hydrogen selenide	7783-07-5	189			0.00008	CAL						
Selenious acid	7783-00-8	189	D									
Selenourea	630-10-4	189										

Table 1. Prioritized Dose-Response Values (10/28/03)			WOE[3] for Cancer		CHRONIC INHALATION				CHRONIC ORAL			
					NONCANCER		CANCER		NONCANCER		CANCER	
CHEMICAL NAME	CAS NO.[1]	HAP NO.[2]	EPA	IARC	mg/m3	SOURCE	1/(ug/m3)	SOURCE	mg/kg/d	SOURCE	1/(mg/kg/d)	SOURCE
Styrene	100-42-5	146		2B	1	IRIS						
Styrene oxide	96-09-3	147		2A	0.006	P-CAL						
2,3,7,8-Tetrachlorodibenzo-p-dioxin	1746-01-6	148	B2		4E-08	CAL	3.3E+01	EPA ORD	1E-09	ATSDR	1.5E+05	EPA ORD
1,1,2,2-Tetrachloroethane	79-34-5	149	C	3			5.8E-05	IRIS				
Tetrachloroethene	127-18-4	150	B2-C	2A	0.27	ATSDR	5.9E-06	CAL				
Titanium tetrachloride	7550-45-0	151			0.0001	ATSDR						
Toluene	108-88-3	152	D	3	0.4	IRIS						
2,4-Toluene diamine	95-80-7	153	B2				1.1E-03	CAL				
2,4/2,6-Toluene diisocyanate mixture (TDI)	26471-62-5	154		2B	0.00007	IRIS	1.1E-05	CAL				
o-Toluidine	95-53-4	155	B2	2B			5.1E-05	CAL				
Toxaphene	8001-35-2	156	B2	2B			3.2E-04	IRIS			1.1E+00	IRIS
1,2,4-Trichlorobenzene	120-82-1	157	D		0.2	HEAST						
1,1,2-Trichloroethane	79-00-5	158	C	3	0.4	P-CAL	1.6E-05	IRIS				
1,1,1-Trichloroethane	71-55-6	107	D		1	CAL						
Trichloroethylene	79-01-6	159	B2-C	2A	0.6	CAL	2.0E-06	CAL				
2,4,5-Trichlorophenol	95-95-4	160										
2,4,6-Trichlorophenol	88-06-2	161	B2				3.1E-06	IRIS				
Triethylamine	121-44-8	162			0.007	IRIS						
Trifluralin	1582-09-8	163	C	3			2.2E-06	Conv. Oral	0.0075	IRIS	7.7E-03	IRIS
Uranium compounds	7440-61-1	188			0.0003	ATSDR						
Uranium, soluble salts	URANSOLS	188										
Vinyl acetate	108-05-4	165		2B	0.2	IRIS						
Vinyl bromide	593-60-2	166	B2	2A	0.003	IRIS	3.2E-05	HEAST				
Vinyl chloride	75-01-4	167	A	1	0.1	IRIS	8.8E-06	IRIS				
Vinylidene chloride	75-35-4	168	C		0.2	IRIS						
m-Xylene	108-38-3	171										
o-Xylene	95-47-6	170										
Xylenes (mixed)	1330-20-7	169			0.1	IRIS						

1Chemical Abstracts Services number for the compound.
2Position of the compound on the HAP list in the Clean Air Act (112[b][2])
3Weight-of-evidence. See http://www.epa/iris/carcino.htm, http://193.51.164.11/monoeval/grlist.html.

Table 2. Acute Dose-Response Values (10/22/03)			AEGL-1	AEGL-2	AEGL-3	ERPG-1	ERPG-2	ERPG-3	IDLH/10	MRL	REL
CHEMICAL NAME	CAS NO.	HAP NO.	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3
Acetaldehyde	75-07-0	1				18	360	1800	360		
Acetonitrile	75-05-8	3							84		
Acrolein	107-02-8	6	0.069 [p]	0.23 [p]	3.2 [p]	0.23	1.1	6.9	0.46	0.00011	0.00019
Acrylamide	79-06-1	7							6		
Acrylic acid	79-10-7	8	2.9 [i]	140 [i]	530 [i]	5.9	150	2200			6
Acrylonitrile	107-13-1	9				22	77	170	19	0.22	
Allyl chloride	107-05-1	10				9.4	130	940	78		
Aniline	62-53-3	12	30 [f]	46 [f]	57 [f]				38		
Anisidine	90-04-0	13							5		
Antimony compounds	7440-36-0	173							5		
Arsenic compounds	7440-38-2	174							0.5		0.00019
Arsine	7784-42-1	174		0.54 [f]	1.6 [f]		1.6	4.8	0.96		0.16
Benzene	71-43-2	15		2600 [p]	13000 [p]	160	480	3200	160	0.16	1.3
Benzyl chloride	100-44-7	18				5.2	52	130	52		0.24
Beryllium compounds	7440-41-7	175					0.025	0.1	0.4		
Bis(chloromethyl)ether	542-88-1	21					0.47	2.4			
Bromoform	75-25-2	22							880		
1,3-Butadiene	106-99-0	23				22	440	11000	440		
Cadmium compounds	7440-43-9	176							9		
Carbaryl	63-25-2	27							10		
Carbon disulfide	75-15-0	28	12 [p]	500 [p]	1500 [p]	3.1	160	1600	160		6.2
Carbon tetrachloride	56-23-5	29	75 [i]	350 [i]	1100 [i]	130	630	4700	130	1.3	1.9
Chlordane	57-74-9	33							10		
Chlorine	7782-50-5	34	1.5 [i]	5.8 [i]	58 [i]	2.9	8.7	58	2.9		0.21
Chloroacetic acid	79-11-8	35		26 [p]							
Chlorobenzene	108-90-7	37							460		
Chloroform	67-66-3	39		430 [p]	8300 [p]		240	24000	240	0.49	0.15
Chloromethyl methyl ether	107-30-2	40		0.2 [i]	3.1 [i]		3.3	33			
Chloroprene	126-99-8	41							110		
Chromium (VI) compounds	18540-29-9	177							1.5		
Chromium (VI) trioxide, chromic acid mist	11115-74-5	177							1.5		
Cobalt compounds	7440-48-4	178							2		
m-Cresol	108-39-4	44							110		
o-Cresol	95-48-7	43							110		
p-Cresol	106-44-5	45							110		
Cresols (mixed)	1319-77-3	42							110		
Cumene	98-82-8	46							440		
Cyanide compounds	57-12-5	180							2.5		
Acetone cyanohydrin	75-86-5	180	2.9 [p]	19 [p]	52 [p]						
Cyanogen chloride	506-77-4	180					1	10			
Hydrogen cyanide	74-90-8	180	2.2 [i]	7.8 [f]	17 [f]		11	28	5.5		0.34
2,4-D, salts and esters	94-75-7	47							10		

Table 2. Acute Dose-Response Values (10/22/03)			AEGL-1	AEGL-2	AEGL-3	ERPG-1	ERPG-2	ERPG-3	IDLH/10	MRL	REL
CHEMICAL NAME	CAS NO.	HAP NO.	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3
Dibutylphthalate	84-74-2	52							400		
p-Dichlorobenzene	106-46-7	53							90	4.8	
Dichloroethyl ether	111-44-4	55							58		
Dichlorvos	62-73-7	57							10	0.018	
Dimethyl formamide	68-12-2	65		270 [p]	540 [p]	6	300	600	150		
Dimethyl phthalate	131-11-3	67							200		
Dimethyl sulfate	77-78-1	68							3.6		
N,N-dimethylaniline	121-69-7	59							50		
1,1-Dimethylhydrazine	57-14-7	66		7.4 [f]	27 [f]				3.7		
4,6-Dinitro-o-cresol	534-52-1	69							0.5		
2,4-Dinitrotoluene	121-14-2	71							5		
1,4-Dioxane	123-91-1	72	61 [p]	1200 [p]	2700 [p]				180		3
Epichlorohydrin	106-89-8	74	19 [p]	91 [p]	270 [p]	7.6	76	380	28		1.3
Ethyl acrylate	140-88-5	76				0.041	120	1200	1400		
Ethyl benzene	100-41-4	77							350		
Ethyl chloride	75-00-3	79							1000	40	
Ethylene dibromide	106-93-4	80							77		
Ethylene dichloride	107-06-2	81				200	810	810	20		
Ethylene glycol	107-21-1	82								1.3	
Ethylene imine (aziridine)	151-56-4	83		8.1 [i]	17 [i]						
Ethylene oxide	75-21-8	84		81 [i]	360 [i]		90	900	140		
Ethylidene dichloride	75-34-3	86							1200		
Formaldehyde	50-00-0	87	0.49 [p]	17 [p]	61 [p]	1.2	12	31	2.5	0.049	0.094
Ethylene glycol butyl ether	111-76-2	181							340	29	14
Ethylene glycol ethyl ether	110-80-5	181							180		0.37
Ethylene glycol ethyl ether acetate	111-15-9	181									0.14
Ethylene glycol methyl ether	109-86-4	181									0.093
Heptachlor	76-44-8	88							3.5		
Hexachlorobutadiene	87-68-3	90				32	110	320			
Hexachloroethane	67-72-1	92								58	
n-Hexane	110-54-3	95							390		
Hydrazine	302-01-2	96	0.13 [i]	17 [i]	46 [i]	0.65	6.5	39	6.5		
Hydrochloric acid	7647-01-0	97	2.7 [i]	33 [i]	150 [i]	4.5	30	220	7.5		2.1
Hydrofluoric acid	7664-39-3	98	0.82 [i]	20 [i]	36 [i]	1.6	16	41	2.5	0.025	0.24
Hydroquinone	123-31-9	99							5		
Lead compounds	7439-92-1	182							10		
Tetraethyl lead	78-00-2	182							4		
Tetramethyl lead	75-74-1	182							4		
Lindane (gamma-HCH)	58-89-9	101							5		
Maleic anhydride	108-31-6	102							1		
Manganese compounds	7439-96-5	183							50		
Mercury (elemental)	7439-97-6	184					1.6	16			0.0018

Table 2. Acute Dose-Response Values (10/22/03)			AEGL-1	AEGL-2	AEGL-3	ERPG-1	ERPG-2	ERPG-3	IDLH/10	MRL	REL
CHEMICAL NAME	CAS NO.	HAP NO.	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3
Mercury compounds	HG_CMPDS	184							1		
Methyl mercury	22967-92-6	184							0.2		
Methanol	67-56-1	103	690 [i]	2700 [i]	10000 [i]	260	1300	6500	790		28
Methoxychlor	72-43-5	104							500		
Methyl bromide	74-83-9	105					190	780	97	0.19	3.9
Methyl chloride	74-87-3	106					830	2100	410	1	
Methyl ethyl ketone	78-93-3	108	290 [p]	5000 [p]	12000 [p]						13
Methyl hydrazine	60-34-4	109		3.6 [f]	11 [f]				7.2		
Methyl iodide	74-88-4	110				150	290	730	58		
Methyl isocyanate	624-83-9	112		0.16 [i]	0.47 [i]	0.058	1.2	12	0.7		
Methyl methacrylate	80-62-6	113							410		
Methyl tert-butyl ether	1634-04-4	114								7.2	
Methylene chloride	75-09-2	116				690	2600	14000	800	2.1	14
Methylene diphenyl diisocyanate	101-68-8	117				0.2	2	25	7.5		
Naphthalene	91-20-3	119							130		
Nickel carbonyl	13463-39-3	186		0.25 [i]	1.1 [i]				1.4		
Nickel compounds	7440-02-0	186							1		0.006
Nitrobenzene	98-95-3	120							100		
2-Nitropropane	79-46-9	123							36		
Parathion	56-38-2	127							1		
Pentachlorophenol	87-86-5	129							0.25		
Phenol	108-95-2	130	17 [i]	58 [i]	180 [i]	38	190	770	96		5.8
Phosgene	75-44-5	132		1.2 [f]	3 [f]		0.81	4	0.81		0.004
Phosphine	7803-51-2	133		2.8 [i]	5 [i]		0.7	7			
Phosphorus, white	7723-14-0	134								0.02	
Phthalic anhydride	85-44-9	135							6		
Propylene dichloride	78-87-5	141							180	0.23	
Propylene oxide	75-56-9	142	140 [i]	690 [i]	1400 [i]	120	590	1800	95		3.1
1,2-Propyleneimine	75-55-8	143		28 [i]	54 [i]						
Quinone	106-51-4	145							10		
Selenium compounds	7782-49-2	189							0.1		
Hydrogen selenide	7783-07-5	189		2.4 [p]	7.3 [p]		0.66	6.6	0.33		0.005
Styrene	100-42-5	146				210	1100	4300	300		21
1,1,2,2-Tetrachloroethane	79-34-5	149							69		
Tetrachloroethene	127-18-4	150	240 [i]	1600 [i]	8100 [i]	680	1400	6800	100	1.4	20
Titanium tetrachloride	7550-45-0	151	0.54 [p]	7.8 [p]	44 [p]	5	20	100			
Toluene	108-88-3	152	750 [i]	1900 [i]	11000 [i]	190	1100	3800	190	3.8	37
2,4-Toluene diisocyanate	584-84-9	154	0.14 [i]	0.59 [i]	3.6 [i]	0.071			1.8		
o-Toluidine	95-53-4	155							22		
1,1,2-Trichloroethane	79-00-5	158							55		
1,1,1-Trichloroethane	71-55-6	107	1300 [i]	3300 [i]	21000 [i]	1900	3800	19000	380	11	68
Trichloroethylene	79-01-6	159	700 [p]	2400 [p]	20000 [p]	540	2700	27000		11	

Table 2. Acute Dose-Response Values (10/22/03)			AEGL-1	AEGL-2	AEGL-3	ERPG-1	ERPG-2	ERPG-3	IDLH/10	MRL	REL
CHEMICAL NAME	CAS NO.	HAP NO.	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3	mg/m3
Triethylamine	121-44-8	162									2.8
Uranium compounds	7440-61-1	188							1		
Uranium hexafluoride	7783-81-5	188	52 [i]	140 [i]	520 [i]	5	15	30			
Vinyl acetate	108-05-4	165				18	260	1800			
Vinyl chloride	75-01-4	167	640 [p]	3100 [p]	12000 [p]					1.3	180
m-Xylene	108-38-3	171							390		
o-Xylene	95-47-6	170							390		
p-Xylene	106-42-3	172							390		
Xylenes (mixed)	1330-20-7	169	560 [p]	1900 [p]	4000 [p]				390	4.3	22
AEGLs: f = final, I = interim, p = proposed											

Appendix D Methodology for Identifying PB-HAP Compounds

This Appendix provides and justifies a list of hazardous air pollutants that have sufficient persistence and bioaccumulation potential to make them candidates for multipathway risk assessments. The list was selected in two stages.

The first stage was to determine which HAPs are already listed as persistent, bioaccumulative, and toxic (PBT) substances by the following EPA programs:

1. Priority PBT Profiles (Pollution Prevention program): http://www.epa.gov/pbt/cheminfo.htm.

2. Great Waters Pollutants of Concern: http://www.epa.gov/oar/oaqps/gr8water/3rdrpt/execsum.html.

3. Toxics Release Inventory: http://www.epa.gov/tri/chemical/pbt_chem_list.htm.

All substances that are both HAPs pursuant to the CAA and listed by at least one of these programs are shown in Exhibit 1.

The second stage was to determine if, based on their toxicity and bioaccumulation potential, any additional substances should be assessed for multipathway risk by the air toxics program. This determination was made by calculating two indexes for all HAPs for which data could be obtained. One index (intended to estimate relative carcinogenic potential by oral exposure) was the product of the oral carcinogenic potency slope and the bioconcentration factor (obtained from the EPA PBT Profiler, http://www.pbtprofiler.net/). The other index (intended to estimate relative noncarcinogenic hazard by oral exposure) was the ratio of the same bioconcentration factor to the oral reference dose. The cancer and noncancer indexes were normalized to a scale of 1 and combined by averaging (with chemicals with no data not averaged, rather than averaged as zero).

The HAPs were then ranked in descending order of the combined index, and the substances that comprised 99.9999% of the total of all substances were selected as potential candidates for multipathway risk assessment. Results of the ranking exercise are shown in Exhibit 1.

Of the 26 substances that comprised 99.9999% of the aggregate index for all HAPs, 19 are classified as polycyclic organic matter under the Clean Air Act. These were combined into a single category in the table. Metals could not be ranked because the PBT Profiler does not contain data for inorganic pollutants, but were included in the table because of their presence on the other lists. Three other substances shown as “NA” fell outside the 99.9999% aggregate limit.

In summary, no substance not already on at least one existing list emerged in this analysis as a significant potential PBT substance. Therefore, based on our current estimates of toxicity and bioaccumulation potential, the 14 substances in the table represent a conservative list for multipathway risk assessments in the air toxics program.

Exhibit 1. Identity and Ranking of Potential PB-HAP Compounds				
PB-HAP Compound	**OAQPS Rank**	**Pollution Prevention Priority PBTs**	**Great Waters Pollutants of Concern**	**TRI PBT Chemicals**
Cadmium compounds	NA[1]		X	
Chlordane	7	X	X	X
Chlorinated dibenzodioxins and furans	1	X[2]	X	X[3]
DDE	8	X	X	
Heptachlor	4			X
Hexachlorobenzene	6	X	X	X
Hexachlorocyclohexane (all isomers)	NA[4]		X	
Lead compounds	NA[1]	X[5]	X	X
Mercury compounds	NA[1]	X	X	X
Methoxychlor	NA[4]			X
Polychlorinated biphenyls	3	X	X	X
Polycyclic organic matter	2[6]	X[7]	X	X[8]
Toxaphene	5	X	X	X
Trifluralin	NA[4]			X

(1) Not ranked because the PBT Profiler lacks data for inorganic compounds
(2) "Dioxins and furans" (denotes the phraseology of the source list)
(3) "Dioxin and dioxin-like compounds"
(4) Did not fall within 99.9999% of cumulative index
(5) Alkyl lead
(6) 19 POM compounds that fell within the top 26 substances were assigned the rank of 7,12-dimethylbenz(a)anthracene, the highest-ranked compound
(7) Benzo[a]pyrene
(8) "Polycyclic aromatic compounds" and benzo[g,h,i]perylene

Appendix E Overview of Air Toxics Emission Sources

This appendix provides general information on the types of air toxics commonly associated with various types of sources. The table begins with the regulated major source categories and is followed by mobile sources, indoor sources, and miscellaneous sources. This table is not meant to be a comprehensive listing of all chemicals that may be emitted from a given source or group of sources in a particular location.

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Commercial / Industrial Sources				
Halogenated Solvent Cleaners (1614)	methylene chloride; perchloroethylene; trichloroethylene; 1,1,1-trichloroethane; carbon tetrachloride; chloroform[c]	SIC: 33, 34, 36, 37 NAICS: 332, 333, 334, 335, 336, 447	MACT/GACT, see 40 CFR Part 63 Subpart T	U.S. EPA. 1995. *Profile of the Iron and Steel Industry.* Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-005. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/iron.html
Acetal Resins Production (1301)		SIC: 2869 NAICS: 325199	MACT, see 40 CFR Part 63 YY (General MACT)	U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry.* Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-008. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Acrylic/Modacrylic Fibers Production (1001)		SIC: 2869 NAICS: 325199	MACT, see 40 CFR Part 63 YY	U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry.* Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-008. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Acrylonitrile-Butadiene-Styrene Production (1302)	styrene; acrylonitrile; butadiene; ethylene glycol; methanol; acetaldehyde; dioxane	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 JJJ	U.S. EPA. 2001. *Polymers and Resins IV Inspection Tool.* Adopt-a-MACT Compliance Tool, Washington, D.C., September 2001. Available at: http://www.epa.gov/ttn/atw/pr4/privinspect.html USEPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry.* Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-008. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Aerospace Industries (0701)	chromium; cadmium; methylene; chloride; toluene; xylene; methyl ethyl ketone; ethylene glycol; glycol ethers	SIC: 3720, 3721, 3724, 3728, 3760, 3761, 3764, 3769 NAICS: 336411, 336412, 336413, 336414, 336419, 481111, 481112	MACT, see 40 CFR Part 63 Subpart GG	U.S. EPA. 1998. *Profile of the Aerospace Industry.* Office of Compliance Sector Notebook Project, Washington, D.C., November 1998. EPA/310-R-98-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/aerospace.html
Amino/Phenolic Resins Production (1347)	formaldehyde, methanol, phenol, xylene, toluene	SIC: 2821 NAICS: 325211	MACT, see 40 CFR Part 63 Subpart OOO	U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry.* Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-006. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html U.S. EPA. 1998. *Hazardous Air Pollutant Emissions from the Manufacture of Amino and Phenolic Resins: Basis and Purpose Document for Proposed Standards.* Emission Standards Division, Washington, D.C., May 1998. Available at: http://www.epa.gov/ttn/atw/amino/p_r3bpd.wpd

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Ammonium Sulfate - Caprolactam By-Product Plants (1401)	toluene; methanol; xylene; methyl ethyl ketone; ethyl benzene; methyl isobutyl ketone; hydrogen chloride; vinyl acetate	NAICS: 3251, 3252, 3253, 3254, 3255, 3256, 3259	MACT, see 40 CFR Part 63 Subpart FFFF	U.S. EPA. 2002. *Profile of the Organic Chemical Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., November 2002. EPA/310-R-02-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/organic.html
Asphalt Roofing and Processing (0418)	formaldehyde; hexane; hydrogen chloride; phenol; polycyclic organic matter; toluene	SIC: 2911, 2952 NAICS: 32411, 324122	MACT, see 40 CFR Part 63 Subpart LLLLL	U.S. EPA. 1995. *Profile of the Stone, Clay, Glass and Concrete Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-017. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/stone.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Asphalt/Coal Tar Application - Metal Pipes (0402)	xylenes; toluene; methyl ethyl ketone; phenol; cresols/cresylic acid; glycol ethers (including ethylene glycol monobutyl ether); styrene; methyl isobutyl ketone; ethyl benzene	NAICS: 335312, 336111, 336211, 336312, 33632, 33633, 33634, 33637, 336399, 331316, 331524, 332321, 332323, 33312, 333611, 333618, 332312, 332722, 332813, 332991, 332999, 334119, 336413, 339999, 33612, 336211, 331319, 331422, 335929, 332311, 33242, 81131, 322214, 326199, 331513, 332439, 331111, 331513, 33121, 331221, 331511, 33651, 336611, 482111, 3369, 331316, 336991, 336211, 336112, 336213, 336214, 336399, 326291, 326299, 332311, 332312, 336212, 336999, 33635, 56121, 8111, 56211	MACT, see 40 CFR Part 63 Subpart MMMM	U.S. EPA. 1995. *Profile of the Fabricated Metal Products Industry*. Office of the Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-007. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/fabric.html U.S. EPA. 1995. *Profile of the Stone, Clay, Glass and Concrete Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-017. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/stone.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Auto & Light Duty Truck (Surface Coating) (0702)	toluene; xylene; glycol ethers; methyl ethyl ketone; methyl isobutyl ketone; ethylbenzene; methanol	NAICS: 336111, 336112, 336211	MACT, see 40 CFR Part 63 Subpart IIII	U.S. EPA. 1995. *Profile of the Motor Vehicle Assembly Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-009. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/motor.html U.S. EPA. 2002. *Regulatory Impact Analysis for the Proposed Automobile and Light Duty Truck Coating NESHAP*. Final Report, Washington, D.C., October 2002. EPA-452/R-01-013. Available at: http://www.epa.gov/ttn/atw/auto/autoriap.pdf U.S. EPA. 1997. *U.S. Auto Assembly Plants and Their Communities -- Environmental, Economic, and Demographic Profile*. Common Sense Initiative Automobile Manufacturing Sector. Washington, D.C., December 1997. Available at: http://www.epa.gov/oar/opar/auto/
Boat Manufacturing (1305)	styrene; methyl methacrylate; methylene chloride (dichloromethane); toluene; xylene; n-hexane; methyl ethyl ketone; methyl isobutyl ketone; methyl chloroform (1,1,1-trichloroethane)	SIC: 3731, 3732 NAICS: 336612	MACT, see 40 CFR Part 63 Subpart VVVV	U.S. EPA. 1997. *Profile of the Shipbuilding and Repair Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., November 1997. EPA/310-R-97-008. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/ship.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Brick and Structural Clay Products Manufacturing (0414)	hydrogen fluoride; hydrogen chloride; antimony; arsenic; beryllium; cadmium; chromium; cobalt; mercury; manganese; nickel; lead; selenium	SIC: 3251, 3253, 3259 NAICS: 327121, 327122, 327123	MACT, see 40 CFR Part 63 Subpart JJJJJ	U.S. EPA. 1995. *Profile of the Stone, Clay, Glass and Concrete Industry.* Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-017. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/stone.html
Butyl Rubber Production (1307)	n-hexane; 1,3-butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1995. *Profile of the Rubber and Plastics Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-016. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/rubber.html
Carbon Black Production (1415)	cyanide compounds; acrylonitrile; acetonitrile; carbonyl sulfide; carbon disulfide; benzene; 1,3 butadiene; toluene; 2,4 toluene diisocyanate	SIC: 2895 NAICS: 325182	General MACT, see 40 CFR Part 63 YY	U.S. EPA. 2002. *Profile of the Organic Chemical Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., November 2002. EPA/310-R-02-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/organic.html
Carbonyl Sulfide (COS) Production (1604)	toluene; methanol; xylene; hydrogen chloride; methylene chloride	NAICS: 3251, 3252, 3253, 3254, 3255, 3256, 3259	MACT, see 40 CFR Part 63 FFFF (General MACT)	U.S. EPA. 2002. *Profile of the Organic Chemical Industry, Second Edition (2002).* Office of Compliance Sector Notebook Project, Washington, D.C., November 2002. EPA/310-R-02-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/organic.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Cellulose Products Manufacturing (1349)	carbon disulfide; carbonyl sulfide; ethylene oxide; methanol; methyl chloride; propylene oxide; toluene	SIC: 2819, 2821, 2823, 2869, 3089 NAICS: 325188, 325199, 325211, 325221, 326121, 326199	MACT, see 40 CFR Part 63 UUUU	U.S. EPA. 2002. Profile of the Pulp and Paper Industry, 2nd Edition. Office of Compliance Sector Notebook Project, Washington, D.C., November 2002. EPA/310-R-02-002. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/pulp.html U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-008. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Mercury Cell Chlor-Alkali Plants (Formerly Chlorine Production)		SIC: chlorine 2812	EPA proposes not to regulate chlorine and hydrochloric acid (HCl) emissions for the Chlorine Production source category.	U.S. EPA. 1995. *Profile of the Inorganic Chemical Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-004. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/inorganic.html
Chromic Acid Anodizing (1607)	chromium	NAICS: 332, 333, 334, 335, 336	MACT, see 40 CFR Part 63 Subpart N	U.S. EPA. 1993. *Chromium Emissions from Chromium Electroplating and Chromic Acid Anodizing Operations*. Background Information for Proposed Standards, Washington, D.C., July 1993. EPA 453/R-93-030a and EPA 453/r-93-030b, Volumes 1 and 2. Available at: http://www.epa.gov/ttn/atw/chrome/chromepg.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Clay Ceramics Manufacturing (0415)	hydrogen flouride; hydrogen chloride; antimony; arsenic; beryllium; cadmium; chromium; cobalt; mercury; manganese; nickel; lead; selenium	SIC: 3253, 3261 NAICS: 327122, 327111	MACT, see 40 CFR Part 63 Subpart KKKKK	U.S. EPA. 1995. *Profile of the Stone, Clay, Glass and Concrete Industry.* Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-017. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/stone.html
Coke Ovens: Charging, Top Side, and Door Leaks (0302)	coal tar (benzene, toluene, and xylene); creosote; coal tar pitch; polycyclic aromatic hydrocarbons (benzo(a)pyrene, benzanthracene, chrysene, phenanthrene)	NAICS: 331111, 324199	MACT, see 40 CFR Part 63 Subpart L	U.S. EPA. 1995. *Profile of the Petroleum Refining Industry*. Office of Compliance, Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-013. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petroleum.html
Coke Ovens: Pushing, Quenching, & Battery Stacks (0303)	polycyclic organic matter; polynuclear aromatic hydrocarbons; benzene; toluene; xylene	NAICS: 331111, 324199	MACT, see 40 CFR Part 63 Subpart CCCCC	U.S. EPA. 1995. *Profile of the Petroleum Refining Industry*. Office of Compliance, Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-013. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petroleum.html
Commercial Sterilization Facilities (1609)	ethylene oxide	NAICS: 3391	MACT, see 40 CFR Part 63 Subpart O	U.S. EPA. 1997. *Ethylene Oxide Commercial Sterilization and Fumigation Operations.* NESHAP Implementation Document. Washington, D.C., September, 1997. EPA-456/R-004. Available at: http://www.epa.gov/ttn/atw/eo/eoguide.pdf

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Cyanide Chemicals Manufacturing (1405)	cyanide compounds; acrylonitrile; acetonitrile; carbonyl sulfide; carbon disulfide; benzene; 1,3 butadiene; toluene; 2,4 toluene diisocyanate	SIC: 2819, 2869 NAICS: 325188, 325199	MACT, see 40 CFR Part 63 YY (General MACT)	
Decorative Chromium Electroplating (1610)	chromium	NAICS: 332, 333, 334, 335, 336	MACT, see 40 CFR Part 63 Subpart N	
Dry Cleaning: Perchloroethylene (1643)	perchloroethylene	NAICS: 8123	MACT, see 40 CFR Part 63 Subpart M	U.S. EPA. 1995. *Profile of the Dry Cleaning Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/dry.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Engine Test Facilities (0101)	toluene; benzene; mixed xylenes; 1,3-butadiene	SIC: 3511, 3519, 3523, 3524, 3531, 3559, 3566, 3599, 3621, 3711, 3714, 3721, 3724, 3761, 3764, 4226, 4512, 4581, 5541, 7538, 7539, 7699, 8299, 8711, 8731, 8734, 8741, 9661, 9711 NAICS: 54171, 92711, 92811, 332212 333111, 333112, 333120, 333319, 333611, 333612, 333618, 335312, 336111, 336112, 336120, 336312, 336350, 336399, 336411, 336412, 336414, 336415, 336992, 481111, 488190, 541380, 611692, 811111, 811118, 811310, 811411	MACT, see 40 CFR Part 63 Subpart PPPPP	
Epichlorohydrin Elastomers Production (1311)	n-hexane; 1,3-butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Epoxy Resins Production (1312)	epichlorohydrin, methanol, hydrochloric acid	SIC: 2821, 2823, 2824	MACT, see 40 CFR Part 63 Subpart W	U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry*. Office of Compliance Sector Notebook Project, Washington, DC, September 1997. EPA/310-R-97-008. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Ethylene Processes (1635)	cyanide compounds; acrylonitrile; acetonitrile; carbonyl sulfide; carbon disulfide; benzene; 1,3 butadiene; toluene; 2,4 toluene diisocyanate	SIC: 2869 NAICS: 325110	MACT, see 40 CFR Part 63 YY	U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry*. Office of Compliance Sector Notebook Project, Washington, DC. EPA/310-R-97-006. http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Ethylene-Propylene Rubber Production (1313)	n-hexane; 1,3-butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1995. *Profile of the Rubber and Plastics Industry*. Office of Compliance Sector Notebook Project, Washington, DC, September 1995. EPA/310-R-95-016. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/rubber.html
Ferroalloys Production (0304)	ferromanganese; silicomanganese; nickel compounds	SIC: 3313	MACT, see 40 CFR Part 63 Subpart XXX	
Flexible Polyurethane Foam Fabrication Operations (1341)	hydrochloric acid; 2,4-toluene diisocyanate; hydrogen cyanide; methylene chloride	SIC: 3086 NAICS: 32615	MACT, see 40 CFR Part 63 Subpart MMMMM	U.S. EPA. 1995. *Profile of the Wood Furniture and Fixtures Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-003. http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/wood.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Flexible Polyurethane Foam Production (1314)	methylene chloride; 2,4-toluene diisocyanate; methyl chloroform; methylene diphenyl diisocyanate; propylene oxide; diethanolamine; methyl ethyl ketone; methanol; toluene	SIC: 3086 NAICS: 32615	MACT, see 40 CFR Part 63 Subpart III	U.S. EPA. 1995. Profile of the Wood Furniture and Fixtures Industry. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-003. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/wood.html
Friction Products Manufacturing (1636)	n-hexane; toluene; trichloroethylene	NAICS: 33634, 327999, 333613	MACT, see 40 CFR Part 63 QQQQQ	
Fumed Silica Production (1406)	hydrochloric acid; chlorine	SIC: 2819, 2821, 2869 NAICS: 325188, 325211, 325199	MACT, see 40 CFR Part 63 Subpart NNNNN	
Gasoline Distribution (Stage I) (0601)	benzene; toluene; hexane; ethyl benzene; naphthalene; cumene; xylenes; n-hexane; 2, 2, 4-trimethylpentane; methyl tert-butyl ether	SIC: 2911, 4226, 4613, 5171 NAICS: 324110, 493190, 486910, 422710	MACT, see 40 CFR Part 63 Subpart R	U.S. EPA. 1995. *Profile of the Petroleum Refining Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-013. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petroleum.html.
Hard Chromium Electroplating (1615)	chromium	NAICS: 332, 333, 334, 335, 336	MACT, see 40 CFR Part 63 Subpart N	

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Hazardous Waste Incineration (0801)	chlorinated dioxins and furans; particulate matter (as a surrogate for antimony, cobalt, manganese, nickel, and selenium); carbon monoxide; mercury; lead; cadmium; arsenic; beryllium; chromium; hydrogen chloride and chlorine gas (combined); hydrocarbons		MACT, see 40 CFR Parts 63, 261 and 270	U.S. EPA. *Hazardous Waste Combustion NESHAP Toolkit.* Available at: http://www.epa.gov/epaoswer/hazwaste/combust/toolkit/index.htm
Hydrochloric Acid Production (1407)	hydrochloric acid; chlorine	SIC: 2819, 2821, 2869 NAICS: 325188, 325211, 325199	MACT, see 40 CFR Part 63 Subpart NNNNN	None found at this writing.
Hydrogen Fluoride Production (1409)		SIC: 2819 NAICS: 325188	MACT, see 40 CFR Part 63 YY (General MACT)	U.S. EPA. *Profile of the Plastic Resins and Man-made Fibers Industry.* Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-006 . Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Hypalon (TM) Production (1315)	n-hexane; 1,3-butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	None found at this writing.

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Industrial/Commercial/ Institutional Boilers & Process Heaters (0107)	arsenic; cadmium; chromium; hydrogen chloride; hydrogen fluoride; lead; manganese; mercury; nickel	SIC: 13, 24, 26, 28, 29, 30, 33, 34, 37, 49, 80, 82 NAICS: 211, 221, 316, 321, 322, 324, 325, 326, 331, 332, 336, 339, 611, 622	MACT, see 40 CFR Part 63 Subpart DDDDD	U.S. EPA. 1999. *Profile of Oil and Gas Extraction Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., October 2000. EPA/310-R-99-006. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/oil.html. Also see *Profile of Lumber and Wood Products Industry, Profile of Organic and Inorganic Chemical Manufacturing Industry, Profile of Petroleum Refining Industry, and Profile of Rubber and Plastic Industry*. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/index.html
Industrial Cooling Towers (1619)	chromium compounds		MACT, see 40 CFR Part 63 Subpart Q	U.S. EPA. 1995. *Profile of the Petroleum Refining Industry*. Office of Compliance, Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-013. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petroleum.html U.S. EPA. 2001. *Profile of the Organic Chemical Industry*. Office of Compliance Assistance and Sector Programs Division. Washington, D.C., September 2001. EPA/310/R-02-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/organic.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Integrated Iron & Steel Manufacturing (0305)	metals (primarily manganese and lead); polycyclic organic matter; benzene; carbon disulfide	SIC: 3312 NAICS: 331111	MACT, see 40 CFR Part 63 Subpart FFFFF	U.S. EPA. 1995. *Profile of the Iron and Steel Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-005. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/iron.html
Iron Foundries (0308)	lead; manganese; cadmium; chromium; nickel; acetophenone; benzene; cumene; dibenzofurans; dioxins; formaldehyde; methanol; naphthalene; phenol; pyrene; toluene; triethylamine; xylene	NAICS: 331511	MACT, see 40 CFR Part 63 Subpart EEEEE	U.S. EPA. 1995. *Profile of the Iron and Steel Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-005. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/iron.html
Large Appliance (Surface Coating) (0704)	glycol ethers; methylene diphenyl diisocyanate; methyl ethyl ketone; toluene; xylene	NAICS: 333312, 333319, 333415, 335221, 335222, 335224, 335228	MACT, see 40 CFR Part 63 Subpart NNNN	U.S. EPA. 1995. *Profile of the Dry Cleaning Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/dry.html.
Leather Tanning & Finishing Operations (1634)	glycol ethers; toluene; xylene	SIC: 3111 NAICS: 3161	MACT, see 40 CFR Part 63 Subpart TTTT	None found as of this writing

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Light Weight Aggregate Manufacturing (0417)	toluene; methanol; methyl ethyl ketone; xylenes; phenol; methylene chloride; ethylene glycol; glycol ethers; hexane; methyl isobutyl ketone; cresols and cresylic acid; dimethylformamide; vinyl acetate; formaldehyde; ethyl benzene	NAICS: 322211, 322212, 322221, 322222, 322223, 322224, 322225, 322226, 322299, 323111, 323116, 325992, 326111, 326112, 326113, 32613, 326192, 32791, 332999, 339944	See MACT in 40 CFR Part 63 Subpart JJJJ	None found as of this writing
Lime Manufacturing (0408)	hydrogen chloride; antimony; arsenic; beryllium; cadmium; chromium; lead; manganese; mercury; nickel; selenium	NAICS: 32741, 33111, 3314	MACT, see 40 CFR Part 63 Subpart AAAAA	None found at this writing.
Magnetic Tapes (Surface Coating) (0705)	methyl ethyl ketone; toluene; methyl isobutyl ketone; toluene diisocyanate; ethylene glycol; methanol; xylenes; ethyl benzene; acetaldehyde; chromium; cobalt	SIC: 3695, 2675	MACT, see 40 CFR Part 63 Subpart EE	
Manufacture of Nutritional Yeast (1101)	acetaldehyde	SIC: 2099 NAICS: 311999	MACT, see 40 CFR Part 63 Subpart CCCC	

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Marine Vessel Loading Operations (0603)	benzene; toluene; hexane		MACT, see 40 CFR Part 63 Subpart Y	U.S. EPA. 1997. *Profile of the Water Transportation Industry (Shipping and Barging).* Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-003. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/water.html
Metal Can (Surface Coating) (0707)	ethylene glycol monobutyl ether; other glycol ethers; xylenes; hexane; methyl isobutyl ketone; methyl ethyl ketone	NAICS: 332115, 332116, 332431, 332812, 332999	MACT, see 40 CFR Part 63 Subpart KKKK	U.S. EPA. 1995. *Profile of the Metal Fabrication Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-007. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/fabric.html
Metal Coil (Surface Coating) (0708)	methyl ethyl ketone; glycol ethers; xylenes (isomers and mixtures); toluene; isophorone.	SIC: 34 NAICS: 332812, 331319, 332312, 332322, 332323, 332311, 33637, 332813, 332999, 333293, 336399, 325992, 42183, 323122, 339991, 326113, 32613, 32614, 331112, 331221, 33121, 331312, 331314, 331315	MACT, see 40 CFR Part 63 Subpart SSSS	U.S. EPA. 1995. *Profile of the Metal Fabrication Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-007. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/fabric.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Metal Furniture (Surface Coating) (0709)	xylene; toluene; ethylene glycol monobutyl ether; other glycol ethers; ethylbenzene; methyl ethyl ketone	NAICS: 81142, 337124, 337127, 337214, 337215, 339111	MACT, see 40 CFR Part 63 Subpart RRRR	U.S. EPA. 1995. *Profile of the Metal Fabrication Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-007. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/fabric.html
Methyl Methacrylate-Acrylonitrile-Butadiene-Styrene Production (1317)	styrene; acrylonitrile; butadiene; ethylene glycol; methanol; acetaldehyde; dioxane	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 JJJ	U.S. EPA. 2001. *Polymers and Resins IV Inspection Tool.* Adopt-a-MACT Compliance Tool, Washington, D.C., September 2001. Available at: http://www.epa.gov/ttn/atw/pr4/privinspect.html
Methyl Methacrylate-Butadiene-Styrene Terpolymers Production (1318)	styrene; acrylonitrile; butadiene; ethylene glycol; methanol; acetaldehyde; dioxane	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 JJJ	U.S. EPA. 2001. *Polymers and Resins IV Inspection Tool.* Adopt-a-MACT Compliance Tool, Washington, D.C., September 2001. Available at: http://www.epa.gov/ttn/atw/pr4/privinspect.html
Mineral Wool Production (0409)	carbonyl sulfide; nine hazardous metals; formaldehyde; phenol	SIC: 3296	MACT, see 40 CFR Part 63 DDD	
Miscellaneous Coatings Manufacturing (1642)	toluene; xylene; glycol ethers; methyl ethyl ketone, and methyl isobutyl ketone	NAICS: 3255	MACT, see 40 CFR Part 63 Subpart HHHHH	U.S. EPA. 1995. *Profile of the Metal Fabrication Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-007. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/fabric.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Miscellaneous Metal Parts & Products (Surface Coating) (0710)	xylene; toluene; methyl ethyl ketone; phenol; cresols/cresylic acid; 2-butoxyethanol; styrene; methyl isobutyl ketone; ethyl benzene; glycol ethers	NAICS: 335312, 336111, 336211, 336312, 33632, 33633, 33634, 33637, 336399, 331316, 331524, 332321, 332323, 33312, 333611, 333618, 332312, 332722, 332813, 332991, 332999, 334119, 336413, 339999, 33612, 336211, 331319, 331422, 335929, 332311, 33242, 81131, 322214, 326199, 331513, 332439, 331111, 331513, 33121, 331221, 331511, 33651, 336611, 482111, 3369, 331316, 336991, 336211, 336112, 336213, 336214, 336399, 326291, 326299, 332311, 332312, 336212, 336999, 33635, 56121, 8111, 56211	MACT, see 40 CFR Part 63 Subpart MMMM	U.S. EPA. 1995. *Profile of the Metal Fabrication Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-007. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/fabric.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Miscellaneous Organic Chemical Products & Processes (1641)	toluene; methanol; xylene; methyl ethyl ketone; ethyl benzene; methyl isobutyl ketone; hydrogen chloride; vinyl acetate	NAICS: 3251, 3252, 3253, 3254, 3255, 3256, 3259	MACT, see 40 CFR Part 63 Subpart FFFF	U.S. EPA. 2002. *Profile of the Organic Chemical Industry, 2nd Edition*. Office of Compliance Sector Notebook Project. Washington, DC., November 2002. EPA/310-R-02-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/organic.html.
Municipal Landfills (0802)	vinyl chloride; ethyl benzene; toluene; benzene	SIC: 4953, 9511 NAICS: 562212, 924110	MACT, see 40 CFR Part 63 Subpart AAAA	None found as of this writing
Natural Gas Transmission & Storage (0504)	benzene; toluene; ethyl benzene; mixed xylenes; n-hexane	SIC: 40,42,46, 49, 1321 NAICS: 211112 Note: Condensate tank batteries, glycol dehydration units, natural gas processing plants, and natural gas transmission and storage facilities not included.	MACT, see 40 CFR Part 63 Subpart HHH	U.S. EPA. 1997. *Profile of the Ground Transportation Industry - Railroad, Trucking, and Pipeline*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-002. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/ground.html
Neoprene Production (1320)	n-hexane; 1,3-butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1997. *Profile of Plastic Resins and Man-Made Fibers Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-006. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Nitrile Butadiene Rubber Production (1321)	n-hexane; 1,3-butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1995. *Profile of the Rubber and Plastic Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-016. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/rubber.html
Nitrile Resins Production (1342)	Styrene, n-hexane, 1,3-butadiene, acrylonitrile, methyl chloride, hydrogen chloride, carbon tetrachloride, chloroprene, toluene		MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1997. *Profile of Plastic Resins and Man-Made Fibers Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-006. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html.
Off-Site Waste and Recovery Operations (0806)	benzene, methylene chloride		MACT, see 40 CFR Part 63 Subpart DD	None found at this writing.
Oil & Natural Gas Production (0501)	benzene; toluene; ethyl benzene; mixed xylenes; n-hexane	SIC: 1311, 1321, 1381, 1382, 1389 NAICS: 211112 (Condensate tank batteries, glycol dehydration units, natural gas processing plants, and natural gas transmission and storage facilities.)	MACT, see 40 CFR Part 63 HH	U.S. EPA. 1999. *Profile of the Oil and Gas Extraction Industry*. Office of Compliance Sector Notebook Project, Washington, D.C. EPA/310-R-99-006. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/oil.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Organic Liquids Distribution (Non-Gasoline) (0602)	benzene; ethylbenzene; toluene; vinyl chloride; xylenes	SIC: 2821, 2865, 2869, 2911, 4226, 4612, 5169, 5171 NAICS: 325211, 325192, 325188, 32411, 49311, 49319, 48611, 42269, 42271	MACT, see 40 CFR Part 63 Subpart EEEE	U.S. EPA. *1997. Profile of the Ground Transportation Industry - Railroad, Trucking and Pipeline.* Office of Compliance Sector Notebook Project. Washington, D.C., September 1997. EPA/310-R-97-002. http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/ground.html U.S. EPA. 1995. *Profile of the Petroleum Refining Industry.* Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-013. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petroleum.html U.S. EPA. 2002. *Organic Chemical Manufacturing Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., November 2002. EPA/310-R-02-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/organic.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Paper & Other Webs (Surface Coating) (0711)	toluene; methanol; methyl ethyl ketone; xylenes; phenol; methylene chloride; ethylene glycol; glycol ethers; hexane; methyl isobutyl ketone; cresols and cresylic acid; dimethylformamide; vinyl acetate; formaldehyde; ethyl benzene	NAICS: 322211, 322212, 322221, 322222, 322223, 322224, 322225, 322226, 322299, 323111, 323116, 325992, 326111, 326112, 326113, 32613, 326192, 32791, 332999, 339944	MACT, see 40 CFR Part 63 JJJJ	MACT Sources: Profile of the Pulp and Paper Industry, 2nd Edition (2002). http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/pulp.html
Pesticide Active Ingredient Production (0911)	toluene; methanol; methyl chloride; hydrogen chloride	SIC: 2869, 2879 NAICS: 32532, 325199	MACT, see 40 CFR Part 63 MMM	U.S. EPA. 2000. *Profile of the Agricultural Chemical, Pesticide, and Fertilizer Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 2000. EPA/310-R-00-003. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/chemical.html
Petroleum Refineries - Catalytic Cracking, Catalytic Reforming, & Sulfur Plant Units (0502)	hydrogen fluoride; hydrogen chloride; 2,2,4-trimethylpentane; methyl tert butyl ether; benzene; naphthalene; cresols/cresylic acid; phenol; ethylbenzene; toluene; hexane; xylenes; methyl ethyl ketone	SIC: 2911	MACT, see 40 CFR Part 63 Subpart CC	U.S. EPA. 1995. *Profile of the Petroleum Refining Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-013. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petroleum.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Petroleum Refineries - Other Sources Not Distinctly Listed (0503)	benzene, toluene, ethyl benzene, 2,2,4-trimethylpentane, cresols/cresylic acid, ethylbenzene, hexane, methyl ethyl ketone	SIC: 2911	MACT, see 40 CFR Part 63 Subpart CC	U.S. EPA. 1995. *Profile of the Petroleum Refining Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-013. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petroleum.html.
Pharmaceuticals Production (1201)	methylene chloride; methanol; toluene; hydrogen chloride; dimethylformamide; hexane	SIC: 2833, 2834 NAICS: 32541, 325412	MACT, see 40 CFR Part 63 GGG	U.S. EPA. 1997. *Profile of the Pharmaceutical Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1997. EPA/310-R-97-005. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/pharmaceutical.html
Phosphate Fertilizers Production (1410)	hydrogen fluoride; arsenic; beryllium; cadmium; chromium; manganese; mercury; nickel; methyl isobutyl ketone	SIC: 2874 NAICS: 325314	MACT, see 40 CFR Part 63 BB	U.S. EPA. 2000. *Profile of the Agricultural Chemical, Pesticide, and Fertilizer Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 2000. EPA/310-R-00-003. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/chemical.html
Phosphoric Acid Manufacturng (1411)	hydrogen fluoride; arsenic; beryllium; cadmium; chromium; manganese; mercury; nickel; methyl isobutyl ketone	SIC: 2874 NAICS: 325314	MACT, see 40 CFR Part 63 AA	U.S. EPA. 2000. *Profile of the Agricultural Chemical, Pesticide, and Fertilizer Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 2000. EPA/310-R-00-003. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/chemical.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Plastic Parts & Products (Surface Coating) (0712)	methyl ethyl ketone; methyl isobutyl ketone; toluene; ethylene glycol monobutyl ether; other glycol ethers; xylenes	NAICS: 32615, 32614, 33422, 33992, 326199, 333313, 336211, 336212, 336213, 336214, 336399, 336999, 337214, 339111, 339112, 339999	MACT, see 40 CFR Part 63 Subpart PPPP	U.S. EPA. 1995. *Profile of the Motor Vehicle Assembly Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-009. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/motor.html
Plywood and Composite Wood Products (1624)	acetaldehyde; acrolein; formaldehyde; methanol; phenol; propionaldehyde	SIC: 2421, 2435, 2436, 2439, 2493 NAICS: 321211, 321212, 321213, 321219, 321999	MACT, see 40 CFR Part 63 Subpart DDDD	The Plywood and Composite Wood Products MACT was proposed on January 9, 2003. The comment period ended on March 10, 2003. The final rule will most likely be promulgated in March 2004, with a compliance date of March 2007.
Polybutadiene Rubber Production (1325)	styrene; n-hexane; 1,3- butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1995. *Profile of the Rubber and Plastic Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-016. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/rubber.html
Polycarbonates Production (1326)	TOC, organic HAPs	SIC: 2869 NAICS: 325199	MACT, see 40 CFR Part 63 YY (Generic MACT)	U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1997. EPA/310-R-97-006 . Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Polyether Polyols Production (1625)	ethylene oxide; propylene oxide; hexane; toluene	SIC: 2843, 2869 NAICS: 325199, 325613	MACT, see 40 CFR Part 63 PPP	None found at this writing.

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Polyethylene Terephthalate Production (1328)	styrene; acrylonitrile; butadiene; ethylene glycol; methanol; acetaldehyde; dioxane	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 JJJ	U.S. EPA. 2001. *Polymers and Resins IV Inspection Tool.* Adopt-a-MACT Compliance Tool, Washington, D.C., September 2001. Available at: http://www.epa.gov/ttn/atw/pr4/privinspect.html
Polystyrene Production (1331)	styrene; acrylonitrile; butadiene; ethylene glycol; methanol; acetaldehyde; dioxane	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 JJJ	U.S. EPA. 2001. *Polymers and Resins IV Inspection Tool.* Adopt-a-MACT Compliance Tool, Washington, D.C., September 2001. Available at: http://www.epa.gov/ttn/atw/pr4/privinspect.html
Polysulfide Rubber Production (1332)	styrene; n-hexane; 1,3- butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 30	MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1995. *Profile of the Rubber and Plastic Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-016. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/rubber.html
Polyvinyl Chloride & Copolymers Production (1336)	vinyl chloride; vinylidene chloride (1,1 dichloroethylene); vinyl acetate	SIC: 2821 NAICS: 325211	MACT, see 40 CFR Part 63 J	None found as of this writing

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Portland Cement Manufacturing (0410)	acetaldehyde; arsenic; benzene; cadmium; chromium; chlorobenzene; dibenzofurans; formaldehyde; hexane; hydrogen chloride; lead; manganese; mercury; naphthalene; nickel; phenol; polycyclic organic matter; selenium; styrene; 2,3,7,8-tetrachlorodibenzo-p-dioxin; toluene; xylenes	SIC: 3241 NAICS: 32731	MACT, see 40 CFR Part 63 Subpart LLL	U.S. EPA. 1995. *Profile of the Stone, Clay, Glass and Concrete Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-017. http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/stone.html
Primary Aluminum Production (0201)	hydrogen flouride; polycyclic aromatic hydrocarbons	NAICS: 331312	MACT, see 40 CFR Part 63 Subpart LL	U.S. EPA. 1995. *Profile of the Nonferrous Metals Industry*. Office of Compliance Sector Notebook Project. Washington, D.C., September 1995. EPA/310-R-95-010. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/nonferrous.html
Primary Copper Smelting (0203)	antimony; arsenic; beryllium; cadmium; cobalt; lead; manganese; nickel; selenium	SIC: 3339	MACT, see 40 CFR Part 63 Subpart QQQ	None found at this writing.
Primary Lead Smelting (0204)	arsenic; antimony; cadmium	SIC: 3339	MACT, see 40 CFR Part 63 Subpart TTT	None found at this writing.
Primary Magnesium Refining (0207)	chlorine; hydrochloric acid; dioxin/furan; trace amounts of several HAP metals	NAICS: 331419	MACT, see 40 CFR Part 63 Subpart TTTTT	None found at this writing.

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Printing, Coating & Dyeing Of Fabrics (0713)	toluene; methyl ethyl ketone; methanol; xylenes; methyl isobutyl ketone; methylene chloride; n-hexane; trichloroethylene; n,n-dimethyl formamide.; 1,1,1-trichloroethane; naphthalene; ethyl benzene; glycol ethers (ethylene glycol); biphenyl; styrene	NAICS: 31321, 31322, 313241, NAICS: 313311, 313312, 313320, 314110	MACT, see 40 CFR Part 63 Subpart OOOO	U.S. EPA. 1997. *Profile of the Textiles Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-009. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/textiles.html
Printing/Publishing (Surface Coating) (0714)	xylene; toluene; ethylbenzene; methyl ethyl ketone; methyl isobutyl ketone; methanol; ethylene glycol; certain glycol ethers	SIC: 2671, 2711, 2721, 2754, 2759	MACT, see 40 CFR Part 63 Subpart KK	U.S. EPA. 1995. *Profile of the Printing Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-014. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/printing.html
Publicly Owned Treatment Works (POTW) Emissions (0803)	xylenes; methylene chloride; toluene; ethyl benzene; chloroform; tetrachloroethylene; benzene; naphthalene	SIC: 4952 NAICS: 22132	MACT, see 40 CFR Part 63 Subpart VVV	None found at this writing.
Pulp & Paper Production - Combustion (Kraft, Soda, Sulfite, & Semi-Chemical) (1626-2)		SIC: 2611, 2621,2631 NAICS: 32211, 32212, 32213	MACT, see 40 CFR Part 63 Subpart S	U.S. EPA. 2002. *Profile of the Pulp and Paper Industry, 2nd Edition*. Office of Compliance Sector Notebook Project, Washington, D.C., November 2002. EPA/310-R-95-015. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/pulp.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Pulp & Paper Production - Non-Combustion (1626-1)		SIC 26	MACT, see 40 CFR Part 63 Subpart S	U.S. EPA. 2002. *Profile of the Pulp and Paper Industry, 2nd Edition*. Office of Compliance Sector Notebook Project, Washington, D.C., November 2002. EPA/310-R-95-015. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/pulp.html
Refractories Products Manufacturing (0406)	ethylene glycol; formaldehyde; hydrogen fluoride; hydrochloric acid; methanol; phenol; polycyclic organic matter	NAICS: 327124, 327125	MACT, see 40 CFR Part 63 Subpart SSSSS	None found at this writing.
Reinforced Plastic Composites Production (1337)	styrene; methyl methacrylate; methylene chloride (dichloromethane)	SIC: 2821, 3084, 3087, 3088, 3089, 3281, 3296, 3431, 3531, 3612, 3613, 3621, 3663, 3711, 3713, 3714, 3716, 3728, 3743, 3792, 3799 NAICS: 33312, 33612, 33651, 33653, 35313, 325211, 325991, 326122, 326191, 327991, 327993, 332998, 333422, 335311, 335312, 336112, 336211, 336213, 336214, 336399, 336413	MACT, see 40 CFR Part 63 Subpart WWWW	None found at this writing.

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Rocket Engine Test Firing (1627)	toluene, benzene, mixed xylenes, 1,3-butadiene	SIC: 3724, 3761, 3764, 9661, 9711 NAICS: 336412, 336414 , 336415, 54171, 92711, 92811	MACT, see 40 CFR Part 63 Subpart PPPPP	U.S. EPA. 1997. *Profile of the Air Transportation Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., February 1998. EPA/310-R-97-001. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/air.html
Rubber Tire Production (1631)	toluene; hexane	SIC: 2296, 3011, 7534 NAICS: 314992, 326211, 326212	MACT, see 40 CFR Part 63 Subpart XXXX	U.S. EPA. *Profile of the Rubber and Plastic Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-016. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/rubber.html
Secondary Aluminum Production (0202)	hydrogen chloride, hydrogen fluoride, chlorine, 2,3,7,8-tetrachlorodibenzo-p-dioxin, organic HAPs, particulate HAP metals	SIC: 3341, 3334, 3353, 3354, 3355, 3363, 3365 NAICS: 331314, 331312, 331315, 331316, 331319, 331521, 331524	MACT, see 40 CFR Part 63 Subpart RRR	None found at this writing.
Secondary Lead Smelting (0205)	lead compounds; arsenic compounds; 1,3-butadiene	NAICS: 331492	MACT, see 40 CFR Part 63 Subpart X	None found at this writing.
Semiconductor Manufacturing (1629)	hydrochloric acid; hydrogen flouride; methanol; glycol ethers; xylene	SIC: 3674 NAICS: 334413	MACT, see 40 CFR Part 63 Subpart BBBBB	U.S. EPA. 2001. *National Emission Standards for Hazardous Air Pollutants: Semiconductor Manufacturing-Background Information for Proposed Standards*. Office of Air Quality Planning and Standards, Research Triangle Park, NC, February 2001. Available at: http://www.epa.gov/ttn/atw/semicon/smatr_bid.pdf

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Shipbuilding & Ship Repair (Surface Coating) (0715)	xylene; toluene; ethylbenzene; methyl ethyl ketone; methyl isobutyl ketone; ethylene glycol; glycol ethers	SIC: 3731	MACT, see 40 CFR Part 63 Subpart II	U.S. EPA. 1997. *Profile of the Shipbuilding and Repair Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., November 1997. EPA/310-R-97-008. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/ship.html
Site Remediation (0805)	benzene; ethyl benzene; toluene; vinyl chloride; xylenes; other volatile organic compounds	NAICS: 325211, 325192, 325188, 32411, 49311, 49319, 48611, 42269, 42271	MACT, see 40 CFR Part 63 Subpart GGGGG	
Solvent Extraction for Vegetable Oil Production (1103)	n-hexane	SIC: 2076, 2079 NAICS: 311223	MACT, see 40 CFR Part 63 Subpart GGGG	None found at this writing.
Spandex Production (1003)	cyanide compounds; acrylonitrile; acetonitrile; carbonyl sulfide; carbon disulfide; benzene; 1,3 butadiene; toluene; 2,4 toluene diisocyanate	SIC: 2824 NAICS: 325222	MACT, see 40 CFR Part 63 YY	U.S. EPA. 1997. *Profile of the Plastic Resins and Man-made Fibers Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1997. EPA/310-R-97-006. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/plastic.html
Stationary Combustion Turbines (0108)	formaldehyde; toluene; benzene; acetaldehyde	SIC: 1311, 1321, 4911, 4922, 4931 NAICS: 221, 2211, 211111, 211112, 486210	MACT, see 40 CFR Part 63 YYYY	
Stationary Reciprocal Internal Combustion Engines (0105)	formaldehyde; acrolein; methanol; acetaldehyde	SIC: 1311, 1321, 4911, 4922, 9711 NAICS: 2211, 48621, 92811, 211111, 211112	MACT, see 40 CFR Part 63 Subpart ZZZZ	

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Steel Pickling - HCL Process (0310)	hydrochloric acid	SIC: 3312, 3315, 3317	MACT, see 40 CFR Part 63 Subpart CCC	
Styrene Acrylonitrile Production (1338)	styrene; acrylonitrile; butadiene; ethylene glycol; methanol; acetaldehyde; dioxane	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 JJJ	U.S. EPA. 2001. *Polymers and Resins IV Inspection Tool.* Adopt-a-MACT Compliance Tool, Washington, D.C., September 2001. Available at: http://www.epa.gov/ttn/atw/pr4/privinspect.html
Styrene-Butadiene Rubber & Latex Production (1339)	styrene; n-hexane; 1,3- butadiene; acrylonitrile; methyl chloride; hydrogen chloride; carbon tetrachloride; chloroprene; toluene	SIC: 2821, 2822 NAICS: 325211, 325212	MACT, see 40 CFR Part 63 Subpart U	U.S. EPA. 1995. *Profile of the Rubber and Plastic Industry*. Office of Compliance Sector Notebook Program, Washington, D.C., September 1995. EPA/310-R-95-016. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/rubber.html
Synthetic Organic Chemical Manufacturing (HON) (1501)	toluene, methanol, xylene, hydrogen chloride, and methylene chloride	NAICS: 3251, 3252, 3253, 3254, 3255, 3256, 3259	MACT, see 40 CFR Part 63 Subpart FFFF and Miscellaneous Organic NESHAP	
Taconite Iron Ore Processing (0411)	metal compounds (such as manganese, arsenic, lead, nickel, chromium, and mercury); products of incomplete combustion (including formaldehyde); hydrogen chloride; hydrogen fluoride	NAICS: 21221	MACT, see 40 CFR Part 63 Subpart RRRRR	None found at this writing.

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Utility Boilers: Coal (1808-1)	arsenic; cadmium; chromium; hydrogen chloride; hydrogen fluoride; lead; manganese; mercury; nickel	SIC: 29 NAICS: 324	See 40 CFR Part 63 Subpart DDDDD	None found at this writing.
Utility Boilers: Natural Gas (1808-2)	arsenic; cadmium; chromium; hydrogen chloride; hydrogen fluoride; lead; manganese; mercury; nickel	SIC: 13, 49 NAICS: 211, 221	See 40 CFR Part 63 Subpart DDDDD	None found at this writing.
Utility Boilers: Oil (1808-3)	arsenic; cadmium; chromium; hydrogen chloride; hydrogen fluoride; lead; manganese; mercury; nickel	SIC: 24, 29 NAICS: 321, 324	See 40 CFR Part 63 Subpart DDDDD	None found at this writing.
Wet-Formed Fiberglass Mat Production (0413)	formaldehyde; methanol; vinyl acetate	SIC: 3229325 NAICS: 327212	MACT, see 40 CFR Part 63 Subpart HHHH	None found at this writing.
Wood Building Products (Surface Coating) (0703)	xylenes; toluene; ethyl benzene; ethylene glycol monobutyl ether; other glycol ethers; methyl ethyl ketone; methyl isobutyl ketone; methanol; styrene; formaldehyde	SIC: 2421, 2426, 2431, 2435, 2436, 2493, 2499 NAICS: 321211, 321212, 321219, 321911, 321918, 321999 Note: The subcategory of the SIC and NAICS code depends on the final end use of the product.	MACT, see 40 CFR Part 63 Subpart QQQQ	U.S. EPA. 1995. *Profile of the Wood Furniture and Fixtures Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-003. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/wood.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Wood Furniture (Surface Coating) (0716)	toluene; xylene; methanol; methyl ethyl ketone; methyl isobutyl ketone; glycol ethers; formaldehyde	SIC: 2511, 2512, 2517, 2519, 2521, 2531, 2541	MACT, see 40 CFR Part 63 Subpart JJ	U.S. EPA. 1995. *Profile of the Wood Furniture and Fixtures Industry*. Office of Compliance Sector Notebook Project, Washington, D.C., September 1995. EPA/310-R-95-003. Available at: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/wood.html
Wool Fiberglass Manufacturing (0412)	arsenic, chromium, lead, formaldehyde, phenol, and methanol	SIC: 3296	MACT, see 40 CFR Part 63 Subpart NNN	None found at this writing.
Mobile Sources				
Mobile sources	acetaldehyde, acrolein, arsenic compounds, benzene, 1,3-butadiene, chromium compounds, diesel particulate matter, diesel exhaust organic gases, dioxin/ furans, ethylbenzene, formaldehyde , n-hexane, lead compounds, manganese compounds, mercury compounds, MTBE, naphthalene, nickel compounds, polycyclic organic matter, styrene, toluene, xylene	N/A	Various, see http://www.epa.gov/otaq/	EPA's Office of Transportation Air Qualtiy provides information on mobile source air toxics at http://www.epa.gov/otaq/toxics.htm In-depth information on desiel engine exhaust can be found at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=29060&CFID=12048081&CFTOKEN=92457493 The Health Effects Institute is an independent, nonprofit corporation chartered in 1980 to provide high-quality, impartial, and relevant science on the health effects of pollutants from motor vehicles and from other sources in the environment (see www.healtheffects.org).

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Indoor Sources				
Tobacco smoke	Many, including benzene, toluene, formaldehyde, acrolein, N-nitrosdimethyl-amine, polycyclic organic matter, methyl chloride, 1,3-butadiene, phenol, catechol, hydroquinone, aniline, o-toluidine, quinoline, polychlorinated dibenzo-p-dioxins, nickel, cadmium, polonium-210	N/A	Voluntary programs to protect children from the effects of secondhand smoke	U.S. EPA. 1992. *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*. Office of Research and Development and Office of Air and Radiation, Washington, D.C., December 1992. EPA/600/6-90/006F. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2835 Smoke-Free Homes Campaign: http://www.epa.gov/smokefree/
Consumer and commercial products	Many organic chemicals and metals, including benzene, toluene, xylenes, aldehydes and ketones, chlorinated solvents, ethylene glycol and glycol ethers, phthalates, pesticides	N/A	Voluntary programs to control exposures/risks	Sources of VOCs indoors: http://www.epa.gov/iaq/voc.html Pesticides: http://www.epa.gov/iaq/pesticid.html

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Building materials	Many, including formaldehyde from pressed wood products; chemicals (see consumer and commercial products) from caulks and sealants, paints and wall coverings, floor coverings, etc.; and asbestos and lead in older buildings	N/A	Voluntary programs to control exposures/risks	Formaldehyde: http://www.epa.gov/iaq/formalde.html Asbestos: http://www.epa.gov/asbestos/ashome.html Lead: http://www.epa.gov/iaq/lead.html
Natural Sources				
Forest fires	Various volatile and semivolatile organic compounds (e.g., dioxins, PAHs)	N/A	No federal programs currently exist	See tables 32-34 in: http://www.epa.gov/ttn/chief/ap42/ch13/related/firerept.pdf. Also see the documentation for the Preliminary 2002 National Emissions Inventory (NEI), pages A58-A70: ftp://ftp.epa.gov/pub/EmisInventory/prelim2002nei/nonpoint/documentation/2002preliminneinonpt_032004.pdf, and and the 1999 final NEI, (pages A56-A60: ftp://ftp.epa.gov/EmisInventory/finalnei99ver3/haps/documentation/nonpoint/nonpt99ver3_aug2003.pdf
Radon	radon	N/A	Voluntary programs to control exposures/risks	Radon in indoor air: http://www.epa.gov/radon

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
Other Sources				
Long-range transport	aldrin, chlordane, DDT, dieldrin, dioxins and furans, endrin, mirex, heptachlor, hexachlorobenzene, mercury, PCBs, toxaphene	N/A	N/A	Information on mercury as a global pollutant can be found on the United Nations Environment Programme website, which also provides in-depth information and assessment of the issue of global mercury (see http://www.chem.unep.ch/mercury/). General information about the health and environmental impacts of persistent organic pollutants (POPs) can be found at http://www.epa.gov/international/toxics/brochure.html. This site describes what actions the United States and some other countries have already taken to address these pollutants, and to describe the actions set into motion by the Stockholm Convention on POPs to address ths issue globally. More in-depth information on global POPs can be found in *The Foundation for Global Action on Persistent Organic Pollutants: a United States Perspective*, Office of Research and Development, U.S. EPA, Research Triangle Park, NC, EPA/600/P-01/003F, 2002 (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=51746). General reference websites with information on the issue of long range transport are EPA's Great Lakes National Program Office (GLNPO; www.epa.gov/glnpo/), the Binational Toxics Strategy (www.epa.gov/glnpo/bns/), and the Artic Monitoring and Assessment Programme (http://www.amap.no/).

Source Name[a]	Typical Pollutants	Typical Industries (SIC)	Regulatory and Control Programs	References and Other Information
[a] HAP Source Category names are followed by MACT source category codes used for source classification in the National Toxics Inventory (see http://www.epa.gov/ttn/chief/codes/index.html#mact). Except for mobile and natural sources, and sources of indoor air toxics, the table does not include sources of criteria pollutants and TRI chemicals that are not also MACT HAP sources.				
(b) Very limited information is available about emissions and risks associated with the many non-HAP compounds used in solvent cleanings since the MACT rule was promulgated. These compounds are not listed in the table.				
[c]The estimate of air toxics emissions from halogenated solvent cleaning is from background analyses conducted for the MACT rule. The estimate is based on estimates and assumptions about the national number of cleaning machines, the types of cleaning machines and processes in use, control equipment and work practice standards in use before and after the MACT rule, solvents used and solvent use rates, and emissions factors for the various machine types and control equipment combinations. A sample of MACT compliance reports collected from states and EPA regions for a residual risk assessment suggest that (1) the population of cleaning machines estimated for the MACT rule may have been substantially overestimated and/or (2) many cleaning machines have been removed from service or changed to solvents not covered by the MACT.				

Appendix F Specific HAPs Included in the National Emissions Inventory (NEI)

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
1,1,1-Trichloroethane	Methyl Chloroform (1,1,1-Trichloroethane)	Methyl Chloroform	71-55-6
1,1,2,2-Tetrachloroethane	1,1,2,2-Tetrachloroethane	1,1,2,2-Tetrachloroethane	79-34-5
1,1,2-Trichloroethane	1,1,2-Trichloroethane	1,1,2-Trichloroethane	79-00-5
1,1'-Biphenyl, chloro derivs.	Polychlorinated Biphenyls (Aroclors)	Polychlorinated Biphenyls	1336-36-3
1,1-Dichloroethane	Ethylidene Dichloride (1,1-Dichloroethane)	Ethylidene Dichloride (1,1-Dichloroethane)	75-34-3
1,1-Dichloroethylene	Vinylidene Chloride (1,1-Dichloroethylene)	Vinylidene Chloride	75-35-4
1,1-Dimethylhydrazine	1,1-Dimethylhydrazine	1,1-Dimethyl Hydrazine	57-14-7
1,2,3,4,6,7,8,9-Octachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	Octachlorodibenzofuran	39001-02-0
1,2,3,4,6,7,8,9-Octachlorodibenzo-p-dioxin	Dioxins/Furans as 2,3,7,8-TCDD TEQs	Octachlorodibenzo-p-Dioxin	3268-87-9
1,2,3,4,6,7,8-Heptachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,4,6,7,8-Heptachlorodibenzofuran	67562-39-4
1,2,3,4,6,7,8-Heptachlorodibenzo-p-dioxin	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,4,6,7,8-Heptachlorodibenzo-p-Dioxin	35822-46-9
1,2,3,4,7,8,9-Heptachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,4,7,8,9-Heptachlorodibenzofuran	55673-89-7
1,2,3,4,7,8-Hexachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,4,7,8-Hexachlorodibenzofuran	70648-26-9
1,2,3,4,7,8-Hexachlorodibenzo-p-dioxin	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,4,7,8-Hexachlorodibenzo-p-Dioxin	39227-28-6
1,2,3,6,7,8-Hexachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,6,7,8-Hexachlorodibenzofuran	57117-44-9
1,2,3,6,7,8-Hexachlorodibenzo-p-dioxin	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,6,7,8-Hexachlorodibenzo-p-Dioxin	57653-85-7
1,2,3,7,8,9-Hexachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,7,8,9-Hexachlorodibenzofuran	72918-21-9
1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,7,8,9-Hexachlorodibenzo-p-Dioxin	19408-74-3
1,2,3,7,8-Pentachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,7,8-Pentachlorodibenzofuran	57117-41-6
1,2,3,7,8-Pentachlorodibenzo-p-dioxin	Dioxins/Furans as 2,3,7,8-TCDD TEQs	1,2,3,7,8-Pentachlorodibenzo-p-Dioxin	40321-76-4

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
1,2,4-Trichlorobenzene	1,2,4-Trichlorobenzene	1,2,4-Trichlorobenzene	120-82-1
1,2-Butylene oxide	1,2-Epoxybutane	1,2-Epoxybutane	106-88-7
1,2-Dibromo-3-chloropropane	1,2-Dibromo-3-Chloropropane	1,2-Dibromo-3-Chloropropane	96-12-8
1,2-Dichloroethane	Ethylene Dichloride (1,2-Dichloroethane)	Ethylene Dichloride	107-06-2
1,2-Dichloropropane	Propylene Dichloride (1,2-Dichloropropane)	Propylene Dichloride	78-87-5
1,2-Diphenylhydrazine	1,2-Diphenylhydrazine	1,2-Diphenylhydrazine	122-66-7
1,3-Butadiene	1,3-Butadiene	1,3-Butadiene	106-99-0
1,3-Dichloropropene	1,3-Dichloropropene	1,3-Dichloropropene	542-75-6
1,3-Propane sultone	1,3-Propane Sultone	1,3-Propanesultone	1120-71-4
1,4-Dichlorobenzene	1,4-Dichlorobenzene	1,4-Dichlorobenzene	106-46-7
1,4-Dioxane	p-Dioxane	p-Dioxane	123-91-1
1,6-Dinitropyrene	Polycyclic Organic Matter	1,6-Dinitropyrene	42397-64-8
1,8-Dinitropyrene	Polycyclic Organic Matter	1,8-Dinitropyrene	42397-65-9
12-Methylbenz[a]anthrancene	Polycyclic Organic Matter	12-Methylbenz(a)Anthracene	2422-79-9
1-Methylnaphthalene	Polycyclic Organic Matter	1-Methylnaphthalene	90-12-0
1-Methylphenanthrene	Polycyclic Organic Matter	1-Methylphenanthrene	832-69-9
1-Methylpyrene	Polycyclic Organic Matter	1-Methylpyrene	2381-21-7
1-Nitropyrene	Polycyclic Organic Matter	1-Nitropyrene	5522-43-0
2,2,4-Trimethylpentane	2,2,4-Trimethylpentane	2,2,4-Trimethylpentane	540-84-1
2,3,4,6,7,8-Hexachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	2,3,4,6,7,8-Hexachlorodibenzofuran	60851-34-5
2,3,4,7,8-Pentachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	2,3,4,7,8-Pentachlorodibenzofuran	57117-31-4
2,3,7,8-Tetrachlorodibenzofuran	Dioxins/Furans as 2,3,7,8-TCDD TEQs	2,3,7,8-Tetrachlorodibenzofuran	51207-31-9
2,3,7,8-Tetrachlorodibenzo-p-dioxin	Dioxins/Furans as 2,3,7,8-TCDD TEQs	2,3,7,8-Tetrachlorodibenzo-p-Dioxin	1746-01-6
2,3,7,8-Tetrachlorodibenzo-p-dioxin, TEQ	Dioxins/Furans as 2,3,7,8-TCDD TEQs	2,3,7,8-TCDD TEQ	No CAS Number
2,4,5-Trichlorophenol	2,4,5-Trichlorophenol	2,4,5-Trichlorophenol	95-95-4
2,4,6-Trichlorophenol	2,4,6-Trichlorophenol	2,4,6-Trichlorophenol	88-06-2
2,4-D	2,4-D (2,4-Dichlorophenoxyacetic Acid)(Including Salts And Esters)	2,4-Dichlorophenoxy Acetic Acid	94-75-7
2,4-Dinitrophenol	2,4-Dinitrophenol	2,4-Dinitrophenol	51-28-5

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
2,4-Dinitrotoluene	2,4-Dinitrotoluene	2,4-Dinitrotoluene	121-14-2
2,4-Toluenediamine	Toluene-2,4-Diamine	Toluene-2,4-Diamine	95-80-7
2-Acetylaminofluorene	2-Acetylaminofluorene	2-Acetylaminofluorene	53-96-3
2-Chloroacetophenone	2-Chloroacetophenone	2-Chloroacetophenone	532-27-4
2-Chloronaphthalene	Polycyclic Organic Matter	2-Chloronaphthalene	91-58-7
2-Ethoxyethanol	Glycol Ethers	Cellosolve Solvent	110-80-5
2-Methoxyethanol	Glycol Ethers	Ethylene Glycol Methyl Ether	109-86-4
2-Methoxyethyl oleate	Glycol Ethers	Methoxyethyl Oleate	111-10-4
2-Methylnaphthalene	Polycyclic Organic Matter	2-Methylnaphthalene	91-57-6
2-Nitrofluorene	Polycyclic Organic Matter	2-Nitrofluorene	607-57-8
2-Nitropropane	2-Nitropropane	2-Nitropropane	79-46-9
2-Propoxyethanol acetate	Glycol Ethers	2-Propoxyethyl Acetate	20706-25-6
3,3'-Dichlorobenzidine	3,3'-Dichlorobenzidene	3,3'-Dichlorobenzidene	91-94-1
3,3'-Dimethoxybenzidine	3,3'-Dimethoxybenzidine	3,3'-Dimethoxybenzidine	119-90-4
3,3'-Dimethylbenzidine	3,3'-Dimethylbenzidine	3,3'-Dimethylbenzidine	119-93-7
3-Butoxy-1-propanol	Glycol Ethers	3-Butoxy-1-Propanol	10215-33-5
3-Methylcholanthrene	Polycyclic Organic Matter	3-Methylcholanthrene	56-49-5
4,4'-Methylenebis(2-chloroaniline)	4,4'-Methylenebis(2-Chloroaniline)	4,4'-Methylenebis(2-Chloraniline)	101-14-4
4,4'-Methylenedi(phenyl isocyanate)	4,4'-Methylenediphenyl Diisocyanate (MDI)	4,4'-Methylenediphenyl Diisocyanate	101-68-8
4,4'-Methylenedianiline	4,4'-Methylenedianiline	4,4'-Methylenedianiline	101-77-9
4,6-Dinitro-o-cresol	4,6-Dinitro-o-Cresol (Including Salts)	4,6-Dinitro-o-Cresol	534-52-1
4-Aminobiphenyl	4-Aminobiphenyl	4-Aminobiphenyl	92-67-1
4-Dimethylaminoazobenzene	4-Dimethylaminoazobenzene	4-Dimethylaminoazobenzene	60-11-7
4-Nitrobiphenyl	4-Nitrobiphenyl	4-Nitrobiphenyl	92-93-3
4-Nitrophenol	4-Nitrophenol	4-Nitrophenol	100-02-7
5-Methylchrysene	Polycyclic Organic Matter	5-Methylchrysene	3697-24-3
6-Nitrochrysene	Polycyclic Organic Matter	6-Nitrochrysene	7496-02-8
7,12-Dimethylbenz[a]anthracene	Polycyclic Organic Matter	7,12-Dimethylbenz[a]Anthracene	57-97-6
9-Methylanthracene	Polycyclic Organic Matter	9-Methylbenz(a)Anthracene	779-02-2
Acenaphthene	Polycyclic Organic Matter as 15-PAH	Acenaphthene	83-32-9
Acenaphthylene	Polycyclic Organic Matter as 15-PAH	Acenaphthylene	208-96-8
Acetaldehyde	Acetaldehyde	Acetaldehyde	75-07-0
Acetamide	Acetamide	Acetamide	60-35-5
Acetonitrile	Acetonitrile	Acetonitrile	75-05-8
Acetophenone	Acetophenone	Acetophenone	98-86-2

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Acrolein	Acrolein	Acrolein	107-02-8
Acrylamide	Acrylamide	Acrylamide	79-06-1
Acrylic acid	Acrylic Acid	Acrylic Acid	79-10-7
Acrylonitrile	Acrylonitrile	Acrylonitrile	107-13-1
Alkylated lead	Lead Compounds	Alkylated Lead	No CAS Number
Allyl chloride	Allyl Chloride	Allyl Chloride	107-05-1
Ammonium dichromate (VI)	Chromium Compounds	Ammonium Dichromate	7789-09-5
Aniline	Aniline	Aniline	62-53-3
Anthracene	Polycyclic Organic Matter as 15-PAH	Anthracene	120-12-7
Antimonate(1-), hexafluoro-, sodium, (OC-6-11)-	Antimony Compounds	Sodium hexafluoroantimenate	16925-25-0
Antimony	Antimony Compounds	Antimony	7440-36-0
Antimony and compounds	Antimony Compounds	Antimony & Compounds	No CAS Number
Antimony oxide (unspecified)	Antimony Compounds	Antimony Oxide	1327-33-9
Antimony pentafluoride	Antimony Compounds	Antimony Pentafluoride	7783-70-2
Antimony trichloride	Antimony Compounds	Antimony Trichloride	10025-91-9
Antimony trioxide	Antimony Compounds	Antimony Trioxide	1309-64-4
Antimony trisulfide	Antimony Compounds	Antimony Trisulfide	1345-04-6
Arsenic	Arsenic Compounds(Inorganic Including Arsine)	Arsenic	7440-38-2
Arsenic acid	Arsenic Compounds(Inorganic Including Arsine)	Arsenic Acid	7778-39-4
Arsenic acid (H3AsO4), lead(2+) salt (1:1)	Lead Compounds	Lead Arsenate	7784-40-9
Arsenic compounds (inorganic including arsine)	Arsenic Compounds(Inorganic Including Arsine)	Arsenic & Compounds (Inorganic Including Arsine)	No CAS Number
Arsenic(III) trioxide	Arsenic Compounds(Inorganic Including Arsine)	Arsenic Trioxide	1327-53-3
Arsenic(V) pentoxide	Arsenic Compounds(Inorganic Including Arsine)	Arsenic Pentoxide	1303-28-2
Arsenous acid, triethyl ester	Arsenic Compounds(Inorganic Including Arsine)	Arsenous Acid	3141-12-6
Arsine	Arsenic Compounds(Inorganic Including Arsine)	Arsine	7784-42-1
Asbestos	Asbestos	Asbestos	1332-21-4
Aurate(1-), bis(cyano-.kappa.C)-, potassium	Cyanide Compounds	Gold (I) Potassium Cyanide	13967-50-5
Aurate(1-), bis(cyano-.kappa.C)-, potassium	Cyanide Compounds	Gold Potassium Cyanide	13967-50-5

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Aziridine	Ethyleneimine (Aziridine)	Ethyleneimine	151-56-4
Benz[a]anthracene	Polycyclic Organic Matter as 7-PAH	Benz[a]Anthracene	56-55-3
Benz[a]anthracene mixt. with chrysene	Polycyclic Organic Matter as 7-PAH	Benz(a)Anthracene/Chrysene	No CAS Number
Benzene	Benzene (Including Benzene From Gasoline)	Benzene	71-43-2
Benzene soluble organics	Coke Oven Emissions	Benzene Soluble Organics (BSO)	No CAS Number
Benzeneacetonitrile	Cyanide Compounds	Benzyl Cyanide	140-29-4
Benzidine	Benzidine	Benzidine	92-87-5
Benzo(b)fluoranthene	Polycyclic Organic Matter as 7-PAH	Benzo[b]Fluoranthene	205-99-2
Benzo[a]fluoranthene	Polycyclic Organic Matter	Benzo(a)fluoranthene	203-33-8
Benzo[a]pyrene	Polycyclic Organic Matter as 7-PAH	Benzo[a]Pyrene	50-32-8
Benzo[b]fluoranthene mixt. with benzo[k]fluoranthene with benzo[k]fluoranthene	Polycyclic Organic Matter as 7-PAH	Benzo[b+k]Fluoranthene	No CAS Number
Benzo[c]phenanthrene	Polycyclic Organic Matter	Benzo(c)phenanthrene	195-19-7
Benzo[e]pyrene	Polycyclic Organic Matter	Benzo[e]Pyrene	192-97-2
Benzo[ghi]fluoranthene	Polycyclic Organic Matter	Benzo(g,h,i)Fluoranthene	203-12-3
Benzo[ghi]perylene	Polycyclic Organic Matter as 15-PAH	Benzo[g,h,i,]Perylene	191-24-2
Benzo[j]fluoranthene	Polycyclic Organic Matter	B[j]Fluoranthen	205-82-3
Benzo[k]fluoranthene	Polycyclic Organic Matter as 7-PAH	Benzo[k]Fluoranthene	207-08-9
Benzofluoranthene	Polycyclic Organic Matter as 7-PAH	Benzofluoranthenes	56832-73-6
Benzotrichloride	Benzotrichloride	Benzotrichloride	98-07-7
Benzyl chloride	Benzyl Chloride	Benzyl Chloride	100-44-7
Beryllium	Beryllium Compounds	Beryllium	7440-41-7
Beryllium and compounds	Beryllium Compounds	Beryllium & Compounds	No CAS Number
Beryllium difluoride	Beryllium Compounds	Beryllium Fluoride	7787-49-7
Beryllium oxide	Beryllium Compounds	Beryllium Oxide	1304-56-9
beta-Propiolactone	Beta-Propiolactone	Beta-Propiolactone	57-57-8
Biphenyl	Biphenyl	Biphenyl	92-52-4
Bis(2-(2-butoxyethoxy)ethyl) phthalate	Glycol Ethers	Di(Ethylene Glycol Monobutyl Ether) Phthalate	16672-39-2
Bis(2-chloroethyl) ether	Dichloroethyl Ether (Bis[2-Chloroethyl]Ether)	Dichloroethyl Ether	111-44-4
Bis(chloromethyl) ether	Bis(Chloromethyl) Ether	Bis(Chloromethyl)Ether	542-88-1
Borate(1-), tetrafluoro-, lead(2+) (2:1)	Lead Compounds	Lead Fluoroborate	13814-96-5

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
C.I. Pigment Blue 28	Cobalt Compounds	Cobalt Aluminate	1345-16-0
Cadmium	Cadmium Compounds	Cadmium	7440-43-9
Cadmium and compounds	Cadmium Compounds	Cadmium & Compounds	No CAS Number
Cadmium dichloride	Cadmium Compounds	Cadmium Chloride	10108-64-2
Cadmium iodide	Cadmium Compounds	Cadmium Iodide	7790-80-9
Cadmium nitrate	Cadmium Compounds	Cadmium Nitrate	10325-94-7
Cadmium oxide	Cadmium Compounds	Cadmium Oxide	1306-19-0
Cadmium sulfide	Cadmium Compounds	Cadmium Sulfide	1306-23-6
Captan	Captan	Captan	133-06-2
Carbaryl	Carbaryl	Carbaryl	63-25-2
Carbon disulfide	Carbon Disulfide	Carbon Disulfide	75-15-0
Carbon tetrachloride	Carbon Tetrachloride	Carbon Tetrachloride	56-23-5
Carbonic acid, lead(2+) salt (1:1)	Lead Compounds	Lead Carbonate	598-63-0
Carbonic acid, nickel(2+) salt (1:1)	Nickel Compounds	Nickel Carbonate	3333-67-3
Carbonyl sulfide	Carbonyl Sulfide	Carbonyl Sulfide	463-58-1
Catechol	Catechol	Catechol	120-80-9
Ceramic fibers, man-made	Fine Mineral Fibers	Ceramic Fibers (Man-Made)	No CAS Number
Chloramben	Chloramben	Chloramben	133-90-4
Chlordane	Chlordane	Chlordane	57-74-9
Chlorinated dibenzo-p-dioxins	Dioxins/Furans (total, non TEQ)	Dioxins, Total, w/o Individ. Isomers Reported {PCDDs}	136677-09-3
Chlorinated dibenzo-p-dioxins	Dioxins/Furans (total, non TEQ)	Polychlorinated Dibenzo-p-Dioxins, Total	136677-09-3
Chlorine	Chlorine	Chlorine	7782-50-5
Chloroacetic acid	Chloroacetic Acid	Chloroacetic Acid	79-11-8
Chlorobenzene	Chlorobenzene	Chlorobenzene	108-90-7
Chlorobenzilate	Chlorobenzilate	Chlorobenzilate	510-15-6
Chlorodibenzofurans	Dioxins/Furans (total, non TEQ)	Dibenzofurans (Chlorinated) {PCDFs}	136677-10-6
Chlorodibenzofurans	Dioxins/Furans (total, non TEQ)	Polychlorinated Dibenzofurans, Total	136677-10-6
Chloroethane	Ethyl Chloride	Ethyl Chloride	75-00-3
Chloroform	Chloroform	Chloroform	67-66-3
Chloromethane	Methyl Chloride (Chloromethane)	Methyl Chloride	74-87-3
Chloromethyl methyl ether	Chloromethyl Methyl Ether	Chloromethyl Methyl Ether	107-30-2
Chloroprene	Chloroprene	Chloroprene	126-99-8

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Chlorpyrifos	Phosphorus Compounds	Phosphorothioic Acid	2921-88-2
Chromic acid (H2CrO4), barium salt (1:1)	Chromium Compounds	Barium Chromate	10294-40-3
Chromic acid (H2CrO4), calcium salt (1:1)	Chromium Compounds	Calcium Chromate	13765-19-0
Chromic acid (H2CrO4), lead(2+) salt (1:1)	Lead Compounds	Lead Chromate	7758-97-6
Chromic acid (H2CrO4), strontium salt (1:1)	Chromium Compounds	Strontium Chromate	7789-06-2
Chromic acid, mixt. with sulfuric acid	Chromium Compounds	Chromic Sulfuric Acid	No CAS Number
Chromic(VI) acid	Chromium Compounds	Chromic Acid	7738-94-5
Chromic(VI) acid	Chromium Compounds	Chromic Acid (VI)	7738-94-5
Chromium	Chromium Compounds	Chromium	7440-47-3
Chromium and compounds	Chromium Compounds	Chromium & Compounds	No CAS Number
Chromium chloride, hexahydrate	Chromium Compounds	Chromium Chloride	10060-12-5
Chromium difluoride dioxide	Chromium Compounds	Chromyl Fluoride	7788-96-7
Chromium oxide (CrO2)	Chromium Compounds	Chromium Dioxide	12018-01-8
Chromium zinc oxide (Cr2ZnO4)	Chromium Compounds	Chromium Zinc Oxide	12018-19-8
Chromium zinc oxide (unspecified)	Chromium Compounds	Zinc Chromite	50922-29-7
Chromium(III)	Chromium Compounds	Chromium III	16065-83-1
Chromium(III) acetylacetonate	Chromium Compounds	Chromium (III)-AA	21679-31-2
Chromium(III) hydroxide	Chromium Compounds	Chromium Hydroxide	1308-14-1
Chromium(III) oxide	Chromium Compounds	Chromic Oxide	1308-38-9
Chromium(VI)	Chromium Compounds	Chromium (VI)	18540-29-9
Chromium(VI) dioxychloride	Chromium Compounds	Chromyl Chloride	14977-61-8
Chromium(VI) trioxide	Chromium Compounds	Chromium Trioxide	1333-82-0
Chrysene	Polycyclic Organic Matter as 7-PAH	Chrysene	218-01-9
Coal tar	Coke Oven Emissions	Coal Tar	8007-45-2
Cobalt	Cobalt Compounds	Cobalt	7440-48-4
Cobalt and compounds	Cobalt Compounds	Cobalt & Compounds	No CAS Number
Cobalt hydrocarbonyl	Cobalt Compounds	Cobalt Hydrocarbonyl	16842-03-8
Cobalt naphthenate	Cobalt Compounds	Cobalt Naphtha	61789-51-3
Cobalt tetraoxide	Cobalt Compounds	Cobalt Oxide (II,III)	1308-06-1
Cobalt(II) oxide	Cobalt Compounds	Cobalt Oxide	1307-96-6
Cobalt(II) sulfide	Cobalt Compounds	Cobalt Sulfide	1317-42-6
Cobalt, tetracarbonylhydro-	Cobalt Compounds	Cobalt Carbonate	16842-03-8
Coke oven emissions	Coke Oven Emissions	Coke Oven Emissions	No CAS Number
Copper(I) cyanide	Cyanide Compounds	Copper Cyanide	544-92-3
Cresol	Cresol/Cresylic Acid (Mixed Isomers)	Cresol	1319-77-3

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Cresol	Cresol/Cresylic Acid (Mixed Isomers)	Cresols (Includes o, m, & p)/Cresylic Acids	1319-77-3
Cumene	Cumene	Cumene	98-82-8
Cyanamide, calcium salt (1:1)	Calcium Cyanamide	Calcium Cyanamide	156-62-7
Cyanide	Cyanide Compounds	Cyanide	57-12-5
Cyanide and compounds	Cyanide Compounds	Cyanide & Compounds	No CAS Number
Cyclonaphthenes	Polycyclic Organic Matter	Naphthenes (Cyclo)	No CAS Number
Di(2-ethylhexyl) phthalate	Bis(2-Ethylhexyl)Phthalate (Dehp)	Bis(2-Ethylhexyl)Phthalate	117-81-7
Diazomethane	Diazomethane	Diazomethane	334-88-3
Dibenz[a,h]anthracene	Polycyclic Organic Matter as 7-PAH	Dibenzo[a,h]Anthracene	53-70-3
Dibenz[a,j]acridine	Polycyclic Organic Matter	Dibenzo[a,j]Acridine	224-42-0
Dibenzo[a,e]pyrene	Polycyclic Organic Matter	Dibenzo[a,e]Pyrene	192-65-4
Dibenzo[a,h]pyrene	Polycyclic Organic Matter	Dibenzo[a,h]Pyrene	189-64-0
Dibenzo[a,i]pyrene	Polycyclic Organic Matter	Dibenzo[a,i]Pyrene	189-55-9
Dibenzo[a,l]pyrene	Polycyclic Organic Matter	Dibenzo[a,l]Pyrene	191-30-0
Dibenzofuran	Dibenzofuran	Dibenzofuran	132-64-9
Dibenzo-p-dioxin	Dioxins/Furans (total, non TEQ)	Dibenzo-p-Dioxin	262-12-4
Dibutyl phthalate	Dibutyl Phthalate	Dibutyl Phthalate	84-74-2
Dichlorvos	Dichlorvos	Dichlorvos	62-73-7
Diethanolamine	Diethanolamine	Diethanolamine	111-42-2
Diethyl sulfate	Diethyl Sulfate	Diethyl Sulfate	64-67-5
Diethylene glycol dibenzoate	Glycol Ethers	Diethylene Glycol Dibenzoate	120-55-8
Diethylene glycol diethyl ether	Glycol Ethers	Diethylene glycol diethyl ether	112-36-7
Diethylene glycol diglycidyl ether	Glycol Ethers	Diethylene Glycol Diglycidyl Ether	4206-61-5
Diethylene glycol dimethyl ether	Glycol Ethers	Diethylene Glycol Dimethyl Ether	111-96-6
Diethylene glycol dinitrate	Glycol Ethers	Diethylene Glycol Dinitrate	693-21-0
Diethylene glycol ethyl methyl ether	Glycol Ethers	Diethylene Glycol Ethyl Methyl Ether	1002-67-1
Diethylene glycol mono-2-cyanoethyl ether	Glycol Ethers	Diethylene Glycol Mono-2-Cyanoethyl Ether	10143-54-1
Diethylene glycol mono-2-methylpentyl ether	Glycol Ethers	Diethyleneglycol-Mono-2-Methyl-Pentyl Ether	10143-56-3
Diethylene glycol monobutyl ether	Glycol Ethers	Diethylene Glycol Monobutyl Ether	112-34-5
Diethylene glycol monobutyl ether acetate	Glycol Ethers	Butyl Carbitol Acetate	124-17-4

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Diethylene glycol monoethyl ether	Glycol Ethers	Diethylene Glycol Monoethyl Ether	111-90-0
Diethylene glycol monoethyl ether acetate	Glycol Ethers	Carbitol Acetate	112-15-2
Diethylene glycol monohexyl ether	Glycol Ethers	N-Hexyl Carbitol	112-59-4
Diethylene glycol monoisobutyl ether	Glycol Ethers	Diethylene Glycol Monoisobutyl Ether	18912-80-6
Diethylene glycol monomethyl ether	Glycol Ethers	Diethylene Glycol Monomethyl Ether	111-77-3
Diethylene glycol monovinyl ether	Glycol Ethers	Diethylene Glycol Monovinyl Ether	929-37-3
Dimethyl mercury	Mercury Compounds	Methyl Mercury	593-74-8
Dimethyl phthalate	Dimethyl Phthalate	Dimethyl Phthalate	131-11-3
Dimethyl sulfate	Dimethyl Sulfate	Dimethyl Sulfate	77-78-1
Dimethylcarbamoyl chloride	Dimethylcarbamoyl Chloride	Dimethylcarbamoyl Chloride	79-44-7
Dioxins	Dioxins/Furans (total, non TEQ)	Dioxins	No CAS Number
Epichlorohydrin	Epichlorohydrin (1-Chloro-2,3-Epoxypropane)	1-Chloro-2,3-Epoxypropane	106-89-8
Ethanol, 2-(phenylmethoxy)-	Glycol Ethers	Ethylene Glycol Monobenzyl Ether	622-08-2
Ethene, [2-(2-ethoxyethoxy)ethoxy]-	Glycol Ethers	Diethylene Glycol Ethylvinyl Ether	10143-53-0
Ethene, 1,1'-[oxybis(2,1-ethanediyloxy)]bis-	Glycol Ethers	Diethylene Glycol Divinyl Ether	764-99-8
Ethyl acrylate	Ethyl Acrylate	Ethyl Acrylate	140-88-5
Ethylbenzene	Ethylbenzene	Ethyl Benzene	100-41-4
Ethylene dibromide	Ethylene Dibromide (Dibromoethane)	Ethylene Dibromide	106-93-4
Ethylene glycol	Ethylene Glycol	Ethylene Glycol	107-21-1
Ethylene glycol bis(2,3-epoxy-2-methylpropyl) ether	Glycol Ethers	Ethylene Glycol Bis(2,3-Epoxy-2-Methylpropyl) Ether	3775-85-7
Ethylene glycol diallyl ether	Glycol Ethers	Ethylene Glycol Diallyl Ether	7529-27-3
Ethylene glycol diethyl ether	Glycol Ethers	Ethylene Glycol Diethyl Ether	629-14-1
Ethylene glycol dimethyl ether	Glycol Ethers	1,2-Dimethoxyethane	110-71-4
Ethylene glycol mono-2,6,8-trimethyl-4-nonyl ether	Glycol Ethers	Ethyleneglycolmono-2,6,8-Trimethyl-4-Nonyl Ether	10137-98-1
Ethylene glycol mono-2-methylpentyl ether	Glycol Ethers	Ethyleneglycol Mono-2-Methylpentyl Ether	10137-96-9
Ethylene glycol monobutyl ether	Glycol Ethers	Butyl Cellosolve	111-76-2

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Ethylene glycol monobutyl ether acetate	Glycol Ethers	2-Butoxyethyl Acetate	112-07-2
Ethylene glycol monoethyl ether acetate	Glycol Ethers	Cellosolve Acetate	111-15-9
Ethylene glycol monohexyl ether	Glycol Ethers	2-(Hexyloxy)Ethanol	112-25-4
Ethylene glycol monoisobutyl ether	Glycol Ethers	Isobutyl Cellosolve	4439-24-1
Ethylene glycol monomethyl ether acetate	Glycol Ethers	Ethylene Glycol Monomethyl Ether Acetate	110-49-6
Ethylene glycol monomethyl ether acrylate	Glycol Ethers	Methyl Cellosolve Acrylate	3121-61-7
Ethylene glycol monophenyl ether	Glycol Ethers	Phenyl Cellosolve	122-99-6
Ethylene glycol monophenyl ether propionate	Glycol Ethers	Ethyleneglycol Monophenyl Ether Propionate	23495-12-7
Ethylene glycol monopropyl ether	Glycol Ethers	Propyl Cellosolve	2807-30-9
Ethylene glycol mono-sec-butyl ether	Glycol Ethers	Ethylene Glycol Mono-Sec-Butyl Ether	7795-91-7
Ethylene glycol monovinyl ether	Glycol Ethers	Ethylene Glycol Monovinyl Ether	764-48-7
Ethylene oxide	Ethylene Oxide	Ethylene Oxide	75-21-8
Ethylene thiourea	Ethylene Thiourea	Ethylene Thiourea	96-45-7
Ethylenebis(oxyethylenenitrilo)tetraacetic acid	Glycol Ethers	(Ethylenebis(Oxyethylenenitrilo)) Tetraacetic Acid	67-42-5
Extractable organic matter (EOM)	Polycyclic Organic Matter	Extractable Organic Matter (EOM)	No CAS Number
Fine mineral fibers	Fine Mineral Fibers	Fine Mineral Fibers	No CAS Number
Fine mineral fibers	Fine Mineral Fibers	Glasswool (Man-Made Fibers)	No CAS Number
Fine mineral fibers	Fine Mineral Fibers	Slagwool (Man-Made Fibers)	No CAS Number
Fine mineral fibers	Fine Mineral Fibers	Rockwool (Man-Made Fibers)	No CAS Number
Fluoranthene	Polycyclic Organic Matter as 15-PAH	Fluoranthene	206-44-0
Fluorene	Polycyclic Organic Matter as 15-PAH	Fluorene	86-73-7
Formaldehyde	Formaldehyde	Formaldehyde	50-00-0
Glycol ethers -- CAA 112B	Glycol Ethers	Glycol Ethers	No CAS Number
Gold cyanide	Cyanide Compounds	Gold Cyanide	37187-64-7
Heptachlor	Heptachlor	Heptachlor	76-44-8
Heptachlorodibenzofuran	Dioxins/Furans (total, non TEQ)	Total Heptachlorodibenzofuran	38998-75-3
Heptachlorodibenzo-p-dioxin	Dioxins/Furans (total, non TEQ)	Total Heptachlorodibenzo-p-Dioxin	37871-00-4
Hexachlorobenzene	Hexachlorobenzene	Hexachlorobenzene	118-74-1
Hexachlorobutadiene	Hexachlorobutadiene	Hexachlorobutadiene	87-68-3
Hexachlorocyclopentadiene	Hexachlorocyclopentadiene	Hexachlorocyclopentadiene	77-47-4

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Hexachlorodibenzofuran	Dioxins/Furans (total, non TEQ)	Total Hexachlorodibenzofuran	55684-94-1
Hexachlorodibenzo-p-dioxin	Dioxins/Furans (total, non TEQ)	Hexachlorodibenzo-p-Dioxin	34465-46-8
Hexachlorodibenzo-p-dioxin	Dioxins/Furans (total, non TEQ)	Hexachlorodibenzo-p-Dioxins, Total	34465-46-8
Hexachloroethane	Hexachloroethane	Hexachloroethane	67-72-1
Hexamethylene-1,6-diisocyanate	Hexamethylene Diisocyanate	Hexamethylene Diisocyanate	822-06-0
Hexamethylphosphoramide	Hexamethylphosphoramide	Hexamethylphosphoramide	680-31-9
Hexane	Hexane	Hexane	110-54-3
Hexanoic acid, 2-ethyl-, cobalt(2+) salt	Cobalt Compounds	Cobalt 2-ethylhexanoate	136-52-7
Hydrazine	Hydrazine	Hydrazine	302-01-2
Hydrochloric acid	Hydrochloric Acid (Hydrogen Chloride [Gas Only])	Hydrochloric Acid	7647-01-0
Hydrofluoric acid	Hydrogen Fluoride (Hydrofluoric Acid)	Hydrogen Fluoride	7664-39-3
Hydrogen cyanide	Cyanide Compounds	Hydrogen Cyanide	74-90-8
Hydroquinone	Hydroquinone	Hydroquinone	123-31-9
Indeno[1,2,3-cd]pyrene	Polycyclic Organic Matter as 7-PAH	Indeno[1,2,3-c,d]Pyrene	193-39-5
Iodine-131	Radionuclides (Including Radon)	Iodine-131	10043-66-0
Isobutyronitrile	Cyanide Compounds	2-Methyl-Propanenitrile	78-82-0
Isophorone	Isophorone	Isophorone	78-59-1
Lead	Lead Compounds	Lead	7439-92-1
Lead acetate	Lead Compounds	Lead Subacetate	1335-32-6
Lead and compounds	Lead Compounds	Lead & Compounds	No CAS Number
Lead and compounds (other than inorganic)	Lead Compounds	Lead Compounds (Other Than Inorganic)	No CAS Number
Lead and compounds, inorganic	Lead Compounds	Lead Compounds (Inorganic)	No CAS Number
Lead arsenite (Pb(AsO2)2)	Lead Compounds	Lead Arsenite	10031-13-7
Lead chromate(VI) oxide	Lead Compounds	Lead Chromate Oxide	18454-12-1
Lead dioxide	Lead Compounds	Lead Dioxide	1309-60-0
Lead dioxide	Lead Compounds	Lead Dioxide, Unknown CAS #	1309-60-0
Lead monoxide	Lead Compounds	Lead (II) Oxide	1317-36-8
Lead naphthenate	Lead Compounds	Lead Naphthenate	61790-14-5
Lead nitrate (Pb(NO3)2)	Lead Compounds	Lead Nitrate	10099-74-8
Lead oxide	Lead Compounds	Lead Oxide	1335-25-7
Lead stearate	Lead Compounds	Lead Stearate	7428-48-0
Lead tetraoxide	Lead Compounds	Lead (II, IV) Oxide	1314-41-6
Lead titanium oxide (PbTiO3)	Lead Compounds	Lead Titanate	12060-00-3

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Lead titanium zirconium oxide (Pb(Ti,Zr)O3)	Lead Compounds	Lead Titanate Zircon	12626-81-2
Lead(II) acetate	Lead Compounds	Lead Acetate	301-04-2
Lindane	1,2,3,4,5,6-Hexachlorocyclyhexane (All Stereo Isomers, Including Lindane)	1,2,3,4,5,6-Hexachlorocyclyhexane	58-89-9
Lithium chromate	Chromium Compounds	Lithium Chromate	14307-35-8
Maleic anhydride	Maleic Anhydride	Maleic Anhydride	108-31-6
Manganese	Manganese Compounds	Manganese	7439-96-5
Manganese and compounds	Manganese Compounds	Manganese & Compounds	No CAS Number
Manganese dioxide	Manganese Compounds	Manganese Dioxide	1313-13-9
Manganese naphthenate	Manganese Compounds	Manganese Napthenate	1336-93-2
Manganese tallate	Manganese Compounds	Manganese Tallate	8030-70-4
Manganese tetraoxide	Manganese Compounds	Manganese Tetroxide	1317-35-7
Manganese(II) hypophosphite monohydrate	Manganese Compounds	Manganesehypophosphi	7783-16-6
Manganese(III) oxide	Manganese Compounds	Manganese Trioxide	1317-34-6
m-Cresol	Cresol/Cresylic Acid (Mixed Isomers)	m-Cresol	108-39-4
Mercuric chloride	Mercury Compounds	Mercuric Chloride	7487-94-7
Mercury	Mercury Compounds	Elemental Gaseous Mercury	7439-97-6
Mercury	Mercury Compounds	Mercury	7439-97-6
Mercury and compounds	Mercury Compounds	Mercury & Compounds	No CAS Number
Mercury, divalent	Mercury Compounds	Gaseous Divalent Mercury	14302-87-5
Mercury, divalent	Mercury Compounds	Particulate Divalent Mercury	14302-87-5
Methanol	Methanol	Methanol	67-56-1
Methoxychlor	Methoxychlor	Methoxychlor	72-43-5
Methyl bromide	Methyl Bromide (Bromomethane)	Methyl Bromide	74-83-9
Methyl cellosolve acetyl ricinoleate	Glycol Ethers	Methyl Cellosolve Acetylricinoleate	140-05-6
Methyl ethyl ketone	Methyl Ethyl Ketone (2-Butanone)	Methyl Ethyl Ketone	78-93-3
Methyl hydrazine	Methylhydrazine	Methylhydrazine	60-34-4
Methyl iodide	Methyl Iodide (Iodomethane)	Methyl Iodide	74-88-4
Methyl isobutyl ketone	Methyl Isobutyl Ketone (Hexone)	Methyl Isobutyl Ketone	108-10-1
Methyl isocyanate	Methyl Isocyanate	Methyl Isocyanate	624-83-9
Methyl methacrylate	Methyl Methacrylate	Methyl Methacrylate	80-62-6
Methyl tert-butyl ether	Methyl Tert-Butyl Ether	Methyl Tert-Butyl Ether	1634-04-4
Methylanthracene	Polycyclic Organic Matter	Methylanthracene	26914-18-1
Methylbenzopyrene	Polycyclic Organic Matter	Methylbenzopyrenes	65357-69-9

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Methylchrysene	Polycyclic Organic Matter	Methylchrysene	41637-90-5
Methylene chloride	Methylene Chloride (Dichloromethane)	Methylene Chloride	75-09-2
Methylene chloride soluble organics	Coke Oven Emissions	Methylene Chloride Soluble Organics (MCSO)	No CAS Number
Methylmercury	Mercury Compounds	Mercury (Organic)	22967-92-6
m-Xylene	Xylenes (Mixed Isomers)	m-Xylene	108-38-3
N,N-Dimethylaniline	N,N-Dimethylaniline	N,N-Dimethylaniline	121-69-7
N,N-Dimethylformamide	N,N-Dimethylformamide	N,N-Dimethylformamide	68-12-2
Naphthalene	Naphthalene	Naphthalene	91-20-3
Neodecanoic acid, lead salt	Lead Compounds	Lead Neodecanoate	27253-28-7
Nickel	Nickel Compounds	Nickel	7440-02-0
Nickel and compounds	Nickel Compounds	Nickel & Compounds	No CAS Number
Nickel carbide	Nickel Compounds	Nickel Carbide	12710-36-0
Nickel carbonyl	Nickel Compounds	Nickel Carbonyl	13463-39-3
Nickel diacetate tetrahydrate	Nickel Compounds	Nickel Diacetate TET	6018-89-9
Nickel hydroxide (Ni(OH)2)	Nickel Compounds	Nickel Hydroxide	12054-48-7
Nickel refinery dust	Nickel Compounds	Nickel Refinery Dust	No CAS Number
Nickel subsulfide	Nickel Compounds	Nickel Subsulfide	12035-72-2
Nickel(II) acetate	Nickel Compounds	Nickel Acetate	373-02-4
Nickel(II) bromide	Nickel Compounds	Nickel Bromide	13462-88-9
Nickel(II) chloride	Nickel Compounds	Nickel Chloride	7718-54-9
Nickel(II) nitrate	Nickel Compounds	Nickel Nitrate	13138-45-9
Nickel(II) oxide	Nickel Compounds	Nickel Oxide	1313-99-1
Nickel(III) oxide	Nickel Compounds	Nickel Peroxide	1314-06-3
Nickel-59	Nickel Compounds	Nickel (NI 059)	14336-70-0
Nickelate(2-), tetrakis(cyano-.kappa.C)-, dipotassium, (SP-4-1)-	Cyanide Compounds	Potass Nickel Cyanid	14220-17-8
Nickelocene	Nickel Compounds	Nickelocene	1271-28-9
Nitric acid, manganese(2+) salt	Manganese Compounds	Manganese Nitrate	10377-66-9
Nitrobenzene	Nitrobenzene	Nitrobenzene	98-95-3
N-Nitrosodimethylamine	N-Nitrosodimethylamine	N-Nitrosodimethylamine	62-75-9
N-Nitrosomorpholine	N-Nitrosomorpholine	N-Nitrosomorpholine	59-89-2
N-Nitroso-N-methylurea	N-Nitroso-N-Methylurea	N-Nitroso-N-Methylurea	684-93-5
o-Anisidine	o-Anisidine	o-Anisidine	90-04-0
o-Cresol	Cresol/Cresylic Acid (Mixed Isomers)	o-Cresol	95-48-7

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
o-Toluidine	o-Toluidine	o-Toluidine	95-53-4
o-Xylene	Xylenes (Mixed Isomers)	o-Xylene	95-47-6
p,p'-DDE	Dde (1,1-Dichloro-2,2-Bis(p-Chlorophenyl) Ethylene)	Dde (1,1-Dichloro-2,2-Bis(p-Chlorophenyl) Ethylene)	72-55-9
Parathion	Parathion	Parathion	56-38-2
p-Cresol	Cresol/Cresylic Acid (Mixed Isomers)	p-Cresol	106-44-5
Pentachlorodibenzofuran	Dioxins/Furans (total, non TEQ)	Total Pentachlorodibenzofuran	30402-15-4
Pentachlorodibenzo-p-dioxin	Dioxins/Furans (total, non TEQ)	Total Pentachlorodibenzo-p-Dioxin	36088-22-9
Pentachloronitrobenzene	Pentachloronitrobenzene (Quintobenzene)	Pentachloronitrobenzene	82-68-8
Pentachlorophenol	Pentachlorophenol	Pentachlorophenol	87-86-5
Perylene	Polycyclic Organic Matter	Perylene	198-55-0
Phenanthrene	Polycyclic Organic Matter as 15-PAH	Phenanthrene	85-01-8
Phenol	Phenol	Phenol	108-95-2
Phenylmercury acetate	Mercury Compounds	Mercury Acetato Phen	62-38-4
Phosgene	Phosgene	Phosgene	75-44-5
Phosphine	Phosphine	Phosphine	7803-51-2
Phosphoric acid	Phosphorus Compounds	Phosphoric Acid	7664-38-2
Phosphoric acid, lead(2+) salt (2:3)	Lead Compounds	Lead Phosphate	7446-27-7
Phosphoric acid, monoammonium monosodium salt	Phosphorus Compounds	Phosphorous Salt	13011-54-6
Phosphoric acid, reaction products with aluminum hydroxide and chromium oxide (CrO3)	Phosphorus Compounds	Phosphoric Acid,Rx P	92203-02-6
Phosphoric acid, zinc salt (2:3)	Phosphorus Compounds	Zinc Phosphate	7779-90-0
Phosphorous acid	Phosphorus Compounds	Phosphorous Acid	10294-56-1
Phosphorus	Phosphorus Compounds	Phosphorus	7723-14-0
Phosphorus and compounds	Phosphorus Compounds	Phosphorus & Compounds	No CAS Number
Phosphorus nitride (P3N5)	Phosphorus Compounds	Phosphorous Nitride	12136-91-3
Phosphorus oxychloride	Phosphorus Compounds	Phosphorus Oxychloride	10025-87-3
Phosphorus pentasulfide	Phosphorus Compounds	Phosphorus Pentasulfide	1314-80-3
Phosphorus pentoxide	Phosphorus Compounds	Phosphorus Pentoxide	1314-56-3
Phosphorus trichloride	Phosphorus Compounds	Phosphorus Trichloride	7719-12-2
Phosphorus trioxide	Phosphorus Compounds	Phosphorus Trioxide	1314-24-5
Phthalic anhydride	Phthalic Anhydride	Phthalic Anhydride	85-44-9

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Polycyclic aromatic hydrocarbons	Polycyclic Organic Matter as 7-PAH	PAH, Total	130498-29-2
Polycyclic aromatic hydrocarbons - 16-PAH	Polycyclic Organic Matter	16-PAH	No CAS Number
Polycyclic aromatic hydrocarbons - 7-PAH	Polycyclic Organic Matter as 7-PAH	7-PAH	No CAS Number
Polycyclic organic matter - including 15-PAH	Polycyclic Organic Matter as 7-PAH	Polycyclic Organic Matter	No CAS Number
Potassium chromate (VI)	Chromium Compounds	Potassium Chromate	7789-00-6
Potassium cyanide	Cyanide Compounds	Potassium Cyanide	151-50-8
Potassium dichromate	Chromium Compounds	Potassium Dichromate	7778-50-9
Potassium ferrocyanide	Cyanide Compounds	Potassium Ferrocyani	13943-58-3
Potassium permanganate	Manganese Compounds	Potassium permanganate	7722-64-7
Potassium zinc chromate hydroxide (KZn2(CrO4)2(OH))	Chromium Compounds	Zinc Potassium Chromate	11103-86-9
p-Phenylenediamine	p-Phenylenediamine	p-Phenylenediamine	106-50-3
Propionaldehyde	Propionaldehyde	Propionaldehyde	123-38-6
Propoxur	Propoxur (Baygon)	Propoxur	114-26-1
Propylene glycol monoisobutyl ether	Glycol Ethers	1-Isobutoxy-2-Propanol	23436-19-3
Propylene oxide	Propylene Oxide	Propylene Oxide	75-56-9
Propyleneimine	1,2-Propylenimine (2-Methylaziridine)	1,2-Propylenimine	75-55-8
p-Xylene	Xylenes (Mixed Isomers)	p-Xylene	106-42-3
Pyrene	Polycyclic Organic Matter as 15-PAH	Pyrene	129-00-0
Quinoline	Quinoline	Quinoline	91-22-5
Quinone	Quinone (p-Benzoquinone)	Quinone	106-51-4
Radionuclides (including radon)	Radionuclides (Including Radon)	Radionuclides (Including Radon)	No CAS Number
Radionuclides (including radon)	Radionuclides (Including Radon)	Radionuclides	No CAS Number
Radon and its decay products	Radionuclides (Including Radon)	Radon And Its Decay Products	No CAS Number
Selenious acid (H2SeO3)	Selenium Compounds	Selenous Acid	7783-00-8
Selenium	Selenium Compounds	Selenium	7782-49-2
Selenium and compounds	Selenium Compounds	Selenium & Compounds	No CAS Number
Selenium dioxide	Selenium Compounds	Selenium Dioxide	7446-08-4
Selenium disulfide	Selenium Compounds	Selenium Disulfide	7488-56-4
Selenium hexafluoride	Selenium Compounds	Selenium Hexafluoride	7783-79-1
Selenium monosulfide	Selenium Compounds	Selenium Monosulfide	7446-34-6
Selenium oxide	Selenium Compounds	Selenium Oxide	12640-89-0
Silver cyanide	Cyanide Compounds	Silver Cyanide	506-64-9
Sodium chromate (VI)	Chromium Compounds	Sodium Chromate	7775-11-3
Sodium chromate(VI), tetrahydrate	Chromium Compounds	Sodium Chromate(VI)	10034-82-9
Sodium cyanide	Cyanide Compounds	Sodium Cyanide	143-33-9

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Sodium dichromate	Chromium Compounds	Sodium Dichromate	10588-01-9
Sodium permanganate	Manganese Compounds	Permanganic acid	10101-50-5
Styrene	Styrene	Styrene	100-42-5
Styrene oxide	Styrene Oxide	Styrene Oxide	96-09-3
Sulfamic acid, nickel(2+) salt (2:1)	Nickel Compounds	Nickel Sulfamate	13770-89-3
Sulfuric acid, beryllium salt (1:1)	Beryllium Compounds	Beryllium Sulfate	13510-49-1
Sulfuric acid, cadmium salt (1:1)	Cadmium Compounds	Cadmium Sulfate	10124-36-4
Sulfuric acid, chromium(3+) salt (3:2)	Chromium Compounds	Chromic Sulfate	10101-53-8
Sulfuric acid, cobalt(2+) salt (1:1)	Cobalt Compounds	Cobalt Sulfate	10124-43-3
Sulfuric acid, lead(2+) salt (1:1)	Lead Compounds	Lead Sulfate	7446-14-2
Sulfuric acid, manganese(2+) salt (1:1)	Manganese Compounds	Manganese Sulfate	7785-87-7
Sulfuric acid, nickel(2+) salt (1:1)	Nickel Compounds	Nickel Sulfate	7786-81-4
Sulfuric acid, nickel(2+) salt (1:1), hexahydrate	Nickel Compounds	Nickel (II) Sulfate Hexahydrate	10101-97-0
Tetrachlorodibenzofuran	Dioxins/Furans (total, non TEQ)	Total Tetrachlorodibenzofuran	30402-14-3
Tetrachlorodibenzo-p-dioxin	Dioxins/Furans (total, non TEQ)	Total Tetrachlorodibenzo-p-Dioxin	41903-57-5
Tetrachloroethylene	Tetrachloroethylene (Perchloroethylene)	Tetrachloroethylene	127-18-4
Tetraethyl lead	Lead Compounds	Tetraethyl Lead	78-00-2
Titanium tetrachloride	Titanium Tetrachloride	Titanium Tetrachloride	7550-45-0
Toluene	Toluene	Toluene	108-88-3
Toluene-2,4-diisocyanate	2,4-Toluene Diisocyanate	2,4-Toluene Diisocyanate	584-84-9
Toxaphene	Toxaphene (Chlorinated Camphene)	Toxaphene	8001-35-2
Tribromomethane	Bromoform	Bromoform	75-25-2
Trichloroethylene	Trichloroethylene	Trichloroethylene	79-01-6
Triethylamine	Triethylamine	Triethylamine	121-44-8
Triethylene glycol	Glycol Ethers	Triethylene glycol	112-27-6
Triethylene glycol dimethyl ether	Glycol Ethers	Triethylene Glycol Dimethyl Ether	112-49-2
Triethylene glycol monobutyl ether	Glycol Ethers	Triglycol Monobutyl Ether	143-22-6
Triethylene glycol monoethyl ether	Glycol Ethers	Ethoxytriglycol	112-50-5
Triethylene glycol monomethyl ether	Glycol Ethers	Methoxytriglycol	112-35-6
Trifluralin	Trifluralin	Trifluralin	1582-09-8
Trimethylene glycol monomethyl ether	Glycol Ethers	3-Methoxy-1-Propanol	1589-49-7
Tri-o-cresyl phosphate	Phosphorus Compounds	Triorthocresyl Phosphate	78-30-8
Triphenyl phosphate	Phosphorus Compounds	Triphenyl Phosphate	115-86-6

Appendix F. Specific HAPs Included in the NEI

EPAChemRegistryName	NEI HAP Category	NEI Pollutant Name	CASRN
Triphenyl phosphite	Phosphorus Compounds	Triphenyl Phosphite	101-02-0
Uranium-238	Radionuclides (Including Radon)	Uranium	7440-61-1
Urethane	Ethyl Carbamate (Urethane) Chloride (Chloroethane)	Ethyl Carbamate Chloride	51-79-6
Vinyl acetate	Vinyl Acetate	Vinyl Acetate	108-05-4
Vinyl bromide	Vinyl Bromide	Vinyl Bromide	593-60-2
Vinyl chloride	Vinyl Chloride	Vinyl Chloride	75-01-4
Xylene	Xylenes (Mixed Isomers)	Xylenes (Mixture of o, m, and p Isomers)	1330-20-7
Zinc chromate	Chromium Compounds	Zinc Chromate	13530-65-9
Zinc chromate	Chromium Compounds	Zinc Chromate	13530-65-9
Zinc cyanide	Cyanide Compounds	Zinc Cyanide	557-21-1

Field Definitions:

- "**EPAChemRegistryName**" (EPA Chemical Registry Name) - the name EPA has selected as the name to be commonly used by EPA in referring to a chemical substance
- "**NEI HAP Category**" - Grouping of related NEI pollutants
- "**NEI Pollutant Name**" - HAP name for NEI pollutant
- "**CASRN**" (Chemical Abstracts Service Registry Number)- the unique number assigned by Chemical Abstracts Service (CAS) to a chemical substance

Table from:
EPA. 2003. *1999 NEI Final Version 3 for Hazardous Air Pollutants Point, non point, and mobile sources. Documentation for the 1999 NEI Final Version 3 for Hazardous Air Pollutants. HAPs list with chemical ID standard fields - August 2003* OAQPS. Available at **http://www.epa.gov/ttn/chief/net/1999inventory.html#final3haps**

Field Definitions from:
1999 NEI Final Version 3 for Hazardous Air Pollutants Point, non point, and mobile sources (September 2003). Documentation for the 1999 NEI Final Version 3 for Hazardous Air Pollutants.Readme file for HAPs list with chemical ID standard fields - August 2003. Available at **http://www.epa.gov/ttn/chief/net/1999inventory.html#final3haps**

Appendix G Atmospheric and Meteorological Concepts Relevant to Dispersal, Transport, and Fate of Air Toxics

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This Appendix defines and discusses atmospheric and meteorological concepts relevant to modeling dispersion, transport, and fate of air toxics. In addition, this appendix provides information on sources of meteorological data that can be used for air toxics modeling. Much of this information was obtained from EPA's primer on air pollution meteorology (see http://www.epa.gov/oar/oaqps/eog/catalog/si409.html). Basic textbooks on meteorology provide more detailed discussions of the material summarized in this Appendix.

1.0 Structure and Composition of the Atmosphere

The atmosphere consists of mixture of about 78 percent nitrogen, 21 percent oxygen and one percent argon up to about 90 km. Within this region trace gases include carbon dioxide, neon, helium, and water vapor. Although the water vapor content of the air is fairly small it is highly variable. Water vapor absorbs six times more radiation energy than any other atmospheric constituent and is therefore a very important component of the atmosphere. Similarly, carbon dioxide is highly variable and is important gas because it absorbs and re-radiates back some of the infrared radiation emitted by the earth.

The atmosphere has been divided into four regions (Exhibit 1) based on temperature changes with height: the troposphere, stratosphere, mesosphere, and ionosphere. The troposphere accounts for about three quarters of the mass of the atmosphere and contains nearly all of the water in the atmosphere (in the forms of vapor, clouds, and precipitation). The depth of the troposphere is on average about 16.5 km (54,000 ft) over the equator and about 8.5 km (28,000 ft) over the poles. The troposphere also tends to be thicker in summer (when the air is warmer) than in the winter. The depth of the troposphere changes constantly due to changes in atmospheric temperature. The troposphere is the most important layer of the atmosphere with respect to air toxics, because this is the region in which most of the air toxics are released. Of the other regions of the atmosphere only the stratosphere has a direct role for some air toxics. Some air toxic emissions can be circulated into the lower stratosphere via weather system or directly emitted from aircraft or volcanic eruption. Once air toxics reach the stratosphere they maybe transported very long distances.

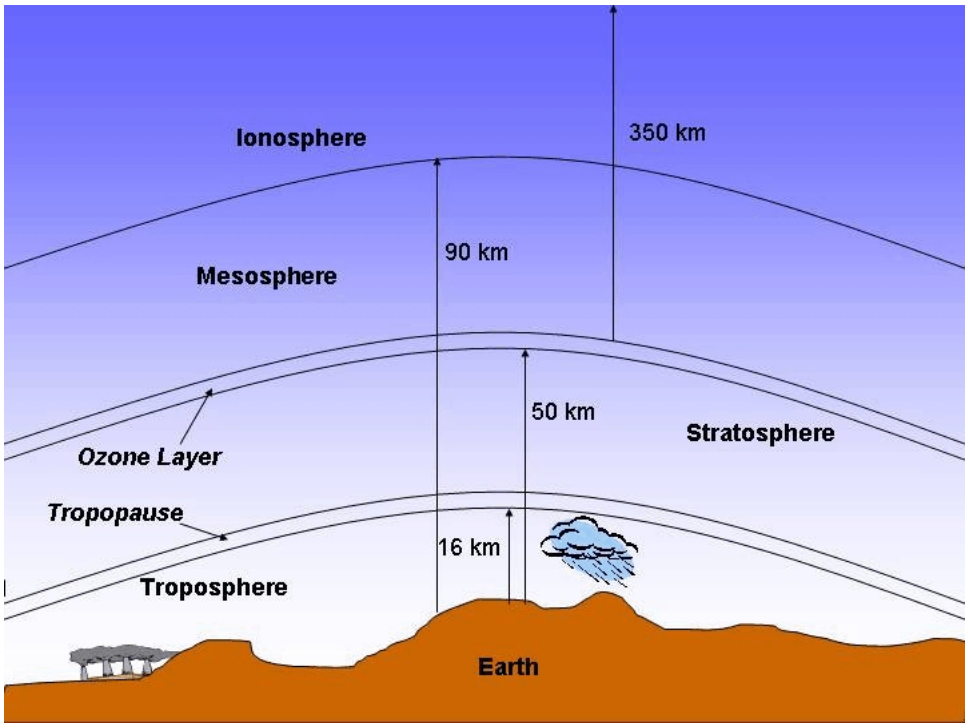
2.0 Atmospheric Energy

The troposphere is the most variable layer of the atmosphere and is the layer where weather occurs. It is where air masses, weather fronts, and storms reside. Weather conditions are governed by a number of factors, including solar radiation, atmospheric circulation, water vapor and topography. However, the underlying driving force in all cases is the radiant energy from the sun.

2.1 Solar Radiation and Differential Heating

The amount of incident sunlight influences the heating of the surface of the earth and the overlying atmosphere. The radiation received directly from the sun is called **solar radiation**. The amount of incoming solar radiation received at a particular time and location (insolation) on the earth is governed by:

Exhibit 1. Structure of the Atmosphere



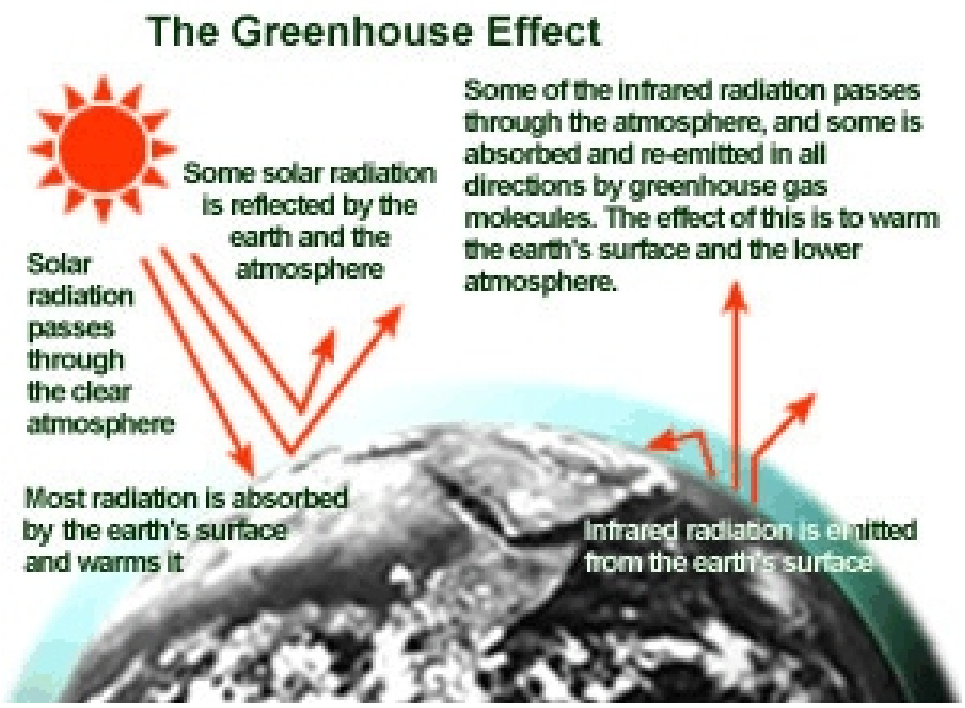
- The transparency of the atmosphere (for example, clouds reflect solar radiation);
- Hours of daylight; and
- The angle at which the sun's rays strike the earth.

The earth's surface absorbs short-wave solar radiation and emits longer wavelength **terrestrial radiation**. In the atmosphere, clouds, water vapor, and to a lesser extent carbon dioxide absorb terrestrial radiation, which causes the atmosphere to warm. The atmosphere absorbs much more terrestrial radiation than solar radiation. The atmosphere also radiates energy to outer space and back to the earth's surface. The earth-atmosphere system emits terrestrial radiation continuously. The atmospheric absorption of terrestrial radiation benefits the earth by retaining energy that would otherwise be radiated to space. This phenomenon explains how air temperatures are generally warmer on nights when cloud cover is present. The **greenhouse effect** is the descriptive name given to the result of the energy exchange process that causes the earth's surface to be warmer than it would be if the atmosphere did not radiate energy back to earth. Gases such as carbon dioxide and methane (and other similarly behaving gases often called **greenhouse gases**) also increase the ability of the atmosphere to absorb radiation (Exhibit 2).

The amount of solar radiation reaching the earth's surface varies from place to place. In addition, different types of earth surfaces (and man-made structures) vary in their ability to absorb and store heat energy. For example, land masses absorb and store heat differently than water masses. The color, shape, surface texture, vegetation and presence of buildings can all influence the heating and cooling of the ground. Generally, dry surfaces heat and cool faster than moist

surfaces. Plowed fields, sandy beaches, and paved roads become hotter than surrounding meadows and wooded areas. During the day, the air over a plowed field is warmer than over a forest or swamp; during the night, the situation is reversed. The property of different surfaces which causes them to heat and cool at different rates is referred to as **differential heating**.

Exhibit 2. The Greenhouse Effect



Source: EPA's "Global Warming Kids Site."[1]

Heat is transferred within the atmosphere by conduction, convection, and advection. These processes affect the temperature of the atmosphere near the surface of the earth. **Conduction** is the process by which heat is transferred through matter without movement of the matter itself. For example, the handle of an iron skillet becomes hot due to the conduction of heat from the stove burner. Conduction occurs from a warmer to a cooler object. Heat transfer also occurs due to the movement of atmospheric gases. Meteorologists use the term **convection** to denote the transfer of heat that occurs mainly by vertical motion. Air that is warmed by a heated land surface will rise because it is lighter than the surrounding air. Likewise, cooler air aloft will sink because it is heavier than the surrounding air. Meteorologists use the term **advection** to denote heat transfer that occurs mainly by horizontal motion. All of these energy exchange processes, particularly between the earth surface and the atmosphere, produce the complex atmospheric motions of weather. As a result of these process air toxics maybe widely distributed far from their location of origin.

2.2 Effects of Topography

The physical characteristics of the earth's surface are referred to as **terrain features** or **topography**. Topography can be grouped into four general categories: flat, mountain/valley,

land/water, and urban. Topography also causes two types of turbulence in the atmosphere. As noted above, topography causes **thermal turbulence** through differential heating. Topography causes **mechanical turbulence** as the result of the wind flowing over different sizes and shapes of objects. Physical features induce a frictional effect on wind speed and direction. For example, urban settings with dense construction and tall buildings exert a strong frictional force on the wind causing it to slow down, change direction, and become more turbulent.

Urban areas have a special effect on the atmosphere due to the high density of man-made features. Building materials such as brick and concrete absorb and store heat more efficiently than soil and vegetation found in rural areas. After sunset, the urban areas continue to radiate the stored heat from buildings and paved surfaces. Air is warmed by this urban complex and rises to create a dome (**heat island**) over an urban area. Large cities continue to emit heat throughout the night and generally never completely cool down to the more stable surrounding conditions before the sun rises and begins to heat the urban complex again. The overall effect of the urban landscape is to increase the dispersion of air toxics through increased mixing.

3.0 Atmospheric Motions

The differential heating of the earth's surface causes imbalances in **air pressure**. The atmospheric pressure at any point is due to the weight of the air pressing down from above due to gravity. In any gas such as air, molecules are moving around in all directions at very high speeds. The speed actually depends on the temperature of the gas. Air pressure is caused by the molecules of atmospheric gases bumping into each other and other surfaces and bouncing off. Air pressure is a function of the number of air molecules in a given volume and the speed at which they are moving. When air is warmed, the molecules speed up, and air pressure increases. As air cools, the molecules slow down, and air pressure decreases.

3.1 Horizontal Air Motions

Air moves in an attempt to equalize response to imbalances in pressure. The movement of air (**wind**) tends to move from areas of high to low pressure. Wind is the basic element in the general circulation of the atmosphere. Wind movements from small gusts to large air masses all contribute to transport of heat, moisture and as well as air toxics around the earth. Winds are always named by the direction from which they blow. Thus a "north wind" is a wind blowing from the north to the south and a "westerly wind" blows from west to east. When wind blows more frequently from one direction than from any other, the direction is termed the **prevailing wind**. Section 4.1 provides further information on how meteorologists measure and describe wind speed and direction.

Wind speed is heavily influenced by the presence or absence of friction ("drag") and increases rapidly with height about the ground level. Wind is commonly not a steady current but is made up of a succession of gusts, slightly variable in direction, separated by lulls. Close to the earth, wind gustiness is caused by irregularities of the surface, which create **eddies**, which are variations from the main current of wind flow. Larger irregularities are caused by convection (vertical transport of heat). These and other forms of turbulence contribute to the movement of heat, moisture, dust, and pollutants into the air. See Section 2.2 for additional information on how topography affects air motions.

Air masses cover hundreds of thousands of square miles and extend upward for several miles. They are relatively homogeneous volumes of air with regard to temperature and moisture, and they acquire the characteristics of the region over which they form and travel. Pollutants released into an air mass tend to travel and disperse within the air mass. Air masses develop more commonly in some regions than in others. Air masses are classified as maritime or continental according to their origin over ocean or land, and as arctic, polar, or tropical depending principally on the latitude of origin. Continental polar air masses are similar to arctic air masses, but not as cold and dry as arctic air masses. The chief air masses that affect the weather of North America are continental polar, maritime polar, and maritime tropical.

Frontal patterns are formed by the interaction of adjacent air masses. A cold front is a transition zone where a cold air mass is moving into the area previously occupied by a warm air mass. The rise of warm air over an advancing cold front and the subsequent expansive cooling of this air lead to cloud formation, and if sufficient moisture is available precipitation near the leading edge of the front. A warm front is a transition zone where a warm air mass is moving into the area previously occupied by a cold air mass. Precipitation commonly occurs in advance of a warm front, as the warm air slowly rises above the cold air.

3.2 Vertical Air Motions

When air is displaced vertically, atmospheric behavior is a function of atmospheric stability. A stable atmosphere resists vertical motion, and air that is displaced vertically in a stable atmosphere tends to return to its original position. This atmospheric characteristic determines the ability of the atmosphere to disperse pollutants. To understand atmospheric stability and the role it plays in pollution dispersion, it is important to understand the mechanics of the atmosphere as they relate to vertical atmospheric motion.

The degree of stability of the atmosphere is determined by the temperature difference between an air parcel and the surrounding air. This difference can cause the parcel to rise or fall. There are three general categories of atmospheric stability.

- In **stable** conditions, vertical movement tends not to occur. Stable conditions occur at night when there is little or no wind. Air that is lifted vertically will remain cooler, and therefore denser than the surrounding air. Once the lifting force is removed, the air that has been lifted will return to its original position.

- **Neutral** conditions ("well mixed") neither encourage nor discourage air movement. Neutral stability occurs on windy days or when there is cloud cover such that there is neither strong heating nor cooling of the earth's surface. Air lifted vertically will generally remain at the lifted height.

- In **unstable** conditions, the air parcel tends to move upward or downward and to continue that movement. Unstable conditions most commonly develop on sunny days with low wind speeds where strong solar radiation is present. The earth rapidly absorbs heat and transfers some of it to the surface air layer. As warm air rises, cooler air moves underneath. The cooler air, in turn, may be heated by the earth's surface and begin to rise. Under such conditions, vertical motion in both directions is enhanced, and considerable vertical mixing occurs.

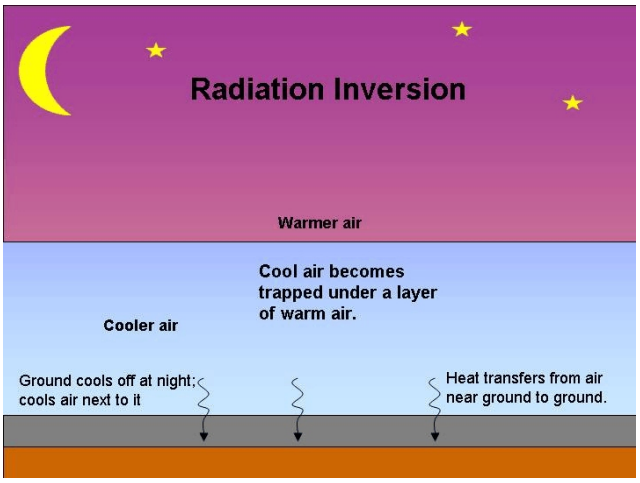
Inversions occur whenever warm over-runs cold air and "traps" the cold air beneath. Within these inversions there is little air motion, and the air becomes relatively stagnant. High air toxic concentrations can occur within inversions due to the limited amount of mixing between the "trapped" air and the surrounding atmosphere. Inversions can limit the volume of air into which emissions are dispersed, even from tall stacks. Exhibit 3 illustrates the three major types of inversions that are caused by different atmospheric interactions and can persist for different amounts of time.

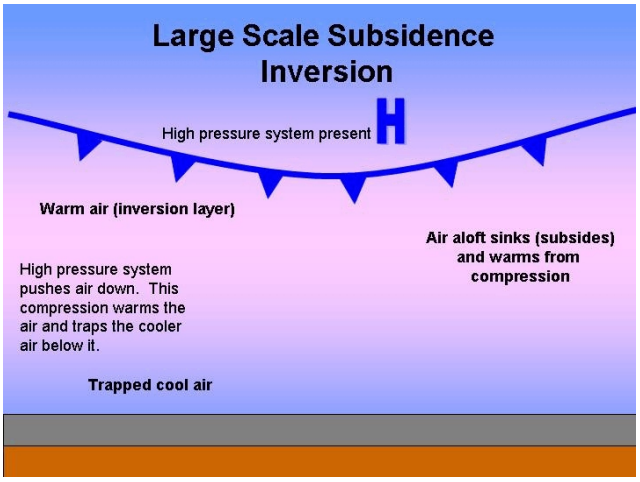
Most common is the **radiation inversion**, which occurs when the earth's surface cools rapidly. As the earth cools, it also cools the layer of air close to the surface, which becomes trapped under the layer of warmer air above. Radiation inversions usually occur in the late evening through the early morning under clear skies with calm winds, when the cooling effect is greatest. In many cases, solar radiation following sunrise results in vigorous vertical mixing, which breaks down the inversion and disperses any trapped air pollutants. Under some conditions (e.g., thick fog), the daily warming may not be strong enough to break down the inversion layer. Inversions persisting for several days may lead to increased pollutant concentrations. This situation is most likely to occur in an enclosed valley, where nocturnal, cool, downslope air movement can reinforce a radiation inversion and encourage fog formation.

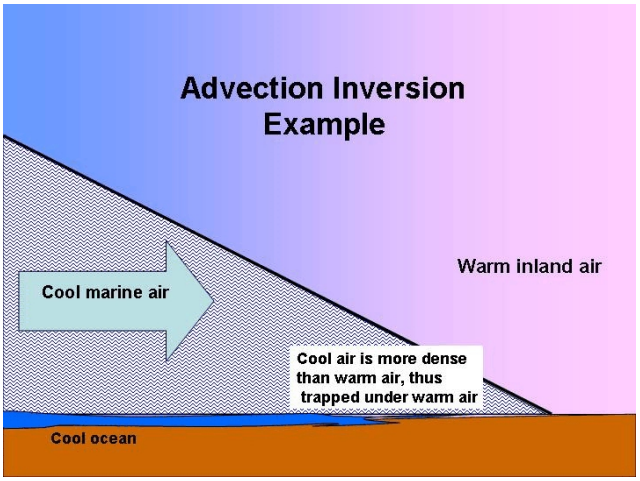
The **subsidence inversion** is almost always associated with high pressure systems. Air in a high pressure system descends and flows outward in a clockwise rotation in the Northern Hemisphere. As the air descends, the higher pressure present at lower altitudes enhances compression and warming. The inversion layer thus formed is often elevated several hundred meters above the ground surface during the day. At night, when the surface air cools, the base of the subsidence inversion often descends, even to the ground. The clear, cloudless days characteristic of high pressure systems encourage radiation inversions, so that there may be a surface inversion at night and an elevated inversion during the day. Although the layer below the inversion may vary diurnally, it will never become very deep. Subsidence inversions, unlike radiation inversions, last a relatively long time. They are associated with both the semi permanent high pressure systems centered on each ocean and the slow-moving high pressure systems that move generally from west to east across the United States. When a high pressure system stagnates, pollutant concentrations may become unusually high. The most severe air pollution episodes in the United States have occurred either under a stagnant high pressure system (for example, New York in November, 1966 and Pennsylvania in October, 1948) or under the eastern edge of the semi permanent high pressure system associated with the Pacific Ocean (Los Angeles).

Advection inversions are associated with air masses moving across surfaces of different temperatures than themselves. When warm air moves over a cold surface, the principles of conduction and convection cool the air nearer to the surface, causing a surface-based inversion. This inversion is most likely to occur in winter when warm air passes over snow cover or extremely cold land. The same type of inversion can occur when air cooled by a cold surface, such as the ocean, flows towards a warmer air mass, such as inland air in the summer.

Table 3. Types of Inversions







4.0 Meteorological Data

Measuring and recording meteorological variables provides the necessary information to manage the release of air contaminants into the atmosphere and to understand the transport and dispersion of emitted air pollutants. The most useful data in air pollution studies are wind speed and direction, ambient temperature and vertical temperature difference, solar radiation and mixing height. For indirect exposure, precipitation data are needed as well. These same variables can be used to make qualitative and quantitative predictions of ambient air toxic concentrations resulting from the release of air toxics, and to conduct quantitative risk assessments.

4.1 Wind Speed and Direction

It is common to consider wind speed and wind direction as separate variables. Wind speed determines the amount of initial dilution experienced by air toxics released into the atmosphere. Wind speed also influences the height to which the toxics will rise after being released from an elevated source - as wind increases, the air toxics are kept lower to the ground, allowing them to impact the ground at shorter distances downwind.

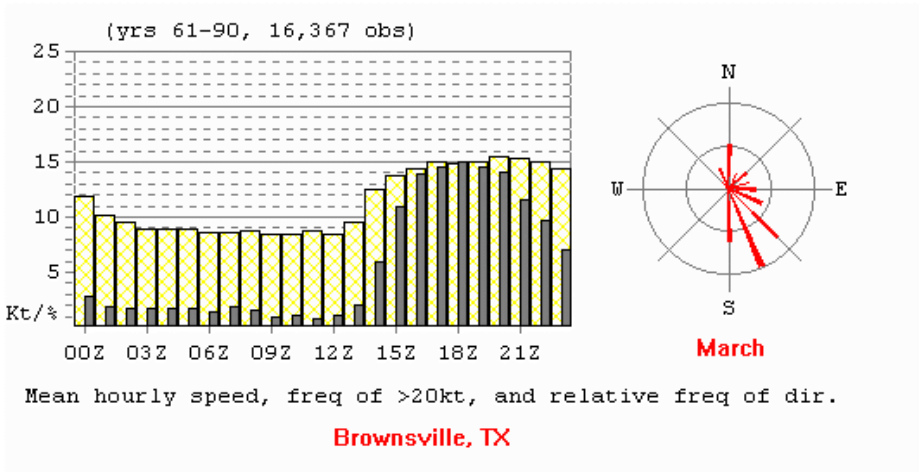
Wind direction for meteorological purposes is defined as the direction from which the wind is blowing. However, wind direction has both horizontal and vertical components. The horizontal and vertical components of the wind direction can be measured with a bi-directional wind vane or an anemometer.

Wind roses are often used to graphically depict the prevailing wind direction of an area. The wind rose depicts the relative frequency of wind direction, typically on a 16-point compass, with north, east, south, and west directions going clockwise. Each ring on the wind rose represents a frequency of the total. The WINDROSE program, which calculates and prints a frequency distribution for wind speed and wind direction for 36 (10 degree) sectors, can be obtained from EPA.[2]

Exhibit 4 presents an example wind rose for Brownsville, Texas. The right hand shows that the winds are predominantly from the south-southeasterly direction. The left hand side shows that the strongest winds occur between 14 and 21 UTC (8 A.M. to 3 P.M. CST). On average, 2 P.M. is the windiest time of day, averaging just over 15 knots (18 UTC). The shaded portion of the bar shows the frequency of winds over 20 knots. At noon CST, winds are over 20 knots approximately 15 percent of the time.

The distribution of pollutants is determined by the wind directions. A wind rose can provide information regarding the percentage of time that the direction(s) and speed(s) associated with a certain air quality can be expected over a time period. However, due to the influences of local terrain, possible coastal effects, exposure of the instruments, and temporal variability of the wind, the wind rose statistics from a nearby weather station may not always be representative of true wind speed and direction for the area of concern.

Exhibit 4. Example of a Wind Rose



Source: Brownsville CLIMATE page at:
http://www.srh.noaa.gov/bro/roshelp.htm

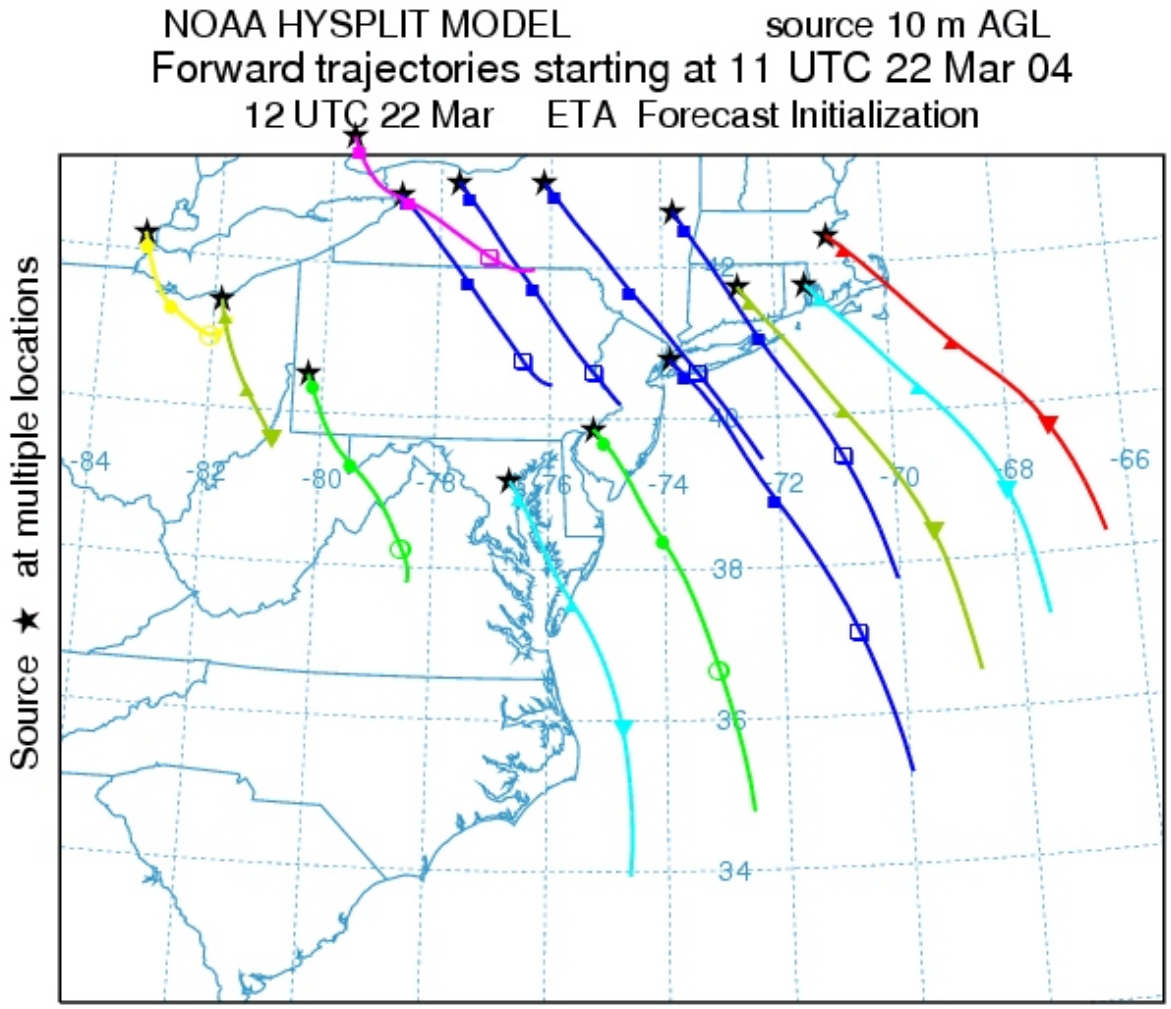
Another tool useful for understanding the distribution of pollutants is wind **trajectories**, which are aerial maps showing the path taken by a parcel of air over a period of time. Trajectories are important for understanding the transport of air toxics and/or the potential geographic regions from which sources of air toxics may emanate. Trajectories illustrate estimates of the general path that air has traveled over a recent time period in order to arrive at a particular location, and where it is likely to be going immediately afterward. The meteorological dynamics that cause air to rise or fall, and that determine its path, can affect air quality by carrying air toxics many miles from their sources. Exhibit 5 presents an example of a trajectory map for the Northeastern United States.

4.2 Other Important Meteorological Data

Both **ambient air temperatures** at a single level (typically 1.5 to 2 m) and **temperature differences** between two levels (typically 2 m and 10 m) are useful in air pollution studies. These temperature measurements are used in calculations of plume rise and can be used in determining atmospheric stability.

Solar radiation is related to the stability of the atmosphere. Cloud cover and ceiling height (height of the base of the cloud deck that obscures at least half the sky) data, taken routinely at National Weather Service (NWS) stations, provide an indirect estimation of radiation effects, and are used in conjunction with wind speed to derive an atmospheric stability category. If representative information is not available from routine NWS observations, it may be appropriate to measure solar radiation for use in determining atmospheric stability. For information on the use of cloud cover and ceiling height data in air toxics modeling, refer to EPA's Guideline on Air Quality Models.[3]

Exhibit 5. Example of a Trajectory Map



Source: National Oceanic and Atmospheric Administration (NOAA) HYSPLIT Model. [4]

The vertical depth of the atmosphere through which vertical mixing takes place is called the **mixing layer**. The top of the mixing layer is referred to as the **mixing height**. The mixing height is an important variable in air toxic studies, as it limits the vertical mixing of air toxics. Daytime mixing heights may reach as high as several kilometers during the day. Although mixing heights are not typically measured directly, they can be approximated from routine upper-air and surface meteorological measurements. In the daytime the mixing height is determined by the depth of the layer thorough which the sun's heating has established a well mixed conditions. On clear nights, radiational cooling might be expected to establish an inversions and reduce the mixing height to near zero. However, it has been found that in metropolitan areas, the urban heat island effect keeps the mixing height between 100 and 200 meters. The mixing heights are used in air quality models as an upper boundary to which air

toxics can be mixed. The level of the mixing height is most important for elevated stacks and much less so for ground level sources.

4.3 Sources of Meteorological Data

The principal federal sources for meteorological data include:

- The National Climatic Data Center (NCDC) located in Asheville, NC.
- The National Weather Service (NWS) Forecast Centers
- The EPA Support Center for Regulatory Models (SCRAM) at Research Triangle Park, NC.

State climatological offices are excellent sources of meteorological data. Data can often be obtained in a text format, and can be used in conjunction with applications that are available as downloads from federal and state data Internet sites. Commercial and university Internet sites are also sources of current weather conditions.

The NCDC is the most extensive source of historical meteorological and climatological data. EPA's SCRAM site has surface and mixing height data that can be used to create wind roses and/or used in air dispersion models. These data are for the major NWS stations throughout the United States. The data are mostly for the years 1984 through 1992 (for surface data) or 1991 (for upper air data used for mixing heights). Exhibit 6 presents a list of Internet sites where meteorological data are available.

Exhibit 6. Internet Sites with Meteorological Data
National Climatic Data Center (http:// www.ncdc.noaa.gov/oa/ncdc.html)
EPA SCRAM Site (http://www.epa.gov/scram001/)
Weather Underground (http://www.wunderground.com/)
UNSYSIS (http://weather.unisys.com/)
NWS Pleasant Hill, MO (http://www.crh.noaa.gov/eax/)
Western Regional Climate Center (http://www.wrcc.dri.edu/)
Northeast Regional Climate Center (http://met-www.cit.cornell.edu/nrcc_home.html)
Midwest Regional Climate Center (http://mcc.sws.uiuc.edu/)
High Plains Regional Climate Center (http://www.hprcc.unl.edu/)
Southern Regional Climate Center (http://www.srcc.lsu.edu/)
Southeast Regional Climate Center (http://www.sercc.com/)
WebMET.com (http://www.webmet.com/)

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3. U.S. Environmental Protection Agency. 2004. Technology Transfer Network. *Support Center for Regulatory Air Models, Guidance/Support, Modeling Guidance.* Updated March 22, 2004. Available at http://www.epa.gov/scram001/tt25.htm#guidance (Last accessed March 2004).

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Appendix H Data Quality Evaluation

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1.0 Introduction

This appendix presents information for assembling the analytical data available after a monitoring investigation has been completed and deciding which of the data are of sufficient quality to be used in the risk assessment. Each sample may have been analyzed for the presence of many different air toxics, and many of those substances may have been detected. The following nine steps describe an approach to organize the data for use in a risk assessment. This stepwise approach is modified from that described in Chapter 5 of EPA's *Risk Assessment Guidance for Superfund*.[1] Note that the application of this stepwise approach requires considerable knowledge related to sampling and analysis methods and risk assessment and therefore should be done in consultation with appropriate experts.

1. Gather all data available from the sampling investigation and sort by medium (Section 2);
2. Evaluate the analytical methods used (Section 3);
3. Evaluate the quality of data with respect to sample quantitation limits (Section 4);
4. Evaluate the quality of data with respect to qualifiers and codes (Section 5);
5. Evaluate the quality of data with respect to blanks (Section 6);
6. Evaluate tentatively identified compounds (Section 7);
7. Compare potential contamination with background (Section 8);
8. Develop a set of data for use in the risk assessment (Section 9); and
9. Further limit the number of chemicals to be carried through the risk assessment, if appropriate (Section 10).
10. Summarize and present data (Section 11).

Acronyms for Appendix H

CLP	=	Contract Laboratory Program
CRDL	=	Contract-Required Detection Limit
CRQL	=	Contract-Required Quantitation Limit
EQL	=	Estimated Quantitation Limits
DL	=	Detection Limit
FIT	=	Field Investigation Team
IDL	=	Instrument Detection Limit
MDL	=	Method Detection Limit
ND	=	Non-detect
PE	=	Performance Evaluation
PQL	=	Practical Quantitation Limit
QA/QC	=	Quality Assurance/Quality Control
QL	=	Quantitation Limit
RfC	=	Inhalation Reference Concentration
RfD	=	Oral Reference Dose
SQL	=	Sample Quantitation Limit
SVOC	=	Semivolatile Organic Chemical
TCL	=	Target Compound List
TIC	=	Tentatively Identified Compound
TOC	=	Total Organic Carbon
TOX	=	Total Organic Halogens
VOC	=	Volatile Organic Chemical

The outcome of this evaluation is (1) the identification of contaminants of potential concern (COPC) that will be carried through the risk assessment and (2) reported concentrations that are of acceptable quality for use in a quantitative risk assessment. If the nine data evaluation steps are followed, the number of air toxics to be considered in the remainder of the risk assessment usually will be less than the number of substances initially identified. A suggested process for averaging acceptable data to develop chemical specific exposure concentrations is provided in Appendix I.

Definitions for Appendix H

Chemicals of Potential Concern. Air toxics that are evaluated in the risk assessment because they have the potential to affect the risk management decision. The corresponding term for ecological risk assessment are chemicals of potential ecological concern (COPEC). The risk assessment often finds that most of the risk is associated with a subset of the COPC. The subset, which drives the risk management decisions, is referred to as chemicals of concern (COC).

Common Laboratory Contaminants. Certain organic chemicals (e.g., acetone, 2-butanone, methylene chloride, toluene, and the phthalate esters) that are commonly used in the laboratory and thus may be introduced into a sample from laboratory cross-contamination.

Contract-required Quantitation Limit (CRQL). Chemical-specific levels that the laboratory must be able to routinely and reliably detect and quantitate in specified sample matrices to meet pre-specified data quality objectives. May or may not be equal to the reported quantitation limit of a given chemical in a given sample. (This term is also used in the Superfund Program under their Contract Laboratory Program.)

Detection Limit (DL). The lowest amount that can be distinguished from the normal "noise" of an analytical instrument or method.

Non-detects (NDs). Chemicals that are not detected in a particular sample above a certain limit, usually the quantitation limit for the chemical in that sample. Non-detects are often indicated by a "U" data qualifier.

Positive Data. Analytical results for which measurable concentrations (i.e., above a quantitation limit) are reported. May have data qualifiers attached (except a U, which indicates a non-detect).

Quantitation Limit (QL). The lowest level at which a chemical can be accurately and reproducibly quantitated. Usually equal to the instrument detection limit multiplied by a factor of three to five, but varies for different chemicals and different samples.

2.0 Step 1: Gather All Data Available from the Sampling Investigation and Sort by Medium

Gather data, which may be from several different sampling periods and based on several different analytical methods, from all available sources. Sort data by medium (i.e., air, water, sediment, soil, and biota, if appropriate). Exhibit 1 illustrates a useful table format for presenting data.

The data should be given to the risk assessor in a data summary report (or reports) that provides information on a number of critical elements that allow the assessor to judge the adequacy of the data to perform the risk analysis. Some of the critical elements include:

- Description of the study area,
- Sampling design and sampling locations,
- Procedures followed to ensure quality data (e.g., SOPs, QAPPs),
- Analytical methods and quantitation limits,

- Chemical-specific results on a per sample basis,

Exhibit 1. Example of Output Format for Validated Data									
Hypothetical Soil Sampling Results from Area X									
Sample medium	Soil			Soil			Soil		
Sample ID	SRB-3-1			SRB-3-1DU			SRB-3-2		
Sample or screen depth	0-1'			0-1'			2-4'		
Date collected	12/14/99			12/14/99			12/14/99		
Air Toxic	SQL[a]	Concen-tration	Quali-fier[b]	SQL[a]	Concen-tration	Quali-fier[b]	SQL[a]	Concen-tration	Quali-fier[b]
toxaphene	80	80	U	80	80	U	80	40	J
2,4,7,8-TCDD	20	10	J	20	8	J	200	200	U/J
lead	160	120	J	160	110	J	400	360	J
mercury	60	30	J	60	44	J	300	300	U/J

Note: All values other than qualifiers must be entered as numbers, not labels.
[a] Sample quantitation limit. Values for illustration only.
[b] Refer to Section 5.1 (Exhibit 3) for an explanation of qualifiers.

- Field conditions, including meteorological conditions,
- Data validation reports (both by the laboratory and any secondary validation), and
- A description of any issues with field collection, transportation/storage, or analysis that impact the veracity of the data.

The data reports provided to the risk assessor must be sufficient to allow the assessor to judge the completeness, comparability, representativeness, precision, and accuracy of the data.

[A more thorough overview of the process for assessing the usability of data for risk assessment purposes, including minimum data and documentation needs, is provided in reference 2. While this document was developed for the Superfund program, it provides relevant information for the evaluation of environmental monitoring data in a risk assessment context and, as such, is referenced here. Assessors are strongly encouraged to review this document prior to planning and scoping a assessment. This will help to ensure that all the information necessary to assess the useability of data for risk assessment purposes will be developed during the sampling and analysis phase of the assessment. (For example, assessing precision of sampling results is usually performed by establishing duplicate monitors at one or more sampling stations. The requirements for duplicate sampling must be written into the analytical plan during the planning and scoping phase of the assessment.) Reference 2 may also be consulted for information on assessing the useability of historical data for risk assessment.][2]

Evaluate data from different time periods to determine if concentrations of air toxics are similar or if changes have occurred between sampling periods (e.g., during different seasons of the year). If the methods used to analyze samples from different time periods are similar in terms of the types of analyses conducted and the QA/QC procedures followed, then the data may be combined for the purposes of quantitative risk assessment. Usually, this means averaging at least one year's worth of data to develop an estimate of long term average concentration (see Appendix I for a suggested methodology for combining results from air monitoring to estimate exposure concentration for the inhalation pathway). If concentrations of air toxics change significantly between sampling periods, it may be useful to also note temporal variation in the risk characterization. If data are available that spans long periods of time (e.g., multiple years) one could use only the most recent data in the quantitative risk assessment and evaluate older data in a qualitative analysis of changes in concentrations over time. When data are eliminated from a data set, justification for such elimination should be fully described in the risk assessment report. (A good understanding of the risk management goals will help in deciding what data to keep and how to combine data.)

3.0 Step 2: Evaluate the Analytical Methods Used

Group data according to the types of analyses conducted (e.g., Toxic Organic method, semivolatiles analyzed by EPA methods for air) to determine which analytical method results are appropriate for use in quantitative risk assessment.

Some types of data usually are ***not*** appropriate for use in quantitative risk assessment, even though they may be available. For example, analytical results that are not specific for a particular compound (e.g., total organic carbon [TOC], total organic halogens [TOX]), or results from insensitive analytical methods (e.g., analyses using portable field instruments such as organic vapor analyzers and other field screening methods) may be useful for identifying potential monitoring locations and/or examining the potential fate and transport of contaminants. These types of analytical results, however, generally are not appropriate for quantitative risk assessment. In addition, the results of analytical methods associated with unknown, few, or no QA/QC procedures are generally eliminated from further quantitative use. (Note that one of the purposes of the data quality objectives (DQO) process described in Chapter 6 and elsewhere in this manual is to avoid the use of sampling and analysis protocols that will not provide data that are useable for the risk assessment). These types of results, however, may be useful for qualitative discussions of risk.

The outcome of this step is a set of study-specific data that has been developed according to a standard set of sensitive, chemical-specific methods (see Chapters 10 and 19 for links to identified, standardized methods).

Note however that even when standardized, verified field and analytical procedures and associated QA/QC have been used during sampling and analysis, there is no guarantee that all analytical results are consistently of sufficient quality and reliability for use in quantitative risk assessment. Instead, it is important to determine – according to the steps discussed below – the limitations and uncertainties associated with the data, so that only data that are appropriate and reliable for use in a quantitative risk assessment are carried through the process.

4.0 Step 3: Evaluate the Quality of Data with Respect to Sample Quantitation Limits

This step involves evaluation of quantitation limits (QLs) and detection limits (DLs) for all of the air toxics assessed. This evaluation may lead to the re-analysis of some samples, the use of "proxy" (or estimated) concentrations, and/or the elimination of certain air toxics from further consideration (because they are believed to be absent in all samples). Types and definitions of QLs and DLs are presented in the box on the next page. Before eliminating an air toxic because they are not detected (or conducting any other manipulation of the data), the following points should be considered:

- The sample quantitation limit (SQL) for a specific air toxic may be greater than corresponding standards, criteria, or concentrations against which the concentrations will be compared (e.g., RfCs, RfDs, or ecological benchmark levels). In this situation, the "undetected" air toxic may be present at levels greater than these benchmarks and their exclusion from the risk assessment may result in an underestimate of risk.

- A particular SQL may be significantly higher than positively detected values in other samples in a data set.

These two points are discussed in detail in the following two subsections. A third subsection provides guidance for situations where only some of the samples for a given medium test positive for a particular chemical. A fourth subsection addresses the special situation where SQLs are not available. The final subsection addresses the specific steps involved with elimination of air toxics from the quantitative risk assessment based on their QLs.

4.1 Sample Quantitation Limits (SQLs) That Are Greater Than Benchmark Concentrations

QLs needed for the sampling and analysis investigation should be specified in the sampling plan. For some air toxics, however, SQLs obtained from available analytical methods may exceed certain concentrations of potential concern (e.g., RfCs, tissue sample concentrations that might result in a dietary intake level that exceeds an RfD). Exhibits 10-10 and 10-11 identify some known deficiencies in available air monitoring methods and some air toxics for which improved monitoring methods are needed. Two points should be noted when considering this situation:

- Review of available information on sources and emissions, a preliminary determination of COPC, and/or the results of fate and transport modeling ***prior to sample collection*** may allow the risk assessor to identify when more sensitive sampling and/or analytical methods may be needed before an investigation begins. This is the most efficient way to minimize the problem of QLs exceeding levels of potential concern.

- Analytical laboratories may not be able to attain QLs in particular samples that meet data quality requirements using standardized, verified procedures.

If an air toxic is not detected in any sample from a particular medium at the QL and a more sensitive method is not available, then modeling data, as well as professional judgment, may be used to evaluate whether the chemical may be present above the concentrations of potential concern. If the available information indicates the chemical is not present, see Section 3.5 of this

Detection Limits and Quantitation Limits

Strictly interpreted, the detection limit (DL) is the lowest amount of a chemical that can be "seen" above the normal, random noise of an analytical instrument or method. A chemical present below that level cannot reliably be distinguished from noise. DLs are chemical-specific and instrument-specific and are determined by statistical treatment of multiple analyses in which the ratio of the lowest amount observed to the electronic noise level (i.e., the signal-to-noise ratio) is determined. On any given day in any given sample, the calculated limit may not be attainable; however, a properly calculated limit can be used as an overall general measure of laboratory performance.

Two types of DLs may be described: instrument DLs (IDLs) and method DLs (MDLs). The IDL is generally the lowest amount of a substance that can be detected by an instrument; it is a measure only of the DL for the instrument, and does not consider any effects that sample matrix, handling, and preparation may have. The MDL, on the other hand, takes into account the reagents, sample matrix, and preparation steps applied to a sample in specific analytical methods.

Due to the irregular nature of instrument or method noise, reproducible quantitation of a chemical is not possible at the DL. Generally, a factor of three to five is applied to the DL to obtain a quantitation limit (QL), which is considered to be the lowest level at which a chemical may be accurately and reproducibly quantitated. DLs indicate the level at which a small amount would be "seen," whereas QLs indicate the levels at which measurements of concentration can be "trusted."

Two types of QLs may be described: estimated quantitation limits (EQL - also sometimes referred to as a practical quantitation limit or PQL) and sample QLs (SQLs). EPA's Superfund Program maintains a Contract Laboratory Program (CLP) as a means to obtain reliable analytical results from many different laboratories. To participate in the CLP, a laboratory must be able to meet EPA's EQL. This EQL is established by contract and, thus, is called a contract required quantitation limit (CRQL). CRQLs are chemical-specific and vary depending on the medium analyzed and the amount of chemical expected to be present in the sample. As the name implies, CRQLs are not necessarily the lowest detectable levels achievable, but rather are levels that a CLP laboratory should routinely and reliably detect and quantitate in a variety of sample matrices. For most air toxics risk assessments, SQLs, not CRQLs, will be the QLs of interest for most samples. In fact, for the same chemical, a specific SQL may be higher than, lower than, or equal to SQL values for other samples. In addition, preparation or analytical adjustments such as dilution of a sample for quantitation of an extremely high level of only one compound could result in non-detects for all other compounds included as analytes for a particular method, even though these compounds may have been present at trace quantities in the environmental sample. Because SQLs take into account sample characteristics, sample preparation, and analytical adjustments, these values are the most relevant QLs for evaluating non-detected chemicals. Also note that because of the inability to accurately measure concentration at the MDL, the SQL is used as he starting point for developing exposure concentrations where some of the samples in a data set have detections of an analyte and others do not (see Appendix I).

appendix for guidance on eliminating chemicals. If there is some indication that the chemical is present, the only choices are to:

- Use modeling results in the risk assessment;
- Re-analyze selected samples using a more sensitive analytical method (if feasible); or
- Address the chemical qualitatively in the risk assessment.

In determining which option is most appropriate for an analysis, it may be helpful to assume the air toxic is present at the SQL for purposes of an initial (tier 1) screening risk assessment. In this way, risks that would be posed if the chemical is present at the SQL can be compared with risks posed by other air toxics in the analysis.

4.2 Unusually High SQLs

Due to one or more sample-specific problems (e.g., matrix interferences), SQLs for a particular chemical in some samples may be unusually high, sometimes greatly exceeding the positive results reported for the same chemical in other samples from the data set. Even if these SQLs do not exceed health-based standards or criteria, they may still present problems. If the SQLs cannot be reduced by re-analyzing the sample, consider excluding the samples from the quantitative risk assessment if they cause the calculated exposure concentration to exceed the maximum detected concentration for a particular sample set. Exhibit 2 presents an example of how to address a situation with unusually high QLs.

Exhibit 2. Example of Unusually High Quantitation Limits

In this hypothetical example, ambient air concentrations of benzene in air have been determined using the TO-1 method.

	Concentration (ppb)			
Chemical	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**
benzene	50 U[(a)]	59	200 U	74

[(a)] U indicates that benzene was analyzed for, but not detected; the value presented (e.g., 50 U) is the SQL.

The ambient air concentrations presented in this example (i.e., 50 to 200 ppb) vary widely from sample to sample. Assume a more sensitive analytical method would not aid in reducing the unusually high QL of 200 ppb noted in Sample 3. In this case, the result for benzene in Sample 3 would be eliminated from the quantitative risk assessment because it would cause the calculated exposure concentrations to exceed the maximum detected concentration (in this case 74 ppb). Thus the data set would be reduced to three samples: the non-detect in Sample 1 and the two detected values in Samples 2 and 4.

4.3 When Only Some Samples in a Medium Test Positive For a Chemical

Most analytes are not positively detected in each sample collected and analyzed. Instead, for a particular chemical the data set generally will contain some samples with positive results and others with non-detected results. The non-detected results usually are reported as SQLs. These limits indicate that the chemical was not measured above certain levels, which may vary from sample to sample. The chemical may be present at a concentration just below the reported quantitation limit, or it may not be present in the sample at all (i.e., the concentration in the sample is zero). Appendix I provides a suggested methodology for combining the results of a dataset where some of the samples test positive for an analyte and others do not.

4.4 When SQLs Are Not Available

In some cases, laboratory data summaries may not provide the SQLs. Instead, MDLs, CRQLs, or even IDLs may have been substituted wherever a chemical was not detected. Sometimes, no detection or quantitation limits may be provided with the data. As a first step in these situations, always attempt to obtain the SQLs, because these are the most appropriate limits to consider when evaluating non-detected air toxics (i.e., they account for sample characteristics, sample preparation, or analytical adjustments that may differ from sample to sample). Good planning and clearly articulated directions to the laboratory will help ensure that the appropriate information is provided to the risk assessor. The problem associated with incorrectly reported data should only be an issue when evaluating historical data for which there was no pre-consultation with the laboratory about what is to be provided in the data package.

If SQLs cannot be obtained, the MDL may be used as the QL, with the understanding that in most cases this will underestimate the SQL (because the MDL is a measure of detection limits only and does not account for sample characteristics or matrix interferences). The IDL should rarely be used for non-detected air toxics since it is a measure only of the detection limit for a particular instrument and does not consider the effect of sample handling and preparation or sample characteristics.

4.5 When Air Toxics Are Not Detected in Any Samples in a Medium

After considering the discussion provided in the above subsections, generally eliminate those air toxics that have not been detected in any samples of a particular medium. If information exists to indicate that the air toxics are present, they should not be eliminated from the analysis. The outcome of this step is a data set that only contains air toxics for which positive data (i.e., analytical results for which measurable concentrations are reported) are available in at least one sample from each medium. Unless otherwise indicated, assume at this point in the evaluation of data that positive data to which no uncertainties are attached concerning either the assigned identity of the chemical or the reported concentration (i.e., data that are not “tentative,” “uncertain,” or “qualitative”) are appropriate for use in the quantitative risk assessment.

5.0 Step 4: Evaluate the Quality of Data with Respect to Qualifiers and Codes

Various qualifiers and codes (hereafter referred to as qualifiers) may be attached to certain data by either the laboratories conducting the analyses or by persons performing data validation. These qualifiers often pertain to QA/QC problems and generally indicate questions concerning

chemical identity, chemical concentration, or both. All qualifiers must be addressed before the chemical can be used in quantitative risk assessment. Qualifiers used by the laboratory may differ from those used by data validation personnel in either identity or meaning.

5.1 Types of Qualifiers

Exhibit 3 provides a list of the qualifiers that laboratories are permitted to use under the Superfund CLP, along with their potential use in risk assessment. Exhibit 4 provides a similar list addressing data validation qualifiers. (Note that the data qualifiers and their meanings provided here are not consistent across all laboratories. In all cases, it is critical to discuss with the lab what they mean by the data qualifiers they report.) In general, because the data validation process is intended to assess the effect of QC issues on data usability, validation data qualifiers are attached to the data after the laboratory qualifiers and supersede the laboratory qualifiers. If data have both laboratory and validation qualifiers and they appear contradictory, ignore the laboratory qualifier and consider only the validation qualifier. If qualifiers have been attached to certain data by the laboratory and have not been removed, revised, or superseded during data validation, then evaluate the laboratory qualifier itself. If it is unclear whether the data have been validated, contact the appropriate data validation and/or laboratory personnel.

The type of qualifier and other site-specific factors determine how qualified data are to be used in a risk assessment. As seen in Exhibits 3 and 4, the type of qualifier attached to certain data often indicates how that data should be used in a risk assessment. For example, most of the laboratory qualifiers for both inorganic chemical data and organic chemical data (e.g., J, E, N) indicate uncertainty in the reported concentration of the chemical, but not in its assigned identity. Therefore, these data can be used just as positive data with no qualifiers or codes. In general, include data with qualifiers that indicate uncertainties in concentrations but not in identification.

Exhibit 3. Example of Data Qualifiers and Their Potential Use in Quantitative Risk Assessment: Superfund Contract Laboratory Program (CLP)

Qualifier	Definition	Indicates:		
		Uncertain Identity?	Uncertain Concentration?	Include Data in Quantitative Risk Assessment?
Inorganic Chemical Data[(a)]				
B	Reported value is <CRDL, but >IDL.	No	No	Yes
U	Compound was analyzed for, but not detected.	Yes	Yes	?
E	Value is estimated due to matrix interferences.	No	Yes	Yes
M	Duplicate injection precision criteria not met.	No	Yes	Yes

Exhibit 3. Example of Data Qualifiers and Their Potential Use in Quantitative Risk Assessment: Superfund Contract Laboratory Program (CLP)				
Qualifier	Definition	Indicates:		
		Uncertain Identity?	Uncertain Concentration?	Include Data in Quantitative Risk Assessment?
N	Spiked sample recovery not within control limits.	No	Yes	Yes
S	Reported value was determined by the Method of Standard Additions (MSA).	No	No	Yes
W	Post-digestion spike for furnace AA analysis is out of control limits, while sample absorbance is <50% of spike absorbance.	No	Yes	Yes
*	Duplicate analysis was not within control limits.	No	Yes	Yes
+	Correlation coefficient for MSA was <0.995.	No	Yes	Yes
Organic Chemical Data[(b)]				
U	Compound was analyzed for, but not detected.	Yes	Yes	?
J	Value is estimated, either for a tentatively identified compound (TIC) or when a compound is present (spectral identification criteria are met, but the value is <CRQL).	No for TCL chemicals Yes for TICs	Yes	?
C	Pesticide results were confirmed by GC/MS.	No	No	Yes
B	Analyte found in associated blank as well as in sample.[©)]	No	Yes	Yes
E	Concentration exceeds calibration range of GC/MS instrument.	No	Yes	Yes
D	Compound identified in an analysis at a secondary dilution factor.	No	No	Yes
A	The TIC is a suspected aldol-condensation product.	Yes	Yes	No

Exhibit 3. Example of Data Qualifiers and Their Potential Use in Quantitative Risk Assessment: Superfund Contract Laboratory Program (CLP)				
Qualifier	Definition	Indicates:		
		Uncertain Identity?	Uncertain Concentration?	Include Data in Quantitative Risk Assessment?
X	Additional flags defined separately.	–(d)	--	--

(a) Source: U.S. EPA, 1988. *Contract Laboratory Program Statement of Work for Inorganics Analysis: Multi-media, Multi-concentration.* Office of Emergency and Remedial Response. SOW No. 788.
(b) Source: U.S. EPA, 1988. *Contract Laboratory Program Statement of Work for Organics Analysis: Multi-media, Multi-concentration.* Office of Emergency and Remedial Response. SOW No. 288.
©) See Section 6 for a discussion of blank contamination.
(d) Data will vary with laboratory conducting analyses.

Exhibit 4. Validation Data Qualifiers and Their Potential Use in Quantitative Risk Assessment				
Qualifier	Definition	Indicates:		
		Uncertain Identity?	Uncertain Concentration?	Include Data in Quantitative Risk Assessment?
Inorganic and Organic Chemical Data[a]				
U	The material was analyzed for, but not detected. The associated numerical value is the SQL.	Yes	Yes	?
J	The associated numerical value is an estimated quantity.	No	Yes	Yes
R	Quality control indicates that the data are unusable (compound may or may not be present). Re-sampling and/or re-analysis is necessary for verification.	Yes	Yes	No
Z	No analytical result (inorganic data only).	--	--	--
Q	No analytical result (organic data only).	--	--	--
N	Presumptive evidence of presence of material (tentative identification)[b]	Yes	Yes	?

Exhibit 4. Validation Data Qualifiers and Their Potential Use in Quantitative Risk Assessment
(a) Source: U.S. EPA. 1988. *Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis*. Office of Emergency and Remedial Response. U.S. EPA. 1988. *Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis (Functional Guidelines for Organics)*. Office of Emergency and Remedial Response. (b) Organic chemical data only

Exhibit 5 provides examples showing the use of two commonly encountered data qualifiers: the J qualifier, and the R qualifier. Basically, the suggestion is to use J-qualified concentrations the same way as positive data that do not have this qualifier. If possible, note potential uncertainties associated with the qualifier, so that if data qualified with a J contribute significantly to the risk, then appropriate caveats can be attached. The R data qualifier indicates that the sample result was rejected by the data validation personnel, and therefore this result should be eliminated from the risk assessment.

Exhibit 5. Example Use of "J" and "R" Data Qualifiers

In this example, concentrations of benzene in an air monitor have been determined using a hypothetical analytical method. Benzene was detected in these four samples at concentrations of 3,200 µg/l, 40 µg/l, and 20 µg/l; therefore, these concentrations – as well as the non-detect – should be used in determining representative concentrations.

Chemical	Sample 1	Sample 2	Sample 3	Sample 4
Benzene	3,200 J[(a)]	40	30 U[(b)]	20 J

(a) J = The numerical value is an estimated quantity
(b) U = Compound was analyzed for, but not detected. Value presented (e.g., 30 U) is the SQL.

In this example, concentrations of lead in surface water have been determined using a hypothetical analytical method. These data have been validated, and therefore the R qualifers indicate that the person conducting the data validation rejected the data for lead in samples 2 and 3. The "UR" qualifier means that lead was not detected in Sample 3; however, the data validator rejected the non-detected result. Eliminate these two samples so that the data set now consists of only two samples (Samples 1 and 4).

Chemical	Sample 1	Sample 2	Sample 3	Sample 4
Lead	310	500 R[(a)]	30 UR[(b)]	500

(a) R = Quality control indicates that the data are unusable (compound may not be present)
(b) U = Compound was analyzed for, but not detected. Value presented (e.g., 30 UR) is the SQL.

5.2 Using the Appropriate Qualifiers

The information presented in Exhibits 3 and 4 is based on 1988 EPA guidance documents concerning qualifiers. The types and definitions of qualifiers may be periodically updated within any analytical program, and EPA regions, states, and local governments may have their own data

qualifiers and associated definitions. In general, the risk assessor should clearly understand the specific data qualifiers used by a particular analytical program and use the resulting data appropriately in the risk assessment. Make sure that definitions of data qualifiers used in the data set for the analysis have been reported with the data and are current. Never guess about the definition of qualifiers.

6.0 Step 5: Evaluate the Quality of Data with Respect to Blanks

Blank samples provide a measure of contamination that has been introduced into a sample set either (1) in the field while the samples were being collected or transported to the laboratory, or (2) in the laboratory during sample preparation or analysis. To prevent the inclusion of non-site-related contaminants in the risk assessment, the concentrations of air toxics detected in blanks must be compared with concentrations of the same air toxics detected in site samples. Exhibit 6 provides detailed definitions of different types of blanks. Blank data should be compared with results from samples with which the blanks are associated. It is often impossible, however, to determine the association between certain blanks and data. In this case, compare the blank data with results from the entire sample data set. EPA's Superfund Program has developed guidelines for comparing sample concentrations with blank concentrations; **note that the requirements or practices for a given air toxic program may differ**.

- **Blanks containing common laboratory contaminants**. As discussed in the EPA documents cited in Exhibits 3 and 4, acetone, 2- butanone (or methyl ethyl ketone), methylene chloride, toluene, and the phthalate esters are considered by EPA to be common laboratory contaminants. If the blank contains detectable levels of common laboratory contaminants, EPA guidance indicates that the sample results should be considered as positive results only if the concentrations in the sample exceed **ten times** the maximum amount detected in any blank. If the concentration of a common laboratory contaminant is less than ten times the blank concentration, then EPA guidance indicates to conclude that the chemical was not detected in the particular sample and consider the blank-related concentrations of the chemical to be the quantitation limit for the chemical in that sample. Note that if all samples contain levels of a common laboratory contaminant that are less than ten times the level of contamination noted in the blank, then completely eliminate that chemical from the set of sample results.

- **Blanks containing chemicals that are not common laboratory contaminants**. As discussed in the previously referenced guidance, if the blank contains detectable levels of one or more organic or inorganic chemicals that are not considered by EPA to be common laboratory contaminants, then consider sample results as positive only if the concentration of the chemical in the sample exceeds **five times** the maximum amount detected in any blank. Treat samples containing less than five times the amount in any blank as non-detects, and consider the blank-related chemical concentration to be the quantitation limit for the chemical in that sample. Again, note that if all samples contain levels of a chemical that are less than five times the level of contamination noted in the blank, then completely eliminate that chemical from the set of sample results.

Exhibit 6. Types of Blanks
Blanks are analytical quality control samples analyzed in the same manner as site samples. They are used in the measurement of contamination that has been introduced into a sample either (1) in the field while the samples were being collected or transported to the laboratory or (2) in the laboratory during sample preparation or analysis. Four types of blanks – trip, field, laboratory calibration, and laboratory reagent (or method) – are described below. A discussion on the water used for the blank also is provided. **Trip Blank**. This type of blank is used to indicate potential contamination due to migration of volatile organic chemicals (VOCs) from the air on the site or in sample shipping containers, through the septum or around the lid of sampling vials, and into the sample. A trip blank consists of laboratory distilled, deionized water in a 40-ml glass vial sealed with a teflon septum. The blank accompanies the empty sample bottles to the field as well as the samples returning to the laboratory for analysis; it is not opened until it is analyzed in the lab with the actual site samples. The containers and labels for trip blanks should be the same as the containers and labels for actual samples, thus making the laboratory "blind" to the identity of the blanks. **Field Blank**. A field blank is used to determine if certain field sampling or cleaning procedures (e.g., insufficient cleaning of sampling equipment) result in cross-contamination of site samples. Like the trip blank, the field blank is a sample of distilled, deionized water taken to the field with empty sample bottles and is analyzed in the laboratory along with the actual samples. Unlike the trip blank, however, the field blank sample is opened in the field and used as a sample would be (e.g., it is poured through cleaned sampling equipment or it is poured from container to container in the vicinity of a gas-powered pump). As with trip blanks, the field blanks' containers and labels should be the same as for actual samples. **Laboratory Calibration Blank**. This type of blank is distilled, deionized water injected directly into an instrument without having been treated with reagents appropriate to the analytical method used to analyze actual site samples. This type of blank is used to indicate contamination in the instrument itself, or possibly in the distilled, deionized water. **Laboratory Reagent or Method Blank**. This blank results from the treatment of distilled, deionized water with all of the reagents and manipulations (e.g., digestions or extractions) to which site samples will be subjected. Positive results in the reagent blank may indicate either contamination of the chemical reagents or the glassware and implements used to store or prepare the sample and resulting solutions. Although a laboratory following good laboratory practices will have its analytical processes under control, in some instances method blank contamination cannot be entirely eliminated. **Water Used for Blanks**. For all the blanks described above, results are reliable only if the water comprising the blank was clean. For example, if the laboratory water comprising the trip blank was contaminated with VOCs prior to being taken to the field, then the source of VOC contamination in the trip blank cannot be isolated (see laboratory calibration blank).

7.0 Step 6: Evaluate Tentatively Identified Compounds

Both the identity and reported concentration of a tentatively identified compound (TIC) is questionable (see Exhibit 7). Two options for addressing TICs exist, depending on the relative number of TICs compared to non-TICs. If the risk assessment involves a regulatory decision, the risk assessor is strongly encouraged to consult the appropriate regulatory authorities about how to address TICs in the risk assessment.

- **When few TICs are present**. When only a few TICs are present, and either (a) no information indicates that either a particular TIC may indeed be present (e.g., it is not present in emissions from the source(s) being evaluated or other nearby sources), or (b) the estimated concentration is relatively low, and therefore, the risk estimate would likely not be dominated by the TIC, then generally do not include the TICs in the risk assessment.

- **When Many TICs are present**. If many TICs are present, or if TIC concentrations appear high or site information indicates that TICs are indeed present, then further evaluation of TICs is necessary. If sufficient time is available, use more sensitive analytical methods to confirm the identity and to positively and reliably measure the concentrations of TICs prior to their use in the risk assessment. If such methods are unavailable or impractical, then the TICs should be included as COPC in the risk assessment and (usually) discussed qualitatively in the risk characterization along with a discussion of the uncertainty in both identity and concentration.

Exhibit 7. Tentatively Identified Compounds (TICs)
The set of compounds analyzed in a particular laboratory protocol may be a limited subset of the organic air toxics that could actually be present in specific emissions being evaluated. Thus, a laboratory analysis may indicate the presence of additional organic compounds not being specifically evaluated. The presence of additional compounds may be indicated, for example, by"peaks" on a chromatogram (a chromatogram is a paper representation of the response of the instrument to the presence of a compound). The laboratory may be required to attempt to identify some of these compounds (e.g., the highest peaks) using computerized searches of a library containing mass spectra (essentially "fingerprints" for particular compounds). When the mass spectra match to a certain degree, the compound (or general class of compound) is named; however, the assigned identity is in most cases highly uncertain. These compounds are called tentatively identified compounds (TICs). The analytical protocols being used by the laboratory may include procedures to obtain a rough estimate of the concentrations of TICs. These estimates, however, generally are highly uncertain and could be orders of magnitude higher or lower than the actual concentration. For TICs, therefore, assigned identities may be inaccurate, and quantitation is certainly inaccurate. Due to these uncertainties, TIC information often is not provided with data summaries. Additional sampling and analysis using different or more sensitive methods may reduce the uncertainty associated with TICs and, therefore, TIC information should be sought even if it is absent from data summaries.

8.0 Step 7: Compare Potential Contamination with Background

In some cases, a comparison of sample concentrations with background concentrations is useful for identifying the relative contribution of the source(s) being evaluated and other potential sources to the total concentrations to which a population may be exposed. Often, however, the comparison of samples with background is unnecessary because the risk estimates resulting from other sources are very low compared to those resulting from the source(s) being evaluated.

Information collected during the risk assessment can provide information on two types of background chemicals: (1) naturally occurring chemicals that have not been influenced by humans and (2) chemicals that are present due to anthropogenic sources. Either type of background chemical can be either localized or widespread. Information on background chemicals may have been obtained by the collection of background samples and/or from other

sources (e.g., County Soil Conservation Service surveys, United States Geological Survey reports). Background concentrations should be from the vicinity of the location sampled. For example, background air samples are generally collected upwind from the study area to estimate concentrations of chemicals in the air mass that is moving into the study area. For water, samples are taken upstream of the area where deposition (or erosion of contaminated soils) is occurring.

Background samples collected during the monitoring effort should not be used if they were obtained from areas influenced or potentially influenced by the source(s) being evaluated. Instead, the literature sources mentioned in the previous paragraph may be consulted to determine expected background levels of air toxics in the study area. Care must be taken in using literature sources, because the data contained therein might represent nationwide variation in a particular parameter rather than variation typical of the geographic region or geological setting in which the site is located. For example, a literature source providing concentrations of chemicals in soil on a national scale may show a wide range of concentrations that is not representative of the variation in concentrations that would be expected within a particular study area.

Both the concentration of the chemical in the study-area and the concentration in background media should be clearly articulated in the risk assessment report. Background concentrations should generally not be subtracted from study-area specific concentrations; rather, they should be compared (e.g., as barcharts). Statistical analyses that indicate whether study-area and background concentrations are different may also be presented. (In cases where background comparisons will be made, the statistical methods that will be used to compare study-area concentrations to background concentrations should be identified prior to the collection of samples.)

As an example, chromium is present in air releases from a source in a study area and chromium is also naturally occurring in study area soils. In this case, it may be necessary to include a careful comparison of the relative magnitude of estimated exposure and risk due to background vs. estimated exposure and risk from total (i.e., deposited chromium + background chromium) . This can be done by the bar chart method mentioned above and may be augmented by statistical analyses that attempt to answer the question about whether study area soil concentrations of chromium are statistically different from background soils. Again, consultation with the appropriate decision making authorities is strongly encouraged to ensure that they get the type of information that they will need to make their risk management decisions. (Note that, in general, comparison with naturally occurring levels is commonly performed primarily for inorganic chemicals such as metals, because the majority of organic air toxics released to the environment are not naturally occurring (even though they may be ubiquitous). Similar to naturally occurring background concentrations, anthropogenic levels resulting from human sources (other than those being evaluated in the air toxics risk assessment) may also be present. For example, an assessment that is evaluating exposures to dioxin from a specific source may also have to contend with dioxin that is also present in the study area that has resulted from numerous other small sources in the area (and possibly also from naturally occurring sources such as forest fires and some amount of longer range transport). Similar to naturally occurring chemicals, some combination of background sampling, literature values, modeling, and statistical analysis can be performed to try and sort out how much of the concentrations and risk are due to the source(s) in question and how much is present due to other human (and non-human) influences.

9.0 Step 8: Develop a Set of Data for Use in the Risk Assessment

After the evaluation of data is complete as specified in previous sections, a list of the samples (by medium) is made that will be used to estimate exposure concentrations. In addition, a list of COPC (also by medium) will be needed for the quantitative risk assessment. This list should include chemicals that were:

- Positively detected in at least one sample in a given medium, including (a) chemicals with no qualifiers attached (excluding samples with unusually high detection limits), and (b) chemicals with qualifiers attached that indicate known identities but unknown concentrations (e.g., J-qualified data);

- Detected at levels significantly elevated above levels of the same chemicals detected in associated blank samples;

- Only tentatively identified but either may be associated with emissions from the source(s) being evaluated based on ancillary information or have been confirmed by additional analysis; and/or

- Transformation products of air toxics demonstrated to be present.

Air toxics that were not detected in samples from a given medium (i.e., non-detects) but that may be present at the site also may be included in the risk assessment if an evaluation of the risks potentially present at the detection limit is desired.

10.0 Step 9: Further Limit the Number of Chemicals to Be Carried Through the Risk Assessment, If Appropriate

For certain assessments, the list of air toxics potentially related to emissions from the source(s) being evaluated and remaining after quantitation limits, qualifiers, blank contamination, and background have been evaluated may be lengthy. ***Note, however, that often a modeling analysis can identify the subset of air toxics in the emissions being evaluated that are most likely to contribute significantly to risk, and therefore limit the scope of any subsequent sampling and analysis effort***. Carrying a large number of chemicals through a quantitative risk assessment may be complex, and it may consume significant amounts of time and resources. The resulting risk assessment report may be difficult to read and understand, and it may distract from the dominant risks. In these cases, the procedures discussed in this section – using chemical classes, frequency of detection, essential nutrient information, and a concentration toxicity screen – may be used to further reduce the number of COPC in each medium.

If conducting a risk assessment on a large number of chemicals is feasible (e.g., because of adequate computer capability), then the procedures presented in this section may be omitted. However, the most important chemicals (e.g., those presenting 99 percent of the risk) – identified after the risk assessment – may be the focus of the main text of the report, and the remaining chemicals could be presented in the appendices.

10.1 Conduct Initial Activities

There are several activities that are useful to conduct before implementing any of the procedures described in this section. The risk assessor is strongly encouraged to consult with appropriate decision making authorities prior to implementing these procedures to ensure that the resulting processed data will meet the decision makers' needs. These remaining initial activities include:

- **Considering how the rationale for the procedure should be documented**. The rationale for eliminating chemicals from the quantitative risk assessment based on the procedures discussed below should be clearly stated in the risk assessment report. This documentation, and its possible defense at a later date, could be fairly resource- intensive. If a continuing need to justify this step is expected, then any plans to eliminate chemicals should be reconsidered.

- **Examining historical information about the source(s) being evaluated**. Chemicals reliably associated with emissions from the source(s) being evaluated based on historical information generally should not be eliminated from the quantitative risk assessment (at least during the initial tiers of analysis), even if the results of the procedures given in this section indicate that such an elimination is possible.

- **Considering mobility, persistence, and bioaccumulation**. Three factors that should be considered are the mobility, persistence, and bioaccumulation of the chemicals. For example, a highly volatile (i.e., mobile) chemical such as benzene, a long-lived (i.e., persistent) chemical such as dioxin, or a readily bioaccumulated chemical such as the PB-HAPs, probably should remain in the risk assessment. These procedures do not explicitly include a mobility, persistence, or bioaccumulation component, and therefore the risk assessor must pay special attention to these factors.

- **Considering special exposure routes**. For some chemicals, certain exposure routes need to be considered carefully before using these procedures. For example, some air toxics may pose a significant risk in certain circumstances due to dermal contact. The procedures described in this section may not account for exposure routes such as this.

10.2 Group Chemicals by Class

Some dose-response values used in characterizing risks are available only for certain chemicals within a chemical class. For example, slope factors are available only for some of the polycyclic aromatic hydrocarbons (PAHs). In such cases, the information provided in Chapter 12 (toxicity evaluation) and information provided on EPA's FERA website (http://www.epa.gov/ttn/fera/).

10.3 Evaluate Frequency of Detection

Chemicals that are infrequently detected may be artifacts in the data due to sampling, analytical, or other problems, and therefore may not be related to the sources being evaluated. Consider the chemical as a candidate for elimination from the quantitative risk assessment if: (1) it is detected infrequently in one or perhaps two environmental media, (2) it is not detected in any other sampled media or at high concentrations, and (3) there is no reason to believe that the chemical may be present in emissions from the source(s) being evaluated. In particular, modeling results may indicate whether monitoring data that show infrequently detected chemicals are representative of only their sampling locations or of broader areas. Because chemical

concentrations within a broad assessment area are spatially variable, the risk assessor can use modeling results to compare infrequently detected chemical concentrations to those estimated over broader areas when determining whether the subject chemicals are relevant to the overall risk assessment. Judicious use of modeling to supplement available monitoring data often can minimize the need to resort to arbitrarily setting limits on inclusion of infrequently detected chemicals in the risk assessment.

In addition to available monitoring data and modeling results, the risk assessor should consider other relevant factors (e.g., presence of sensitive subpopulations) in recommending appropriate site-specific limits on inclusion of risk assessment.

The reported or modeled concentrations and locations of chemicals should be examined to check for "hotspots" (localized areas of particularly high concentrations), which may be especially important for short-term exposures and which therefore should not be eliminated from the risk assessment. For PB-HAPs, always consider detection of particular chemicals in all sampled media because some media may be sources of contamination for other media. In addition, infrequently detected chemicals with concentrations that greatly exceed reference concentrations should not be eliminated.

10.4 Use a Toxicity-Weighted or Risk-based Screening Analysis

The objective of this screening procedure is to identify the chemicals in a particular analysis that, based on concentration and toxicity, are most likely to contribute significantly to the resulting risk estimates. These procedures are described, along, with examples, in Chapter 6.

11.0 Summarize and Present Data

The section of the risk assessment report summarizing the results of the data collection and evaluation should be titled "Identification of COPC." Information in this section should be presented in ways that readily support the calculation of exposure concentrations in the exposure assessment portion of the risk assessment. Exhibits 8 and 9 present examples of tables to be included in this section of the risk assessment report.

11.1 Summarize Data Collection and Evaluation Results in Text

In the introduction for this section of the risk assessment report, clearly discuss in bullet form the steps involved in data evaluation. If the optional screening procedure described in Section 9 was used in determining COPC, these steps should be included in the introduction. If both historical data and current data were used in the data evaluation, state this in the introduction. Any special site-specific considerations in collecting and evaluating the data should be mentioned. General uncertainties concerning the quality associated with either the collection or the analysis of samples should be discussed so that the potential effects of these uncertainties on later sections of the risk assessment can be determined.

In the next part of the report, discuss the samples from each medium selected for use in quantitative risk assessment. Provide information concerning the sample collection methods used (e.g., grab, composite) as well as the number and location of samples. If any samples (e.g., field screening/analytical samples) were excluded specifically from the quantitative risk

assessment prior to evaluating the data, document this along with reasons for the exclusion. Again, remember that such samples, while not used in the quantitative risk assessment, may be useful for qualitative discussions and therefore should not be entirely excluded from the risk assessment.

Discuss the data evaluation within the appropriate context for the risk assessment. For example, the focus may be on a particular neighborhood within the assessment area; specific types of modeled receptors; or specific geographic features such as a water body. For PB-HAPs, the discussion should include those media (e.g., wastes, soils) that are potential sources of contamination for other media (e.g., surface water/sediments). If no samples or data were available for a particular medium, discuss this in the text. For soils data, discuss surface soil results separately from those of subsurface soils. Discuss surface water/sediment results by the specific surface water body sampled.

Exhibit 8. Example of Table Format for Presenting Air Toxics Sampled in Specific Media

Air Toxic	Concentration in Medium X			
	Frequency of Detection[a]	Range of Sample Quantitation Limits (SQLs) (units)	Range of Detected Concentrations (units)	Background Levels
Chemical A	3/25	2 - 30	320 - 4600	100 - 140
Chemical B[b]	25/25	1 - 32	17 - 72	--

-- Not sampled
[a] Number of samples in which the chemical was positively detected over the number of samples available
[b] Identified as a COPC based upon evaluation of data according to procedures described in text of report

For each medium, identify in the report the chemicals for which samples were analyzed, and list the analytes that were detected in at least one sample. If any detected chemicals were eliminated from the quantitative risk assessment based on evaluation of data (i.e., based on evaluation of data quality, background comparisons, and the optional screening procedures, if used), provide reasons for the elimination in the text (e.g., chemical was detected in blanks at similar concentrations to those detected in samples or chemical was infrequently detected).

Exhibit 9. Example of Table Format for Summarizing COPC in All Media Sampled				
Air Toxic	Concentration			
	Air ($\mu g/m^3$)	Soils (mg/kg)	Surface Water (µg/l)	Sediments (µg/l)
Chemical A	0.5 - 225	5 - 1,100	2 - 30	--
Chemical B	0.1 - 22	0.5 - 6.4	--	12 - 3650
Chemical C	0.01 - 2.2	--	50 - 440	100 - 11,000
Chemical D	3 - 854	2 - 12	--	
-- Not sampled				

The final subsection of the text is a discussion of general trends in the data results. For example, the text may mention (1) whether concentrations of COPC in most media were close to the detection limits or (2) trends concerning chemicals detected in more than one medium or in more than one operable unit at the site. In addition, the location of hot spots should be discussed, as well as any noticeable trends apparent from sampling results at different times.

11.2 Summarize Data Collection and Evaluation Results in Tables and Graphics

As shown in Exhibit 8, a separate table that includes all chemicals detected in a medium can be provided if appropriate. Chemicals that have been determined to be of potential concern based on the data evaluation should be designated in the table with an asterisk to the left of the chemical name.

For each chemical, present the frequency of detection in a certain medium (i.e., the number of times a chemical was detected over the total number of samples considered) and the range of detected or quantified values in the samples. Do not present the QL or similar indicator of a minimum level (e.g., <10 mg/L, ND) as the lower end of the range; instead, the lower and upper bound of the range should be the minimum and maximum detected values, respectively. The range of reported QLs obtained for each chemical in various samples should be provided in a separate column. Note that these QLs should be sample-specific; other types of non-sample-specific values (e.g., MDLs or CRQLs) should be provided only when SQLs are not available. Note that the range of QLs would not include any limit values (e.g., unusually high QLs) eliminated based on the guidance in Section 3. Finally, naturally occurring concentrations of chemicals used in comparing sample concentrations may be provided in a separate column. The source of these naturally occurring levels should be provided in a footnote. List the identity of the samples used in determining concentrations presented in the table in an appropriate footnote.

The final table in this section is a list of the COPC presented by medium at the site or by medium within each operable unit at the site. A sample table format is presented in Exhibit 9. Ths isopleth is another useful type of presentation of chemical concentration data (not shown). This

graphic characterizes the monitored or modeled concentrations of chemicals at a site and illustrates the spatial pattern of contamination.

References

1. U.S. Environmental Protection Agency. 1989. *Risk Assessment Guidance for Superfund: Volume I. Human Health Evaluation Manual (Part A).* Office of Emergency and Remedial Response. Washington, DC, EPA/541/1-89/002, available at: http://www.epa.gov/superfund/programs/risk/ragsa/index.htm

2. U.S. Environmental Protection Agency. 1992. Guidance for Data Useability in Risk Assessment (Part A). Office of Emergency and Remedial Response, Washington, DC. Publication 92857-09A, PB92-93356, available at: http://www.epa.gov/oerrpage/superfund/programs/risk/datause/parta.htm.

Appendix I Use of Air Monitoring Data to Develop Estimates of Exposure Concentration (Data Analysis and Reduction)

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1.0 Introduction

This appendix discusses the process of air monitoring data analysis and reduction, the goals of which are to (1) extract and summarize air monitoring data needed for the risk assessment, (2) use the data to develop estimates of exposure concentration (EC), and (3) present the results of the air monitoring study in an informative and understandable format. In short, this Appendix describes how to take the refined air monitoring data sets developed according to the processes described in Appendix H and use them to develop estimates of exposure concentration. Standard computer software packages, such as Microsoft Excel® or the Statistical Analysis System,® may be used to generate summary statistics for each chemical and monitoring location. Summary statistics should include:

- The frequency of detection, or the proportion of total valid measurements collected which were present at or above the respective sample quantitation limit (SQL) and including detections marked with certain data qualifier (e.g., "J" values - see Appendix H);

- The range of concentrations detected (highest and lowest concentrations measured for each chemical at each monitoring site – including J values);

- The statistical description of the data (e.g., normally distributed, log-normally distributed), based on standardized statistical tests;

- The range of sample quantitation limits (SQLs); and

- An arithmetic mean value, the standard deviation, the median value (i.e., 50th percentile), and the 95th percentile upper confidence limit (95% UCL) of the arithmetic mean.

Tentatively Identified Compounds (TICs)

As noted in Appendix H, TICs are chemicals identified in the laboratory, but which cannot be identified with complete accuracy. Given that there is not certainty as to their identify (and because, there often is no toxicity data for them), TICs are often assess only qualitatively in the risk assessment. The level of detail applied to TICs depends on their tentative identification (are they known toxic compounds), their concentration, known sources, and frequency of detection. Depending on the answers to these questions, the analyst may recommend that re-sampling be performed to try to more accurately determine the nature of the TICs.

The mathematical formulas and procedures for calculating these summary statistics are provided in Section 3 below.

Statistical analysis of air monitoring data may be conducted using standard methods such as those outlined in EPA's *Guidance for Data Quality Assessment - Practical Methods for Data Analysis*.[1] This manual provides a detailed description of the formulae that should be used in estimating the parameters mentioned above, and reviews issues associated with data treatment (e.g., treatment of non-detects, use of J-qualified data). EPA's *Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites* [2] is also an important reference to consider when evaluating air monitoring data for exposure assessments. Readers are encouraged to review both of these document prior to using monitoring data to calculate exposure concentrations.

Data Qualifiers

Having obtained a monitoring result, it is necessary to assign a qualifier to it so decision-makers can understand the quality of the result and, hence, the role the result might play in decisions (a more complete discussion of data qualifiers is provided in Appendix H).

- **U Flag**. If the value is below the MDL, the result should be flagged as <MDL or as U or "undetected." This indicates that it cannot be determined, within the limits described in the DQOs, that the compound is present in the sample. (Note, however, that some labs flag data below the SQL as U, even though they actually detect it. It is important to work through such details with a laboratory prior to analysis of samples.)

- **J Flag**. If the result is above the MDL, but less than the SQL, the result should be flagged as J or "estimated concentration." This indicates that the compound was detected in the sample, and can be quantified, but not within the limits on accuracy described in the DQOs.

- **R Flag**. If there are significant problems with the sample (e.g. improper calibration, or extensive holding time, or very low recovery efficiency), the result should be flagged as R or "unusable." This might occur, for example, if calibration procedures are judged inadequate. If the compound is of interest, and/or other results suggest the potential for significant concentration, then re-sampling or re-analysis is usually necessary.

Interpretation of these flagged results in the context of a risk assessment is described in Chapters 5 and 6 of the EPA document *Guidance for Data Usability in Risk Assessment, Part A* (Publication 9285.7-09A, Washington, DC, April 1992; available at www.epa.gov/superfund/programs/risk/datause/parta.htm). Another excellent source is Exhibits 5-4 and 5-5 in EPA's *Risk Assessment Guidance for Superfund (RAGS) Part A*, available at www.epa.gov/oerrpage/superfund/programs/risk/ragsa/index.htm. Appendix H of this volume also discusses this subject in some detail.

2.0 Data Treatment and Handling of Non-Detects

Calculation of summary descriptive statistics (arithmetic mean, standard deviation, median, 95% upper confidence limit) requires resolution of certain issues regarding the treatment of sampling data. Specifically, assumptions must be made regarding:

- Treatment of duplicate samples;
- Treatment of instances in which chemicals are not detected; and
- Use of measurements in which the identity of a chemical is certain but its concentration is estimated with some uncertainty (often reported as "J-qualified" data).

Duplicate samples refer to the simultaneous collection or analysis of multiple (usually two) samples under conditions that are kept as similar as possible. Field duplicates usually refer to separate samples collected side-by-side in the field, while laboratory duplicates involve separately analyzing portions of the contents of a single sample. Both types of duplicates serve the similar purpose of providing a sense of the reliability, reproducibility, and precision of measurements. Ideally, duplicate samples should yield the same results. Large differences in the results of duplicate measurements potentially indicate uncertainty in data quality.

In general, once it is clear that there are no issues with field duplicate samples, they should be treated as a single sample by simply averaging their results. In cases where a chemical is detected in one but not both duplicates (or the data is J-qualified), the chemical should be assumed to be present and the two values should be averaged using the procedure for handling non-detects as described below.

When a chemical is not detected in any sample at a monitor, that chemical can usually be removed from further consideration if there are no known problems with the method, the method meets DQOs, and there is no reason to suspect that the chemical should have been detected (e.g., there are no known sources, and the chemical was also not found at other monitors). In some instances, the monitoring methodology (or interferences by other substances) do not allow for the detection of a substance, even when it is present. The assessors must weigh these types of evidence when deciding to drop a chemical from further consideration.

Various procedures have been used in risk assessments to treat non-detects (i.e., samples in which the chemical concentration is not present at or higher than the sample quantification limit (SQL)), ranging from the assumption that the chemical is absent (i.e., the true concentration is zero) to the assumption that the chemical was present in a sample at a level infinitesimally beneath the SQL (i.e. very close to the SQL and so essentially equal to the SQL). Some algorithms differentiate assignment of values to non-detects based upon the frequency of a chemical's detection. For example, if a chemical is detected in almost all samples, a concentration equal to (or some fraction of) the analytical SQL is assigned to non-detects, but if the chemical is detected in few or no samples, a concentration of zero is assumed for non-detects. In general, the strategy described below may be used to address the issue of non-detects. References 1 and 2 provide more information on this subject and analysts are encouraged to become familiar with both of these documents prior to beginning data analysis. Also note that the generic upon which the procedure described below is based assumes approximately 30 or more samples collected over the course of a year are being averaged to develop an estimate of long term exposure concentration; however, air toxics monitoring sampling schemes usually collect samples on at least a one-in-six day schedule, giving the analyst approximately 60 or more samples to work with. Sampling frequencies are sometimes even greater.

The MDL or the SQL: Which One Should I Use for Risk Assessment?

When including non-detected data in the averaging processes described on this page, one may either include the non-detected sample as ½ the MDL or ½ the SQL. The MDL ***is not appropriate*** for this task because it is a statistical measure developed by each lab for each analytical instrument and can fluctuate from day to day. In other words, it is not a stable measure of true detection "limit." In addition, many labs that actually do detect a chemical in a sample at levels less than the quantitation limit do not routinely report the detection because they cannot accurately quantitate its concentration). It is for these two reasons that ½ the SQL is used when including nondetected samples in the averaging process. This holds even when the lab in question routinely reports J-valued data.

- If less than 15% of the monitored concentrations of a given chemical at a given location are below the SQL, then a value equal to ½ of the respective SQL is assigned to these concentrations and these values are used in the calculation of summary statistics as described below.

- If greater than 90% of the monitored concentrations of a given chemical at a given location are less than the respective SQL, no estimation of the statistical descriptors is undertaken initially. If concentrations were only detected on a limited number of days (i.e., 1 to 3 days) then an investigation may be undertaken to assess the potential sources for these chemicals and the validity of the measurements. A knowledgeable statistician can help determine an appropriate method for developing summary statistics from such a data set, if appropriate.

- If between 15% and 90% of the monitored concentrations of a given chemical at a given location are greater than the respective SQL, then a value equal to ½ of the respective SQL is assigned to these concentrations and these values are used in the calculation of summary statistics as described below. For chemicals in this group that end up contributing significantly to risk, a knowledgeable statistician may reevaluate the data according to the procedures in appropriate guidance (e.g., those provided in references 1 and 2).

3.0 Statistical Methods: Characterization of Concentration Data

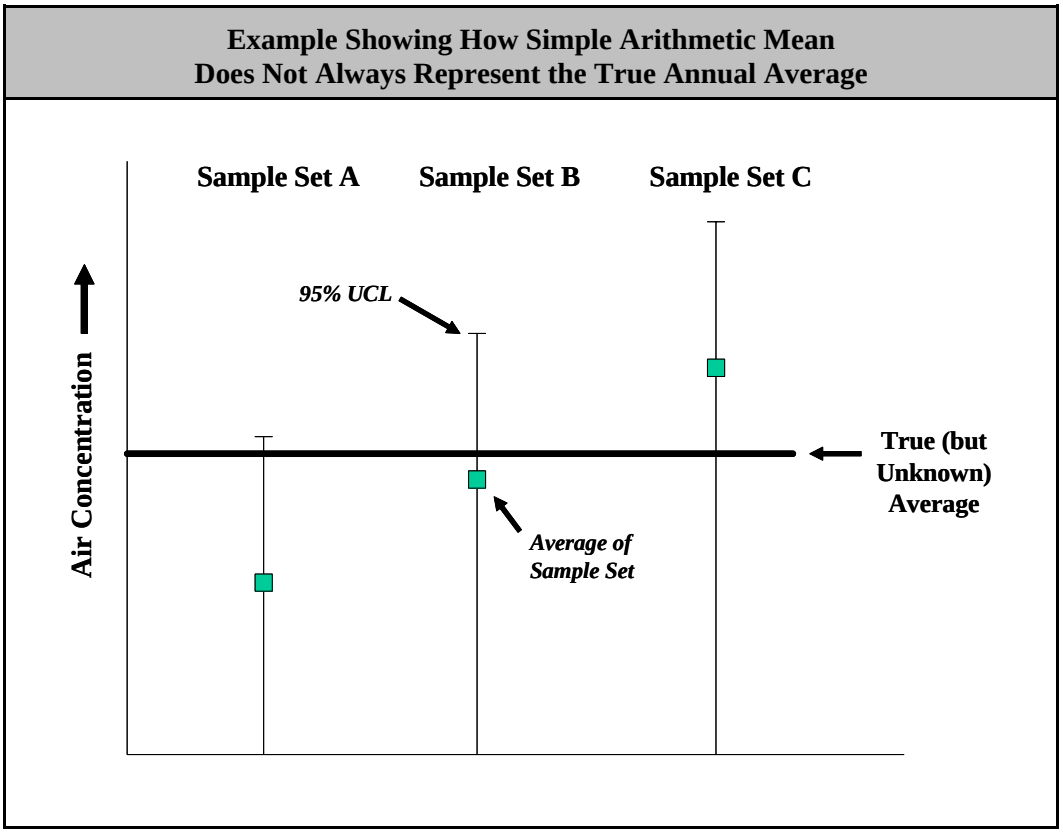
One method to estimate the long-term annual average concentration would be to calculate a simple arithmetic mean for each analyte/monitor combination. The arithmetic mean, or average is constructed from discrete sample measurements taken at the monitor over time. As noted previously, constraints on resources almost always place limits on the amount of sampling possible (e.g., air toxics samples usually cannot be collected every day). Instead, samples are usually collected roughly one out of every six days and in a manner to eliminate obvious sources of bias (e.g., samples are not uniformly collected on the same day of the week, or only on weekdays or only on weekends). In addition, collecting samples for a year allows for an evaluation of seasonal variability.

All factors being equal, one would expect the sampling results from such a monitoring program to contain equal probabilities of sampling on days when pollutant concentrations may have been relatively high as on days when pollutant concentrations may have been relatively low (or on days when meteorological conditions were conducive to high ground-level concentrations and days when they were not). Since samples are usually not collected every single day, however, one cannot be absolutely certain that all possible conditions were sampled equally. The arithmetic mean concentration is thus subject to uncertainty due to a number of factors, including:

- Daily variability in concentrations;
- The ability to measure only a finite number of instances from the distribution of concentrations over time; and
- Potential inaccuracy in individual measurements of concentrations.

This uncertainty produces a result in which the simple arithmetic mean of sampling results may underestimate, approach, or overestimate the true annual average. (The example below illustrates how three different monitoring data sets taken at the same monitor may result in an average concentration that underestimates, overestimates, or is close to the true long term average concentration.) Given this uncertainty in the use of the arithmetic mean concentration to describe “average” exposure concentration, the 95% Upper Confidence Limit of the mean (95% UCL) is commonly used as a public health protective estimate of the true annual average. Proceeding in this manner is likely to overestimate the true long-term average exposure;

however, this method virtually obviates the risk of underestimating the true exposure. EPA's Superfund program has routinely used this procedure to evaluate exposures at hazardous sites and this process has garnered long term acceptance as a public health protective approach, in light of the uncertainties.



Distributional Analysis

To calculate the 95% UCL for a chemical data set from a monitor, it is necessary to understand its underlying statistical distribution, including whether the sampling results are normally or lognormally distributed. Once the analysis goes beyond these commonly understood distributional types, the level of statistical sophistication can increase substantially. EPA's Office of Air Quality Planning and Standards (OAQPS) has developed the following pragmatic strategy to evaluate the distribution of monitoring data sets; however, other approaches are available (see references 1 and 2). Specifically, EPA suggests the following procedure:

- Inspect each data set for normality using standard test procedures (e.g., Shapiro-Wilk Test, Komolgorov-Smirnoff Test, or Filibens Test). If the assumption of normality holds, then the summary descriptive statistics, including the 95% UCL, should be calculated as described below with the equations based on the statistical assumption of a normal distribution.

- If the data are not normally distributed, then they are *presumed to be lognormal* and are log-transformed by taking the natural logarithm of the measured concentrations. The assumption of normality is then used to test the transformed data. If the assumption of normality holds for the transformed data, the summary descriptive statistics, including he

95% UCL, are developed with the transformed data using the equations based on the statistical assumption of a lognormal distribution.

- If the transformed data are not lognormal, they may be treated initially as lognormal. For chemicals in this group that significantly contribute to risk, a knowledgeable statistician may reevaluate the data (e.g., according to the procedures suggested in References 1 and 2).

The use of this simple and pragmatic approach to data analysis allows most scientists and engineers with a basic background in statistics to perform these analyses without access to advanced statistical analysis resources. Presuming a data set is lognormally distributed generally results in a 95% UCL that is conservative and, thus, public health protective. Only those chemicals that the initial risk characterization identifies as being significant risk drivers would be reevaluated with more robust statistical procedures, depending on the needs of the risk manager.

STATISTICAL FORMULAS

The following Exhibits provide the basic equations for developing the 95% UCL for chemical data sets that are either normally distributed (Exhibits 1 and 2) or lognormally – or presumed to be lognormally – distributed (Exhibits 3 and 4). The Students t and H statistics that are needed to perform these calculations are available in Gilbert's 1987 book *Statistical Methods for Environmental Pollution Monitoring*.[3]

Normally Distributed Data Sets

Exhibit 1. Directions for Computing UCL for the Mean of a Normal Distribution – Student's *t*

Let $X_1, X_2, \ldots, X_n$ represent the *n* randomly sampled concentrations.

STEP 1: Compute the sample mean $\overline{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$

STEP 2: Compute the sample standard deviation $s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(X_i - \overline{X})^2}$

STEP 3: Use a table of quantiles of the Student's *t* distribution to find the $(1-\alpha)^{th}$ quantile of the Student's *t* distribution with *n*-1 degrees of freedom. For example, the value at the 0.05 level with 40 degrees of freedom is 1.684. A table of Student's *t* values can be found in Gilbert (1987, page 255, where the values are indexed by p = 1-α, rather than α level). The *t* value appropriate for computing the 95% UCL can be obtained in Microsoft Excel® with the formula TINV ((1-0.95)*2, *n*-1).

STEP 4: Compute the one-sided (1-α) upper confidence limit on the mean

$$UCL_{1-\alpha} = \overline{X} + t_{\alpha,n-1}\, s / \sqrt{n}$$

Exhibit 2. An Example Computation of UCL for a Normal Distribution – Student's *t*
25 VOC samples were collected from an air monitoring station and analyzed for a specific chemical. The values observed are 228, 552, 645, 208, 755, 553, 674, 151, 251, 315, 731, 466, 261, 240, 411, 368, 492, 302, 438, 751, 304, 368, 376, 634, and 810 µg/m^3. It seems reasonable that the data are normally distributed, and the Shapiro-Wilk *W* test for normality fails to reject the hypothesis that they are (*W* = 0.937). The UCL based on Student's *t* is computed as follows: STEP 1: The sample mean of the *n* = 25 values is $\bar{x} = 451$ STEP 2: The sample standard deviation of the values is $s = 198$ STEP 3: The *t*-value at the 0.05 level for 25-1 degrees of freedom is $t_{0.05,25-1} = 1.710$ STEP 4: The one-sided 95% upper confidence limit on the mean is therefore: $$95\%\ UCL = 451 + (1.710 \times 198 / \sqrt{25}) = 519$$

Lognormally Distributed Data

Exhibit 3. Directions for Computing UCL for the Mean of a Lognormal Distribution – Land Method
Let $X_1, X_2, \ldots, X_n$ represent the *n* randomly sampled concentrations. STEP 1: Compute the arithmetic mean of the log-transformed data $\overline{\ln X} = \frac{1}{n}\sum_{i-1}^{n} \ln(X_i)$ STEP 2: Compute the associated standard deviation $s_{\ln X} = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(\ln(X_i) - \overline{\ln X})^2}$ STEP 3: Look up the $H_{1-\alpha}$ statistic for sample size *n* and the observed standard deviation of the log-transformed data. Tables of these values are given by Gilbert (1987, Tables A-10 and A-12) and Land (1975). STEP4: Compute the one-sided (1-α) upper confidence limit on the mean $$UCL_{1-\alpha} = \exp(\overline{\ln X} + s^2_{\ln X} / 2 + H_{1-\alpha}\ s_{\ln X} / \sqrt{n-1}$$

Exhibit 4. An Example Computation of UCL for a lognormal Distribution – Land Method
31 VOC samples were collected from an air monitoring stations and analyzed for a specific chemical. The values observed are 2.8, 22.9, 3.3, 4.6, 8.7, 30.4, 12.2, 2.5, 5.7, 26.3, 5.4, 6.1, 5.2, 1.8, 7.2, 3.4, 12.4, 0.8, 10.3, 11.4, 38.2, 5.6, 14.1, 12.3, 6.8, 3.3, 5.2, 2.1, 19.7, 3.9, and 2.8 µg/m^3. Because of their skewness, the data may be lognormally distributed. The Shapiro-Wilk *W* test for normality rejects the hypothesis, at both the 0.05 and 0.01 levels, that the distribution is normal. The same test fails to reject at either level the hypothesis that the distribution is lognormal. The UCL on the mean based on Land's H statistic is computed as follows:
STEP 1: Compute the arithmetic mean of the log-transformed data $\overline{\ln X} = 1.8797$
STEP 2: Compute the associated standard deviation $s_{\ln X} = 0.8995$
STEP 3: The H statistic for $n = 31$ and $s_{\ln X} = 0.90$ is 2.31
STEP4: The one-sided 95% upper confidence limit on the mean is therefore:
$$95\%\ UCL = \exp(1.8797 + 0.8995^2 / 2 + 2.31 \times 0.8995 / \sqrt{31-1}) = 14.4$$

It is statistically possible for the 95% UCL confidence limit of the mean to exceed the maximum measured concentration for a chemical. If this exceeding occurs, the maximum concentration of the chemical is commonly used in place of the 95th percentile upper confidence limit as the exposure concentration, with certain caveats (see reference 2).

References

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3. Gilbert, R.O. 1987. *Statistical Methods for Environmental Pollution Monitoring*. John Wiley & Sons, New York, NY.

Appendix J Air Monitoring and Sampling Methods

This appendix contains a summary of monitoring and sampling methods for a variety of organic and inorganic compounds in ambient air. Each approach is described briefly, with a listing of compounds for which it is appropriate, the detection limit, and a summary of advantages and disadvantages in using the approach. Descriptions of the methods can be downloaded from the EPA's Ambient Monitoring Technology Information Center (AMTIC) website (www.epa.gov/ttn/amtic/airtox.html).

The measurement process generally relies on collecting a sample in the field, followed by a return to the lab for analysis. A number of methods are used for initial collection of samples in the field:

1. **Sampling tubes**, in which air is drawn through a tube containing a sorbent specific to the compound being sampled, and the tube returned to the lab for analysis. Possible sorbents in the tube are organic polymers; carbon (molecular, activated, etc); polyurethane foam; silica gel; and dinitrophenylhydrazone (DNPH). Multi-sorbents also are available.

2. **Filters**, in which air is drawn through a fiber (often a glass fiber) filter, collecting the sampled compound, and returned to the lab for analysis. In some methods, air is drawn over an absorbent onto which the chemical sorbs. In some methods, a chemical reaction occurs that converts the air toxics to another material that is then analyzed.

3. **Cryogenic traps**, in which air is drawn into a chamber at low temperature, condensing the compound out of the air. The trap and condensate are returned to the lab for analysis.

4. **Evacuated chambers**, in which air is drawn into a chamber under vacuum. The chamber is returned to the lab for analysis.

An important consideration in the use of such methods is the available time between collection and analysis of samples. The compounds will degrade during the intervening holding period, and so this holding period should not exceed maximum allowed times (holding times depend on the method and compound (consult the AMTIC website for information on QA/QC for air monitoring).

Method Designation	Applicable Compounds	Approach	Detection Limit	Advantages	Disadvantages
TO-1	VOCs (80º to 200º C); e.g. benzene, toluene, xylenes.	Ambient air is drawn through organic polymer sorbent where certain compounds are trapped. The cartridge is transferred to the lab, thermally desorbed and analyzed using GC/MS or GC/FID.	0.01 to 100 ppbv	Good data base; large sample volume; water vapor not collected; wide variety of compounds collected; low detection limits; standard procedures available; practical for field use.	Highly volatile compounds and certain polar compounds not collected; rigorous clean-up of absorbent required; no possibility of multiple analyses; low breakthrough volume for some compounds; desorption of some compounds difficult; interference from structural isomers; possible contamination of sorbent and blank; artifact formation.
TO-2	Highly volatile VOCs (-15º to 120º C); e.g. vinyl chloride, chloroform, chlorobenzene.	Selected volatile organic compounds are captured on carbon molecular sieve absorbents. Compounds are thermally desorbed and analyzed by GC/MS or GC/FID techniques.	0.1 to 200 ppbv	Trace levels of VOCs are collected and concentrated; efficient collection of polar compounds; wide range of application; highly volatile compounds are absorbed; easy to use in field.	Some trace levels of organic species are difficult to recover from sorbent; interferences from structural isomers; water is collected and can de-activate absorption sites; thermal desorption of some compounds difficult.
TO-3	Nonpolar VOCs (-10º to 200º C); e.g. vinyl chloride, methylene chloride, acrylonitrile.	Vapor phase organics are condensed in a cryogenic trap. Carrier gas transfers the condensed sample to a GC column. Absorbed compounds are eluted from the GC column and measured by FID or ECD.	0.1 to 200 ppbv	Collects a wide variety of VOCs; standard procedures are available; contaminants common to absorbent materials are avoided; low blanks; consistent recovery; large data base.	Moisture levels in air can cause freezing problems in cryogenic trap; difficult to use in field; expensive; integrated sampling is difficult; compounds with similar retention times interfere.
TO-4	Pesticides and PCBs; e.g. PCBs, 4,4-DDE, DDT, DDD.	Pesticides/PCBs trap on filter and PUF absorbent trap. Trap is returned to lab, solvent extracted and analyzed by GC/FID/ECD or GC/MS.	0.2 pg/m^3 to 200 ng/m^3	Low detection limits; effective for broad range of pesticides and PCBs; PUF reusable; low blanks; excellent collection and retention efficiencies for common pesticides and PCBs.	Breakdown of PUF absorbent may occur with polar extraction solvents; contamination of glassware may increase detection limits; loss of some semi-volatile organics during storage; interference by extraneous organics; difficulty in identifying individual pesticides and PCBs if ECD used.
TO-5	Aldehydes and Ketones; e.g. formaldehyde, acetaldehyde, acrolein.	Air sample is drawn through DNPH impinger solution using a low volume pump. The solution is analyzed using HPLC with a UV detector.	1 to 50 ppbv	Specific for aldehydes and ketones; good stability for derivative compounds formed in the impingers; low detection limits.	Sensitivity limited by reagent purity; potential for evaporation of liquid over long term sampling; isomeric aldehydes and ketones may be unresolved by the HPLC system.

Method Designation	Applicable Compounds	Approach	Detection Limit	Advantages	Disadvantages
TO-6	Phosgene	Ambient air is drawn through a midget impinger containing 10 ml of 2/98 aniline/toluene (v/v). Phosgene reacts with aniline to form 1,3-diphenylurea and is analyzed using reverse-phase HPLC with a UV absorbance detector operating at 254 nm.	1 to 50 ppbv	Good specificity; good stability for derivative compounds formed in the impingers; low detection limits.	Chloroformates and acidic materials may interfere; contamination of aniline reagents may interfere; use of midget impingers in field application may not be practical.
TO-7	N-nitroso dimethylamine	Ambient air is drawn through a cartridge containing Thermosorb/N absorbant to trap N-nitrosodimethyl amine. The cartridge is returned to the lab and eluted with 5 ml of dichloromethane. The cartridge then is eluted in reverse direction with 2 ml of acetone. The N-nitrosodimethylamine is determined by GC/MS.	1 to 50 ppbv	Good specificity; good stability for derivative compounds formed on the cartridge; low detection limit for n-nitrosodimethylamine; placement of sorbent as first compound in sample train minimizes contamination; sampling system portable and lightweight.	Compounds with similar GC retention times and detectable MS ions may interfere; specificity is a limiting factor if looking for other organic amines.
TO-8	Cresol and phenol	Ambient air is drawn through two midget impingers. Phenols are trapped as phenolates in NaOH solution, which is returned to the lab and analyzed by HPLC.	1 to 250 ppbv	4,6-dinitro-2-methylphenol specific to class of compounds; good stability; detects non-volatile as well as volatile phenol compounds.	Compounds having the same HPLC retention times may interfere; phenolic compounds of interest may be oxidized; limited sensitivity.
TO-9A*	Dioxin, furan and PCBs	Ambient air is drawn through a glass fiber filter and a polyurethane foam (PUF) absorbent cartridge with a high volume sampler. The filter and PUF cartridge are returned to the lab and extracted using toluene. The extract is concentrated using the Kudrena-Danish technique, diluted with hexane, and cleaned up using column chromatography. The cleaned extract then is analyzed by high resolution GC/high resolution MS.	0.25 to 5000 pg/m^3	Cartridge is reusable; excellent detection limits; easy to preclean and extract; excellent collection and retention efficiencies; brad database; proven methodology.	Analytical interferences may occur from PCBs, methoxybiphenyls, chlorinated hydroxydiphenylethers, napthalenes, DDE and DDT with similar retention times and mass fractions; inaccurate measurement Ds/Fs are retained on particulate matter and may chemically change during sampling and storage; analytical equipment required (HRGC/HRMS) expensive and not readily available; operator skill level important; complex preparation and analysis process; can't separate particles from gas phase.

Method Designation	Applicable Compounds	Approach	Detection Limit	Advantages	Disadvantages
TO-10A	Pesticides; e.g. heptachlor, chlordane, dieldrin, aldrin	A low volume sample (1-5 L/min) is pulled through a PUF plug to trap organochlorine pesticides. After sampling, the plug is returned to the lab, extracted and analyzed by GC coupled to multi-detectors (ECID, PID, FID, etc).	1 to 100 ng/m^3	Easy field use; proven methodology; easy to clean; effective for broad range of compounds; portable; good retention of compounds.	ECD and other detectors (except MS) are subject to responses from a variety of compounds other than target analytes; PCBs, dioxins and furans may interfere; certain organochlorine pesticides (e.g. chlordane) are complex mixtures and can make accurate quantification difficult; may not be sensitive enough for all target analytes.
TO-11A	Formaldehyde, other aldehydes and ketones; e.g. formaldehyde, acetaldehyde, acrolein.	An ambient air sample is drawn through a DNPH cartridge at a rate of 500 to 1200 ml/minute. The cartridge is returned to the lab in screw-cap glass vials. The cartridge then is removed from the vial and washed with acetonitrile by gravity feed elution. The eluate is diluted volumetrically and an aliquot is removed for determination of the DNPH-formaldehyde derivative by isocratic reverse phase HPLC with UV detection at 350 nm.	0.5 to 100 ppbv	Placement of sorbent as first element in the sampling train minimizes contamination; large database; proven technology; sampling system is portable and lightweight.	Isometric aldehydes and ketones and other compounds with the same HPLC retention time as formaldehyde might interfere; Carbonyls on the DNPH cartridge may degrade if an ozone denuder is not used; liquid water captured on the DNPH cartridge during sampling may interfere; ozone and UV light deteriorates trapped carbonyls on cartridge.
TO-12	Non-methane organic compounds (NMOC)	Ambient air is drawn into a cryogenic trap, where the non-methane organic compounds (NMOCs) are concentrated. The trap is heated to move the NMOCs to the FID. Concentration of NMOCs is determined by integrating under the broad peak. Water correction is necessary.	0.1 to 200 ppmvC	Standard procedures are available; contaminants common to absorbent materials are avoided; low blanks; consistent recoveries; large data base; good sensitivity; useful for screening areas or samples; analysis much faster than GC.	Moisture levels in air can cause freezing problems; non-speciated measurement; precision is limited.
TO-15	VOCs (polar and non-polar); methanol, benzene, xylene, nitrobenzene	Whole air samples are collected in a specifically-prepared canister. VOCs are concentrated on a solid sorbent trap or other arrangement, separated on a GC column, and passed to an MS detector for identifaction and quantification.	0.2 to 25 ppbv	Incorporates a multi-sorbent/dry purge technique to manage water; has established methods performance criteria; provides enhanced provisions for QC; unique water management approach allows analysis of polar VOCs.	Expensive analytical equipment; depends critically on operator skill level.

Method Designation	Applicable Compounds	Approach	Detection Limit	Advantages	Disadvantages
TO-16	Polar and non-polar VOCs; e.g. alcohols, ketones, benzene, toluene, o-xylene, chlorobenzene.	VOCs are monitored using real-time long-path open-path Fourier transform infrared spectroscopy (FTIR).	25 to 500 ppbv	Open path analysis maintains integrity of samples; multi-gas analysis saves money and time; path-integrated pollutant concentration measurement minimizes possible sample contamination and provides real-time pollutant concentration; applicable for special survey monitoring; monitoring at inaccessible areas possible using open-path FTIR.	High levels of operator skill required; requires spectra interpretation; Limited spectral library available; higher detection limits than most alternatives; must be skilled in computer operation; substantial limitations from ambient CO_2 and humidity levels associated with spectral analysis.
TO-17	Polar and non-polar VOCs; e.g. alcohols, ketones, benzene, toluene, o-xylene, chlorobenzene.	Ambient air is drawn through a multi-bed sorbent tube where VOCs are trapped. The cartridge is returned to the lab, thermally desorbed and analyzed by GC/MS or other methods.	0.2 to 25 ppbv	Placement of the sorbent as the first element minimizes contamination from other sample train components; large selection of sorbents to match with target analyte list; includes polar VOCs; better water management using hydrophobic sorbents than Compendium Method TO-14A; large database; proven technology; size and cost advantages in sampling equipment.	Distributed volume pairs required for quality assurance; rigorous clean-up of sorbent required; no possibility of multiple analysis; must purchase thermal desorption unit for analysis; desorption of some VOCs is difficult; contamination of absorbent can be a problem.
IO-1	Suspended particulate matter (SPM); continuous measurement.	Ambient air is drawn at a rate of approximately 16 to 17 L/minute through a virtual impact or cyclonic flow filter. Particle build-up on a filter tape is determined continuously either through measurement of attenuation of beta particles incident on the tape or through an oscillating pendulum.	3 micrograms/m^3.	Less sensitive to temperature, pressure and humidity fluctuations than other continuous methods.	Results can be biased by water collection on the filter tape; oscillator must be isolated from external noise and vibrations.
IO-2	Suspended particulate matter (SPM); integrated measurement.	Ambient air is drawn through a filter with a high volume sampler, with large (> 10 micron) particles removed prior to the filter. The filter is weighed before and after sampling, with dessication to remove water vapor. Mean particulate concentration is determined from mass gain and air flow rate.	1 microgram/m^3	Well established methodology; relatively simply technique to employ	Balance used in measurement must be precise; subject to bias due to collection of water vapor if complete dessication is not obtained;

Method Designation	Applicable Compounds	Approach	Detection Limit	Advantages	Disadvantages
IO-3	Chemical species analysis of filter-collected SPM.	Ambient air is drawn through a filter with a high volume sampler, with large (> 10 micron) particles removed prior to the filter. The filter is weighed before and after sampling, with dessication to remove water vapor. The filter then is subsampled and strips digested using a microwave or hot acid extraction technique. Specific extracts are analyzed by the appropriate method.	Depends on compound considered.	Advantages depend on chemical species analyzed, but particle collection has the advantages noted in IO-2.	Disadvantages depend on chemical species analyzed.
IO-4	Reactive acidic and basic gases; strong acidity of atmospheric fine particles. HNO_3, NH_3, HCL, SO_2, NH_4, SO_4, NO_3	Based on measurement of the fine particle strong acidity component of the atmosphere. Air is drawn through an annular denuder followed by a 37 mm Teflon filter to trap the fine particle acid aerosol. The filter is returned to the lab for extraction and analysis using an aequeous solution of perchloric acid followed by titration or pH determination.		Simple method of analysis; well established methodology.	Without denuders employed to remove ammounia and other acid gases, interference can occur.
IO-5	Atmospheric mercury	Low flow (for vapor phase) or higher flow (for particulate phase) ambient air stream is flowed over gold coated bead traps and glass fiber filters. Mercury content is determined by cold-vapor atomic fluorescence spectrometry after thermal desorption.	30 pg/m^3 (particulate phase) or 45 pg/m^3 for vapor phase.	No known positive interferences using the 253.7 nm wavelength to excite the mercury atoms.	Possible interferences from PAHs and water vapor; excessive water quenches signal; free halogens can degrade trap.

Appendix K Equations For Estimating Concentrations of PB-HAP Compounds in Food and Drinking Water

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1.0 Introduction

This Appendix describes equations used by some multimedia models to estimate media concentrations for the recommended exposure scenarios presented in Part III. Most risk assessments will use a multimedia fate and transport model to perform these calculations; the particular equations used in a given model may differ slightly from those presented here, which are taken largely from EPA's 1998 *Peer Review Draft Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Volume I.*[1] The equations, and descriptions of the associated parameters, are presented here simply as a general reference, and are not intended to imply a recommendation over other equations, methods, or values for describing these processes. EPA's 1998 *Risk Assessment Protocol for Hazardous Waste Combustion Facilities* provides a more detailed discussion of the origin and development of each of these equations and many of their specific parameters. It should be noted that reference made throughout this chapter to "particle phase" is generic and made without distinction between particle and particle-bound. The remainder of this chapter is divided into seven sections:

- Section 2 describes the estimating media concentration equations for soils contaminated by PB-HAP compounds.
- Section 3 describes the estimating media concentration equations used to determine PB-HAP compound concentrations in produce.
- Sections 4 through 6 describe equations used to determine PB-HAP compound concentrations in animal products (such as milk, beef, pork, poultry, and eggs) resulting from animal ingestion of contaminated feed and soil.
- Section 7 describes equations used to determine PB-HAP compound concentrations in fish through bioaccumulation (or, for some compounds, bioconcentration) from the water column, dissolved water concentration, or bed sediment – depending on the PB-HAP compound.
- Section 8 describes equations for estimating the concentrations of doxins in breast milk.

2.0 Calculation of PB-HAP Compound Concentrations in Soil

PB-HAP compound concentrations in soil are calculated by summing the vapor phase and particle phase deposition of PB-HAP compounds to the soil. Wet and dry deposition of particles and vapors are considered, with dry deposition of vapors calculated from the vapor air concentration and the dry deposition velocity. The calculation of soil concentration incorporates a term that accounts for loss of PB-HAP compounds by several mechanisms, including leaching, erosion, runoff, degradation (biotic and abiotic), and volatilization. These loss mechanisms all lower the soil concentration associated with the deposition rate.

Soil concentrations may require many years to reach steady state. As a result, the equations used to calculate the average soil concentration over the period of deposition were derived by integrating the instantaneous soil concentration equation over the period of deposition. For carcinogenic PB-HAP compounds, EPA (1998)[1] recommends using two variations of the equation (average soil concentration over exposure duration). One form should be used if the exposure duration is greater than or equal to the operating lifetime of the emission source(s), and the other should be used if the exposure duration is less than the operating lifetime of the emission source(s).

For noncarcinogenic PB-HAP compounds, EPA (1998)[1] recommends using the second form of the carcinogenic equation to calculate the highest annual average PB-HAP compound soil concentration occurring during the exposure duration. These equations are described in more detail in Section 2.1.

Soil conditions such as pH, structure, organic matter content, and moisture content affect the distribution and mobility of PB-HAP compounds. Loss of PB-HAP compounds from the soil is modeled by using rates that depend on the physical and chemical characteristics of the soil. These variables and their use are described in the following subsections, along with the recommended equations.

2.1 Calculating Cumulative Soil Concentration (*Cs*)

EPA (1998)[1] recommends the use of Equations 1A, 1B, and 1C to calculate the cumulative soil concentration (*Cs*).

Carcinogens:

For $T_2 \leq tD$

$$Cs = \frac{Ds}{k_s \cdot (tD - T_1)} \cdot \left[\left(tD + \frac{\exp(-ks \cdot tD)}{ks} \right) - \left(T_1 + \frac{\exp(-ks \cdot T_1)}{ks} \right) \right] \qquad \text{(Equation 1A)}$$

For $T_1 < tD < T_2$

$$Cs = \frac{\left(\frac{Ds \cdot tD - Cs_{tD}}{ks} \right) + \left(\frac{Cs_{tD}}{ks} \right) \cdot \left(1 - \exp\left[-ks \cdot (T_2 - tD) \right] \right)}{(T_2 - T_1)} \qquad \text{(Equation 1B)}$$

Noncarcinogens:

$$Cs_{tD} = \frac{Ds \cdot \left[1 - \exp(-ks \cdot tD) \right]}{ks} \qquad \text{(Equation 1C)}$$

where

Cs	=	Average soil concentration over exposure duration (mg PB-HAP compound/kg soil)
Ds	=	Deposition term (mg PB-HAP compound/kg soil/yr)
T_1	=	Time period at the beginning of emissions (yr)
ks	=	PB-HAP compound soil loss constant due to all processes (yr^{-1})
tD	=	Time period over which deposition occurs (time period of emissions) (yr)
Cs_{tD}	=	Soil concentration at time tD (mg/kg)
T_2	=	Length of exposure duration (yr)

EPA (1998)[1] recommends Equation 1C when an exposure duration that is less than or equal to the operating lifetime of the emission source(s) ($T_2 \leq tD$); when an exposure duration greater than the operating lifetime of the emissions source(s) ($T_1 < tD < T_2$), Equation 1B is recommended. For noncarcinogenic PB-HAP compounds, Equation 1C is recommended.

The PB-HAP compound soil concentration averaged over the exposure duration, represented by *Cs*, can be used for carcinogenic compounds, where risk is averaged over the lifetime of an individual. Because the hazard quotient associated with noncarcinogenic PB-HAP compounds is based on a threshold dose rather than a lifetime exposure, the highest annual average PB-HAP compound soil concentration occurring during the exposure duration period is recommended to be used for noncarcinogenic PB-HAP compounds. The highest annual average PB-HAP compound soil concentration, Cs_{tD}, will typically occur at the end of the operating life of the emission source(s).

EPA (1998) [1] recommends using the highest 1-year annual average soil concentration, determined by using Equation 1C, to evaluate risk from noncarcinogenic PB-HAP compounds.

2.2 Calculating the PB-HAP compound Soil Loss Constant (*ks*)

Organic and inorganic PB-HAP compounds may be lost from the soil by several processes that may or may not occur simultaneously. The rate at which a PB-HAP compound is lost from the soil is known as the soil loss constant (*ks*). The constant *ks* is determined by using the soil's physical, chemical, and biological characteristics to consider the loss resulting from leaching, runoff, erosion, biotic and abiotic degradation, and volatilization. EPA (1998)[1] recommends that Equation 2 be used to calculate the PB-HAP compound soil loss constant (*ks*).

$$ks = ksg + kse + ksr + ksl + ksv \qquad \text{(Equation 2)}$$

where

ks	=	PB-HAP compound soil loss constant due to all processes (yr^{-1})
ksg	=	PB-HAP compound loss constant due to biotic and abiotic degradation (yr^{-1})
kse	=	PB-HAP compound loss constant due to soil erosion (yr^{-1})
ksr	=	PB-HAP compound loss constant due to surface runoff (yr^{-1})
ksl	=	PB-HAP compound loss constant due to leaching (yr^{-1})
ksv	=	PB-HAP compound loss constant due to volatilization (yr^{-1})

As highlighted in Section 2.1, the use of Equation 2 in Equations 1A and 1B assumes that PB-HAP compound loss can be defined by using first-order reaction kinetics. First-order reaction rates depend on the concentration of one reactant.[2] The loss of a PB-HAP compound by a first-order process depends only on the concentration of the PB-HAP compound in the soil, and a constant fraction of the PB-HAP compound is removed from the soil over time. Those processes that apparently exhibit first-order reaction kinetics without implying a mechanistic dependence on a first-order loss rate are termed "apparent first-order" loss rates.[3] The assumption that PB-HAP compound loss follows first-order reaction kinetics may be an oversimplification because – at various concentrations or under various environmental conditions – the loss rates from soil systems will resemble different kinetic expressions. However, at low concentrations, a

first-order loss constant may be adequate to describe the loss of the PB-HAP compound from soil (EPA 1990)[4].

PB-HAP compound loss in soil can also follow zero or second-order reaction kinetics. Zero-order reaction kinetics are independent of reactant concentrations (Bohn, McNeal, and O'Connor 1985).[2] Zero-order loss rates describe processes in which the reactants are present at very high concentrations. Under zero-order kinetics, a constant amount of a PB-HAP compound is lost from the soil over time, independent of its concentration. Processes that follow second-order reaction kinetics depend on the concentrations of two reactants or the concentration of one reactant squared (Bohn, McNeal, and O'Connor 1985)[2]. The loss constant of a PB-HAP compound following a second-order process can be contingent on its own concentration, or on both its concentration and the concentration of another reactant, such as an enzyme or catalyst.

Because PB-HAP compound loss from soil depends on many complex factors, it may be difficult to model the overall rate of loss. In addition, because the physical phenomena that cause PB-HAP compound loss can occur simultaneously, the use of Equation 2 may also overestimate loss rates for each process (Valentine 1986).[5] When possible, the common occurrence of all loss processes should be taken into account. Combined rates of soil loss by these processes can be derived experimentally; values for some PB-HAP compounds are presented in EPA (1986).[6]

Sections 2.2.1 through 2.2.5 discuss issues associated with the calculation of the *ksl*, *kse*, *ksr*, *ksg*, and *ksv* variables.

2.2.1 PB-HAP compound Loss Constant Due to Biotic and Abiotic Degradation *(ksg)*

Soil losses resulting from biotic and abiotic degradation (*ksg*) are determined empirically from field studies and should be addressed in the literature (EPA 1990).[4] Lyman et al. (1982)[7] states that degradation rates can be assumed to follow first order kinetics in a homogenous medium. Therefore, the half-life of a compound can be related to the degradation rate constant. Ideally, *ksg* is the sum of all biotic and abiotic rate constants in the soil media. Therefore, if the half-life of a compound (for all of the mechanisms of transformation) is known, the degradation rate can be calculated. However, literature sources do not provide sufficient data for all such mechanisms, especially for soil. EPA (1994a)[8] recommends that *ksg* values for all PB-HAP compounds other than polycyclic organic matter (specifically 2,3,7,8-TCDD) should be set equal to zero. EPA (1998) [1] presents EPA recommended values for this compound-specific variable.

The rate of biological degradation in soils depends on the concentration and activity of the microbial populations in the soil, the soil conditions, and the PB-HAP compound concentration (Jury and Valentine 1986).[9] First-order loss rates often fail to account for the high variability of these variables in a single soil system. However, the use of simple rate expressions may be appropriate at low chemical concentrations (e.g., nanogram per kilogram soil) at which a first-order dependence on chemical concentration may be reasonable. The rate of biological degradation is PB-HAP compound-specific, depending on the complexity of the PB-HAP compound and the usefulness of the PB-HAP compound to the microorganisms. Some substrates, rather than being used by the organisms as a nutrient or energy source, are simply degraded with other similar PB-HAP compounds, which can be further utilized. Environmental and PB-HAP compound-specific factors that may limit the biodegradation of PB-HAP compounds in the soil environment (Valentine and Schnoor 1986)[10] include (1) availability of

the PB-HAP compound, (2) nutrient limitations, (3) toxicity of the PB-HAP compound, and (4) inactivation or nonexistence of enzymes capable of degrading the PB-HAP compound.

Chemical degradation of organic compounds can be a significant mechanism for removal of PB-HAP compounds in soil (EPA 1990).[4] Hydrolysis and oxidation-reduction reactions are the primary chemical transformation processes occurring in the upper layers of soils (Valentine 1986).[5] General rate expressions describing the transformation of some PB-HAP compounds by all non-biological processes are available, and these expressions are helpful when division into component reactions is not possible.

Hydrolysis in aqueous systems is characterized by three processes: acid-catalyzed, base-catalyzed, and neutral reactions. The overall rate of hydrolysis is the sum of the first-order rates of these processes (Valentine 1986).[5] In soil systems, sorption of the PB-HAP compound can increase, decrease, or not affect the rate of hydrolysis, as numerous studies cited in Valentine (1986)[5] have shown. The total rate of hydrolysis in soil can be predicted by adding the rates in the soil and water phases, which are assumed to be first-order reactions at a fixed pH (Valentine 1986).[5] Methods for estimating these hydrolysis constants are described by Lyman et al. (1982).[7]

Organic and inorganic compounds also undergo oxidation-reduction (redox) reactions in the soil (Valentine 1986).[5] Organic redox reactions involve the exchange of oxygen and hydrogen atoms by the reacting molecules. Inorganic redox reactions may involve the exchange of atoms or electrons by the reactants. In soil systems where the identities of oxidant and reductant species are not specified, a first-order rate constant can be obtained for describing loss by redox reactions (Valentine 1986).[5] Redox reactions involving metals may promote losses from surface soils by making metals more mobile (e.g., leaching to subsurface soils).

2.2.2 PB-HAP compound Loss Constant Due to Soil Erosion (*kse*)

EPA (1998) [1] recommends that the constant for the loss of soil resulting from erosion (*kse)* is recommended to be set equal to zero in most cases. If soil erosion is a significant issue in the assessment area, EPA (1993b)[11] recommends the use of Equation 3 to calculate the constant for soil loss resulting from erosion (*kse*).

$$kse = \frac{0.1 \cdot X_e \cdot SD \cdot ER}{BD \cdot Z_s} \cdot \frac{Kd_s \cdot BD}{\theta_{sw} + \left(Kd_s \cdot BD\right)} \qquad \text{(Equation 3)}$$

where

kse	=	PB-HAP compound soil loss constant due to soil erosion
0.1	=	Units conversion factor (1,000 g-kg/10,000 cm^2-m^2)
X_e	=	Unit soil loss (kg/m^2-yr)
SD	=	Sediment delivery ratio (unitless)
ER	=	Soil enrichment ratio (unitless)
Kd_s	=	Soil-water partition coefficient (mL water/g soil)
BD	=	Soil bulk density (g soil/cm^3 soil)
Z_s	=	Soil mixing zone depth (cm)
θ_{sw}	=	Soil volumetric water content (mL water/cm^3 soil)

Unit soil loss (X_e) is calculated by using the Universal Soil Loss Equation (USLE) (See Section 7.2). Soil bulk density (*BD*) is described in Section 2.4.2. Soil volumetric water content (θ_{sw}) is described in Section 2.5.4.

For additional information on addressing *kse*, EPA (1998)[1] recommends consulting the methodologies described in EPA NCEA document, *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions* (EPA 1998)[12].

2.2.3 PB-HAP compound Loss Constant Due to Runoff (*ksr*)

EPA (1998)[1] recommends that Equation 4 be used to calculate the constant for the loss of soil resulting from surface runoff (*ksr*).

$$ksr = \frac{RO}{\theta_{sw} \cdot Z_s} \cdot \left(\frac{1}{1 + \left(Kd_s \cdot BD / \theta_{sw} \right)} \right) \qquad \text{(Equation 4)}$$

where

ksr	=	PB-HAP compound loss constant due to runoff (yr^{-1})
RO	=	Average annual surface runoff from pervious areas (cm/yr)
θ_{sw}	=	Soil volumetric water content (mL water/cm^3 soil)
Z_s	=	Soil mixing zone depth (cm)
Kd_s	=	Soil-water partition coefficient (mL water/g soil)
BD	=	Soil bulk density (g soil/cm^3 soil)

Soil bulk density (*BD*) is described in Section 2.5.2. Soil volumetric water content (θ_{sw}) is described in Section 2.5.4.

2.2.4 PB-HAP compound Loss Constant Due to Leaching (*ksl*)

Losses of soil PB-HAP compounds due to leaching (*ksl*) depend on the amount of water available to generate leachate and soil properties such as bulk density, soil moisture, soil porosity, and soil sorption properties. EPA (1998)[1] recommends that Equation 5 be used to calculate the PB-HAP compound loss constant due to leaching (*ksl)* to account for runoff.

$$ksl = \frac{P + I - RO + E_v}{\theta_{sw} \cdot Z_s \cdot \left[1.0 + \left(BD \cdot Kd_s / \theta_{sw} \right) \right]} \qquad \text{(Equation 5)}$$

where

ksl	=	PB-HAP compound loss constant due to leaching (yr^{-1})
P	=	Average annual precipitation (cm/yr)
I	=	Average annual irrigation (cm/yr)
RO	=	Average annual surface runoff from pervious areas (cm/yr)
E_v	=	Average annual evapotranspiration (cm/yr)
θ_{sw}	=	Soil volumetric water content (mL water/cm^3 soil)

Z_s = Soil mixing zone depth (cm)
Kd_s = Soil-water partition coefficient (cm^3 water/g soil)
BD = Soil bulk density (g soil/cm^3 soil)

The average annual volume of water ($P + I - RO - E_v$) available to generate leachate is the mass balance of all water inputs and outputs from the area under consideration. These variables are described in Section 2.5.3. Soil bulk density (BD) is described in Section 2.5.2. Soil volumetric water content (θ_{sw}) is described in Section 2.5.4.

2.2.5 PB-HAP compound Loss Constant Due to Volatilization (*ksv*)

Semi-volatile and volatile PB-HAP compounds emitted in high concentrations may become adsorbed to soil particles and exhibit volatilization losses from soil. The loss of a PB-HAP compound from the soil by volatilization depends on the rate of movement of the PB-HAP compound to the soil surface, the chemical vapor concentration at the soil surface, and the rate at which vapor is carried away by the atmosphere (Jury 1986).[13]

EPA (1998)[1] recommends that in cases where high concentrations of volatile organic compounds are expected to be present in the soil that Equation 6A be used to calculate the constant for the loss of soil resulting from volatilization (*ksv)*.

$$ksv = \left(\frac{3.1536 \times 10^7 \cdot H}{Z_s \cdot Kd_s \cdot R \cdot T_a \cdot BD}\right) \cdot \left(\frac{D_a}{Z_s}\right) \cdot \left[1 - \left(\frac{BD}{\rho_{soil}}\right) - \theta_{sw}\right] \qquad \text{(Equation 6A)}$$

where

ksv = PB-HAP compound loss constant due to volatization (yr^{-1})
3.1536×10^7 = Units conversion factor (s/yr)
H = Henry's Law constant (atm-m^3/mol)
Z_s = Soil mixing zone depth (cm)
Kd_s = Soil-water partition coefficient (mL/g)
R = Universal gas constant (atm-m^3/mol-K)
T_a = Ambient air temperature (K) = 298.1 K
BD = Soil bulk density (g soil/cm^3 soil) = 1.5 g/cm^3
D_a = Diffusivity of PB-HAP compound in air (cm^2/s)
θ_{sw} = Soil volumetric water content (mL/cm^3 soil) = 0.2 mL/cm^3
ρ_{soil} = Solids particle density (g/cm^3) = 2.7 g/cm^3

The gas-phase mass transfer coefficient, K_t, based on general soil properties, can also be written as follows (Hillel 1980; Miller and Gardiner 1998)[14]:

$$K_t = \frac{D_a \cdot \theta_v}{Z_s} \qquad \text{(Equation 6B)}$$

where

K_t = Gas phase mass transfer coefficient (cm/s)
Z_s = Soil mixing zone depth (cm)
D_a = Diffusivity of PB-HAP compound in air (cm^2/s)
θ_v = Soil void fraction (cm^3/cm^3)

The soil void fraction (θ_v) is the volumetric fraction of a soil that does not contain solids or water and can be expressed as:

$$\theta_v = 1 - \left(\frac{BD}{\rho_{soil}}\right) - \theta_{sw} \qquad \text{(Equation 6C)}$$

where

θ_v = Soil void fraction (cm^3/cm^3)
θ_{sw} = Soil volumetric water content (mL water/cm^3 soil) = 0.2 mL/cm^3
BD = Soil bulk density (g/cm^3) = 1.5 g/cm^3
ρ_{soil} = Solids particle density (g/cm^3) = 2.7 g/cm^3

The expression containing bulk density (*BD*) divided by solids particle density (ρ_{soil}) gives the volume of soil occupied by pore space or voids (Miller and Gardiner 1998).[14] Soil bulk density is affected by the soil structure, such as looseness or compaction of the soil, depending on the water and clay content of the soil (Hillel 1980)[14]; a range of 0.83 to 1.84 was originally cited in Hoffman and Baes (1979).[15] A default soil bulk density value of 1.5 g/cm^3 is recommended based on a mean value for loam soil from Carsel et al. (1988).[16] Blake and Hartge (1996)[17] and Hillel (1980)[14] both suggests that the mean density of solid particles is about 2.7 gm/cm^3. The soil water content depends on both the available water and the soil structure of a particular soil. Values for θ_{sw} range from 0.03 to 0.40 mL/cm^3 depending on soil type (Hoffman and Baes 1979).[15] The lower values are typical of sandy soils, which cannot retain much water; the higher values are typical of soils such as clay or loam soils which can retain water. A mid-point default value of 0.2 mL water/cm^3 soil is recommended as a default in the absence of site-specific information. However, since the soil water content of soil is unique for each soil type, site-specific information is highly recommended.

2.3 Calculating the Deposition Term (*Ds*)

EPA (1998)[1] recommends that Equation 7 be used to calculate the deposition term *(Ds)*.

$$Ds = \left[\frac{100 \cdot Q}{Z_s \cdot BD}\right] \cdot \left[F_v \cdot \left(Dydv + Dywv\right) + \left(Dydp + Dywp\right) \cdot \left(1 - F_v\right)\right] \qquad \text{(Equation 7)}$$

where

Ds = Deposition term (mg PB-HAP compound/kg soil/yr)
100 = Units conversion factor (mg-m^2/kg-cm^2)
Q = PB-HAP compound emission rate (g/s)
Z_s = Soil mixing zone depth (cm)

BD = Soil bulk density (g soil/cm^3 soil)
F_v = Fraction of PB-HAP compound air concentration in vapor phase (unitless)
$Dydv$ = Unitized yearly average dry deposition from vapor phase (s/m^2-yr)
$Dywv$ = Unitized yearly average wet deposition from vapor phase (s/m^2-yr)
$Dydp$ = Unitized yearly average dry deposition from particle phase (s/m^2-yr)
$Dywp$ = Unitized yearly average wet deposition from particle phase (s/m^2-yr)

2.4 Universal Soil Loss Equation (USLE)

EPA (1998)[1] recommends that the universal soil loss equation (USLE) be used to calculate the unit soil loss (X_e). This equation is further described in Section 7.2.

2.5 Site-Specific Parameters for Calculating Cumulative Soil Concentration

Calculating average soil concentration over the exposure duration (Cs) requires the use of site-specific parameters including the following:

- Soil mixing zone depth (Z_s)
- Soil bulk density (BD)
- Available water ($P + I - RO - E_v$)
- Soil volumetric water content (q_{sw})

Determination of values for these parameters is further described in the following subsections.

2.5.1 Soil Mixing Zone Depth (Z_s)

When exposures to PB-HAP compounds in soils are modeled, the depth of contaminated soils is important in calculating the appropriate soil concentration. PB-HAP compounds deposited onto soil surfaces may be moved into lower soil profiles by tilling, whether manually in a garden or mechanically in a large field.

EPA (1998)[1] recommends the following values for the soil mixing zone depth (Z_s):

- 2 cm for untilled soils; and
- 20 cm for tilled soils.

The assumption made to determine the value of Z_s may affect the outcome of the risk assessment, because soil concentrations that are based on soil depth are used to calculate exposure via several pathways: (1) ingestion of plants contaminated by root uptake; (2) direct ingestion of soil by humans, cattle, swine, or chicken; and (3) surface runoff into water bodies.

2.5.2 Soil Dry Bulk Density (BD)

Soil dry bulk density (BD) is the ratio of the mass of soil to its total volume. EPA (1998)[1] recommends the value of 1.50 g/cm^3 for the soil dry bulk density (BD). EPA (1994c)[18] recommended that wet soil bulk density be determined by weighing a thin-walled, tube soil sample (e.g., a Shelby tube) of known volume and subtracting the tube weight (ASTM Method

D2937).[19] Moisture content can then be calculated (ASTM Method 2216)[20] to convert wet soil bulk density to dry soil bulk density.

2.5.3 Available Water ($P + I - RO - E_v$)

The average annual volume of water available ($P + I - RO - E_v$) for generating leachate is the mass balance of all water inputs and outputs from the area under consideration. A wide range of values for these site-specific parameters may apply in the various EPA regions.

The average annual precipitation (P), irrigation (I), runoff (RO), and evapotranspiration (E_v) rates and other climatological data may be obtained from either data recorded on site or from the Station Climatic Summary for a nearby airport.

Meteorological variables such as the evapotranspiration rate (E_v) and the runoff rate (RO) may also be found in resources such as Geraghty, Miller, van der Leeden, and Troise (1973).[21] Surface runoff may also be estimated by using the Curve Number Equation developed by the U.S. Soil Conservation Service (EPA 1990).[4] EPA (1985)[22] cited isopleths of mean annual cropland runoff corresponding to various curve numbers developed by Stewart, Woolhiser, Wischmeier, Caro, and Frere (1975).[23] Curve numbers are assigned to an area on the basis of soil type, land use or cover, and the hydrologic conditions of the soil (EPA 1990).[4]

Using these different references, however, introduces uncertainties and limitations. For example, Geraghty, Miller, van der Leeden, and Troise (1973)[21] presented isopleths for annual surface water contributions that include interflow and ground water recharge. As noted in EPA (1994a)[8], these values are recommended to be adjusted downward to reflect surface runoff only. EPA (1994a)[8] recommended that these values be reduced by 50 percent.

2.5.4 Soil Volumetric Water Content (θ_{sw})

The soil volumetric water content (θ_{sw}) depends on the available water and the soil structure. A wide range of values for these variables may apply in the various EPA regions. EPA (1998)[1] recommends a value for θ_{sw} of 0.2 ml/cm^3.

3.0 Calculation of PB-HAP Compound Concentrations in Produce

Indirect exposure resulting from ingestion of produce depends on the total concentration of PB-HAP compounds in the leafy, fruit, and tuber portions of the plant. Because of general differences in contamination mechanisms, consideration of indirect exposure separates produce into two broad categories: aboveground produce and belowground produce. In addition, aboveground produce can be further subdivided into exposed and protected aboveground produce for consideration of contamination as a result of indirect exposure.

Aboveground Produce

Aboveground exposed produce is assumed to be contaminated by three possible mechanisms:

- **Direct deposition of particles**—wet and dry deposition of particle phase PB-HAP compounds on the leaves and fruits of plants (Section 3.1).

- **Vapor transfer**—uptake of vapor phase PB-HAP compounds by plants through their foliage (Section 3.2).
- **Root uptake**—root uptake of PB-HAP compounds available from the soil and their transfer to the aboveground portions of the plant (Section 3.3).

The total PB-HAP compound concentration in aboveground exposed produce is calculated as a sum of contamination occurring through all three of these mechanisms. However, edible portions of aboveground protected produce, such as peas, corn, and melons, are covered by a protective covering; hence, they are protected from contamination through deposition and vapor transfer. Therefore, root uptake of PB-HAP compounds is the primary mechanism through which aboveground protected produce becomes contaminated (Section 3.3).

Belowground Produce

For belowground produce, contamination is assumed to occur only through one mechanism – root uptake of PB-HAP compounds available from soil (Section 3.3). Contamination of belowground produce via direct deposition of particles and vapor transfer are not considered because the root or tuber is protected from contact with contaminants in the vapor phase.

3.1 Aboveground Produce Concentration Due to Direct Deposition (*Pd*)

EPA (1998)[1] recommends the use of Equation 8 to calculate PB-HAP compound concentration in exposed and aboveground produce due to direct deposition.

$$Pd = \frac{1{,}000 \cdot Q \cdot \left(1 - F_v\right) \cdot \left[Dydp + \left(Fw \cdot Dywp\right)\right] \cdot Rp \cdot \left[1.0 - \exp\left(-kp \cdot T_p\right)\right]}{Yp \cdot kp} \qquad \text{(Equation 8)}$$

where

Pd	=	Plant (aboveground produce) concentration due to direct (wet and dry) deposition (mg PB-HAP compound/kg DW)
1,000	=	Units conversion factor (mg/g)
Q	=	PB-HAP compound emission rate (g/s)
F_v	=	Fraction of PB-HAP compound air concentration in vapor phase (unitless)
Dydp	=	Unitized yearly average dry deposition from particle phase (s/m^2-yr)
Fw	=	Fraction of PB-HAP compound wet deposition that adheres to plant surfaces (unitless)
Dywp	=	Unitized yearly wet deposition from particle phase (s/m^2-yr)
Rp	=	Interception fraction of the edible portion of plant (unitless)
kp	=	Plant surface loss coefficient (yr^{-1})
Tp	=	Length of plant exposure to deposition per harvest of the edible portion of the *i*th plant group (yr)
Yp	=	Yield or standing crop biomass of the edible portion of the plant (productivity) (kg DW/m^2)

3.1.1 Interception Fraction of the Edible Portion of Plant (*Rp*)

EPA (1998)[1] recommends the use of the weighted average *Rp* value of 0.39 as a default *Rp* value because it represents the most current parameters including standing crop biomass and relative ingestion rates.

3.1.2 Plant Surface Loss Coefficient (*kp*)

EPA (1998)[1] recommends use of a plant surface loss coefficient (*kp*) value of 18. The primary uncertainty associated with this variable is that the calculation of *kp* does not consider chemical degradation processes. However, information regarding chemical degradation of contaminants on plant surfaces is limited. The inclusion of chemical degradation processes would result in decreased half-life values and thereby increase *kp* values. Note that effective plant concentration decreases as *kp* increases. Therefore, use of a *kp* value that does not consider chemical degradation processes is protective.

3.1.3 Length of Plant Exposure to Deposition per Harvest of Edible Portion of Plant (*Tp*)

This value represents the time required from when a plant first emerges until harvest. EPA (1998)[1] recommends using a *Tp* value of 0.164 year as the best available default value. The primary uncertainty associated with the use of this value is that it is based on the growing season for hay rather than aboveground produce. The average period between successive hay harvests (60 days) may not reflect the length of the growing season or the period between successive harvests for aboveground produce at specific sites. To the extent that information documenting the growing season or period between successive harvests for aboveground produce is available, this information may be used to estimate a site-specific *Tp* value. Calculated plant concentrations will be affected most if the site-specific value of *Tp* is significantly less than 60 days.

3.1.4 Standing Crop Biomass (Productivity) (*Yp*)

EPA (1998)[1] recommends the use of the weighted average *Yp* value of 2.24 as a default *Yp* value based on this value representing the most complete and thorough information available. The primary uncertainty associated with this variable is that the harvest yield (*Yh*) and area planted (*Ah*) may not reflect site-specific conditions. To the extent to which site-specific information is available, the magnitude of the uncertainty introduced by the default *Yp* value can be estimated.

3.2 Aboveground Produce Concentration Due to Air-to-Plant Transfer (*Pv*)

The methodology used to estimate PB-HAP compound concentration in exposed and aboveground produce due to air-to-plant transfer (*Pv*) considers limitations of PB-HAP compounds concentrations to transfer from plant surfaces to the inner portions of the plant. These limitations result from mechanisms responsible for inhibiting the transfer of the lipophilic PB-HAP compound (e.g., the shape of the produce) and the removal of the PB-HAP compounds from the edible portion of the produce (e.g., washing, peeling, and cooking). EPA (1998)[1] recommends the use of Equation 9 to calculate aboveground produce concentration due to air-to-plant transfer (*Pv*).

$$Pv = Q \cdot F_v \cdot \frac{Cyv \cdot Bv_{ag} \cdot VG_{ag}}{\rho_a} \qquad \text{(Equation 9)}$$

where

Pv	=	Concentration of PB-HAP compound in the plant resulting from air-to-plant transfer (µg PB-HAP compound/g DW)
Q	=	PB-HAP compound emission rate (g/s)
F_v	=	Fraction of PB-HAP compound air concentration in vapor phase (unitless)
Cyv	=	Unitized yearly average air concentration from vapor phase (µg-s/g-m^3)
Bv_{ag}	=	PB-HAP compound air-to-plant biotransfer factor ([mg PB-HAP compound/g DW plant]/[mg PB-HAP compound/g air]) (unitless)
VG_{ag}	=	Empirical correction factor for aboveground produce (unitless)
ρ_a	=	Density of air (g/m^3)

As discussed below in Section 3.2.1, the parameter VG_{ag} is dependent on lipophilicity of the PB-HAP compound, and assigned a value of 0.01 for lipophilic PB-HAP compounds (log K_{ow} greater than 4) or a value of 1.0 for PB-HAP compounds with a log K_{ow} less than 4.

Empirical Correction Factor for Aboveground Produce (VG_{ag})

The parameter VG_{ag} has been incorporated into Equation 9 to address the potential overestimation for lipophilic PB-HAP compounds to be transferred to the inner portions of bulky produce, such as apples. Because of the protective outer skin, size, and shape of bulky produce, transfer of lipophilic PB-HAP compounds (log K_{ow} greater than 4) to the center of the produce is not as likely as for non-lipophilic PB-HAP compounds and, as a result, the inner portions will be less affected. EPA (1998)[1] recommends the following empirical VG_{ag} values for aboveground produce:

- 0.01 for lipophilic PB-HAP compounds (log K_{ow} greater than 4); and
- 1.0 for PB-HAP compounds with a log K_{ow} less than 4 (these PB-HAP compounds are assumed pass more easily through the skin of produce).

Uncertainty may be introduced by the assumption of VG_{ag} values for leafy vegetables (such as lettuce) and for legumes (such as snap beans). Underestimation may be introduced by assuming a VG_{ag} value of 0.01 for legumes and leafy vegetables because these species often have a higher ratio of surface area to mass than other bulkier fruits and fruiting vegetables, such as tomatoes.

3.3 Produce Concentration Due to Root Uptake (*Pr*)

Root uptake of contaminants from soil may also result in PB-HAP compound concentrations in aboveground exposed produce, aboveground protected produce, and belowground produce. EPA (1998)[1] recommends the use of Equations 10A and 10B to calculate PB-HAP compound concentration aboveground and belowground produce due to root uptake (*Pr*).

Exposed and protected aboveground produce:

$$Pr = Cs \cdot Br \qquad \text{(Equation 10A)}$$

Belowground produce:

$$Pr = \frac{Cs \cdot RCF \cdot VG_{rootveg}}{Kd_s \cdot 1\ kg\ /\ L} \qquad \text{(Equation 10B)}$$

where

Pr	=	Concentration of PB-HAP compound in produce due to root uptake (mg/kg)
Br	=	Plant-soil bioconcentration factor for produce (unitless)
$VG_{rootveg}$	=	Empirical correction factor for belowground produce (unitless)
Kd_s	=	Soil-water partition coefficient (L/kg)
Cs	=	Average soil concentration over exposure duration (mg PB-HAP compound/kg soil)
RCF	=	Root concentration factor (unitless)

Equation 10A is appropriate for evaluation of exposed and protected aboveground produce; however, it may not be appropriate for soil-to-belowground plant transfers. For belowground produce, Equation 10B includes a root concentration factor (RCF) developed by Briggs et al. (1982).[24] RCF is the ratio of PB-HAP compound concentration in the edible root to the PB-HAP compound concentration in the soil water. Since Briggs et al. (1982)[24] conducted their experiments in a growth solution, the PB-HAP compound soil concentration (Cs) must be divided by the PB-HAP compound-specific soil-water partition coefficient (Kd_s) (EPA 1994b).[25]

Similar to VG_{ag} and as discussed in Section 3.2.1, $VG_{rootveg}$ is based on the lipophilicity of the PB-HAP compound. EPA (1998)[1] recommends the following empirical values for $VG_{rootveg}$:

- 0.01 for lipophilic PB-HAP compounds (log K_{ow} greater than 4) based on root vegetables like carrots and potatoes; and
- 1.0 for PB-HAP compounds with a log K_{ow} less than 4.

4.0 Calculation of PB-HAP Compound Concentrations in Beef and Dairy Products

PB-HAP compound concentrations in beef tissue and milk products are estimated on the basis of the amount of PB-HAP compounds that cattle are assumed to consume through their diet. The cattle's diet is assumed to consist of forage (primarily pasture grass and hay); silage (forage that has been stored and fermented), and grain. Additional contamination may occur through the cattle's ingestion of soil. The total PB-HAP compound concentration in the feed items (e.g., forage, silage, and grain) is calculated as a sum of contamination occurring through the following mechanisms:

- **Direct deposition of particles**—wet and dry deposition of particle phase PB-HAP compounds onto forage and silage (Section 4.1).

- **Vapor transfer**—uptake of vapor phase PB-HAP compounds by forage and silage through foliage (Section 4.2).

- **Root uptake**—root uptake of PB-HAP compounds available from the soil and their transfer to the aboveground portions of forage, silage, and grain (Section 4.3).

Feed items consumed by animals can be classified as exposed and protected, depending on whether it has a protective outer covering. Because the outer covering on the protected feed acts as a barrier, it is assumed that there is negligible contamination of protected feed through deposition of particles and vapor transfer. In this analysis, grain is classified as protected feed. As a result, grain contamination is assumed to occur only through root uptake. Contamination of exposed feed items, including forage and silage, is assumed to occur through all three mechanisms.

The amount of grain, silage, forage, and soil consumed is assumed to vary between dairy and beef cattle. Sections 4.4 (beef) and 4.5 (dairy) describe methods for estimating consumption rates and subsequent PB-HAP compound concentrations in cattle. EPA (1998)[1] recommends that 100 percent of the plant materials eaten by cattle be assumed to have been grown on soil contaminated by emission sources. Therefore, 100 percent of the feed items consumed are assumed to be contaminated.

4.1 Forage and Silage Concentrations Due to Direct Deposition (*Pd*)

PB-HAP compound concentrations in forage and silage result from wet and dry deposition onto exposed plant surfaces; similar to aboveground produce (Section 3.1). Equation 8, described in Section 3.1, is recommended for calculation of PB-HAP compound concentrations resulting from direct deposition onto plant surfaces of leafy plants and exposed produce (*Pd*). Therefore, EPA (1998)[1] recommends that Equation 8 also be used in calculating forage and silage concentrations due to direct deposition.

4.1.1 Interception Fraction of the Edible Portion of Plant (*Rp*)

EPA (1998)[1] recommends use of the *Rp* value of 0.5 for forage and the *Rp* value of 0.46 for silage. Note that the empirical relationships used to develop the default values for silage may not accurately represent site-specific silage types. However, the range of empirical constants used to develop the default value for forage is fairly small, and therefore the use of the midpoint should not significantly affect the *Rp* value and the resulting estimate of plant PB-HAP compound concentration.

4.1.2 Plant Surface Loss Coefficient (*kp*)

Section 3.1.2 presents the recommended value for plant surface loss coefficient *kp* for aboveground produce. The *kp* factor is derived in exactly the same manner for cattle forage and silage, and the uncertainties of *kp* for cattle forage and silage are similar to its uncertainties for aboveground produce.

4.1.3 Length of Plant Exposure to Deposition per Harvest of the Edible Portion of Plant (*Tp*)

As discussed in Section 3.1.3, *Tp* is treated as a constant, based on the average period between successive hay harvests. This periodrepresents the length of time that aboveground vegetation (in this case, hay) would be exposed to particle deposition before being harvested. EPA (1998)[1] recommends the following *Tp* values: 0.12 year for forage; and 0.16 year for silage. The primary uncertainties associated with *Tp* are similar to those for aboveground produce, and are discussed in Section 3.1.3.

4.1.4 Standing Crop Biomass (Productivity) (Yp)

As discussed in Section 3.1.4, the best estimate of *Yp* is productivity, requires consideration of dry harvest yield (*Yh*) and area harvested (*Ah*). EPA (1998)[1] recommends that forage *Yp* be calculated as a weighted average of the calculated pasture grass and hay *Yp* values. Weightings are assumed to be 0.75 for forage and 0.25 for hay, based on the fraction of a year that cattle are assumed to be pastured and eating grass (9 months per year) or not pastured and fed hay (3 months per year). The resulting value of 0.24 kg DW/m^2 is recommended as the *Yp* for forage. For silage, EPA (1998)[1] recommends that a production-weighted U.S. average *Yp* of 0.8 kg DW/m^2 be assumed. The primary uncertainty associated with this variable is that the harvest yield (*Yh*) and area planted (*Ah*) may not reflect site-specific conditions. To the extent that site-specific information is available, the magnitude of the uncertainty introduced by the default *Yp* value can be estimated. In addition, the weightings assumed in this discussion for the amount of time that cattle are pastured (and foraging) or stabled (and being fed silage) should be adjusted to reflect site-specific conditions, as appropriate.

4.2 Forage and Silage Concentrations Due to Air-to-Plant Transfer (*Pv*)

PB-HAP compound concentration in aboveground produce resulting from air-to-plant transfer (*Pv*), is calculated by using Equation 9 (Section 3.2). *Pv* is calculated for cattle forage and silage similarly to the way that it is calculated for aboveground produce. A detailed discussion of *Pv* is provided in Section 3.2. Differences in VG_{ag} values for forage and silage, as compared to the values for aboveground produce described in Section 3.2.1, are presented below in Section 4.2.1.

Empirical Correction Factor for Forage and Silage (VG_{ag})

EPA (1998)[1] recommends the use of VG_{ag} values of 1.0 for forage and 0.5 for silage. As discussed, the primary uncertainty associated with this variable is the lack of specific information on the proportions of each vegetation type of which silage may consist, leading to the default assumption of 0.5.

4.3 Forage, Silage, and Grain Concentrations Due to Root Uptake (*Pr*)

PB-HAP compound concentration in aboveground and belowground produce resulting from root uptake is calculated by using Equations 10A and 10B (Section 3.3). *Pr* is also calculated for cattle forage, silage, and grain in exactly the same way that it is calculated for aboveground produce. A detailed discussion describing calculation of *Pr* is provided in Section 3.3.

4.4 Beef Concentration Resulting from Plant and Soil Ingestion (A_{beef})

EPA (1998)[1] recommends that PB-HAP compound concentration in beef tissue (A_{beef}) be calculated by using Equation11. Equation 11 calculates the daily amount of a PB-HAP compound that is consumed by cattle through the ingestion of contaminated feed items (plant) and soil. The equation includes biotransfer and metabolism factors to transform the daily animal intake of a PB-HAP compound (mg/day) into an animal PB-HAP compound tissue concentration (mg PB-HAP compound/kg tissue).

$$A_{beef} = \left(\sum\left(F_i \cdot Qp_i \cdot P_i\right) + Qs \cdot Cs \cdot Bs\right) \cdot Ba_{beef} \cdot MF \qquad \text{(Equation 11)}$$

where

A_{beef}	=	Concentration of PB-HAP compound in beef (mg PB-HAP compound/kg FW tissue)
F_i	=	Fraction of plant type *i* grown on contaminated soil and ingested by the animal (cattle) (unitless)
Qp_i	=	Quantity of plant type *i* eaten by the animal (cattle) per day (kg DW plant/day)
P_i	=	Concentration of PB-HAP compound in each plant type *i* eaten by the animal (cattle) (mg/kg DW)
Qs	=	Quantity of soil eaten by the animal (cattle) each day (kg/day)
Cs	=	Average soil concentration over exposure duration (mg PB-HAP compound/kg soil)
Bs	=	Soil bioavailability factor (unitless)
Ba_{beef}	=	PB-HAP compound biotransfer factor for beef (day/kg FW tissue)
MF	=	Metabolism factor (unitless)

The parameters F_i, Qp_i, P_i, Qs, Cs, Bs, and MF are described in Sections 4.4.1 through 4.4.7, respectively.

4.4.1 Fraction of Plant Type *i* Grown on Contaminated Soil and Eaten by the Animal (Cattle)(F_i)

EPA (1998)[1] recommends that 100 percent of the plant materials eaten by cattle be assumed to have been grown on soil contaminated by the emission sources being evaluated and therefore recommends a default value of 1.0 for F_i.

4.4.2 Quantity of Plant Type *i* Eaten by the Animal (Cattle) Each Day (Qp_i)

EPA (1998)[1] recommends the following beef cattle ingestion rates of forage, silage, and grain. These values are based on the total daily intake rate of about 12 kg DW/day.

- Forage = 8.8 kg DW/day;
- Silage = 2.5 kg DW/day; and
- Grain = 0.47 kg DW/day.

The principal uncertainty associated with Qp_i is the variability between forage, silage, and grain ingestion rates for cattle.

4.4.3 Concentration of PB-HAP compound in Plant Type *i* Eaten by the Animal (Cattle) (P_i)

The total PB-HAP compound concentration in forage, silage, and grain are recommended to be calculated by using Equation 12. Values for *Pd*, *Pv*, and *Pr* can be derived for each type of feed by using Equations 8, 17, and 10, respectively.

$$P_i = \sum_i \left(Pd + Pv + Pr \right) \qquad \text{(Equation 12)}$$

where

P_i	=	Concentration of PB-HAP compound in each plant type *i* eaten by the animal (mg PB-HAP compound/kg DW)
Pd	=	Plant concentration due to direct deposition (mg PB-HAP compound/kg DW)
Pv	=	Plant concentration due to air-to-plant transfer (mg PB-HAP compound/kg DW)
Pr	=	Plant concentration due to root uptake (mg PB-HAP compound/kg DW)

4.4.4 Quantity of Soil Eaten by the Animal (Cattle) Per Day (*Qs*)

Additional cattle contamination occurs through ingestion of soil. EPA (1998)[1] recommends a value of 0.5 kg/day for the quantity of soil ingested by the animal (cattle).

4.4.5 Average Soil Concentration Over Exposure Duration (*Cs*)

PB-HAP compound concentration in soil is recommended to be calculated as discussed in Section 2.1, by using Equations 1A, 1B, and 1C.

4.4.6 Soil Bioavailability Factor (*Bs*)

The efficiency of transfer from soil may differ from efficiency or transfer from plant material for some PB-HAP compounds. If the transfer efficiency is lower for soils, than this ratio would be less than 1.0. If it is equal or greater than that of vegetation, the *Bs* value would be equal to or greater than 1.0. Until more PB-HAP compound-specific data becomes available for this parameter, EPA (1998)[1] recommends a default value of 1 for *Bs*.

4.4.7 Metabolism Factor (*MF*)

The metabolism factor (*MF*) represents the estimated amount of PB-HAP compound that remains in fat and muscle. EPA (1998)[1] recommends a *MF* of 1.0 for all PB-HAP compounds. Considering the recommended values for this variable, *MF* has no quantitative effect on A_{beef}. *MF* applies only to mammalian species, including beef cattle, dairy cattle, and pigs. It does not relate to metabolism in produce, chicken, or fish. In addition, since exposures evaluated in this chapter are intake driven, the use of a metabolism factor applies only to ingestion of beef, milk, and pork. In summary, use of a *MF* does not apply for direct exposures to soil or water, or to ingestion of produce, chicken, or fish.

4.5 PB-HAP compound Concentration In Milk Due to Plant and Soil Ingestion (A_{milk})

Equation 11 (Section 4.4) describes the calculation of PB-HAP compound concentrations in beef cattle (A_{beef}). Equation 11 can be modified to calculate PB-HAP compound milk concentrations (A_{milk}), as follows:

$$A_{milk} = \left(\sum\left(F_i \cdot Q_{pi} \cdot P_i\right) + Qs \cdot Cs \cdot Bs\right) \cdot Ba_{milk} \cdot MF \qquad \text{(Equation 13)}$$

where

A_{milk}	=	Concentration of PB-HAP compound in milk (mg PB-HAP compound/kg milk)
F_i	=	Fraction of plant type *i* grown on contaminated soil and ingested by the animal (dairy cattle) (unitless)
Qp_i	=	Quantity of plant type *i* eaten by the animal (dairy cattle) each day (kg DW plant/day)
P_i	=	Concentration of PB-HAP compound in plant type *i* eaten by the animal (dairy cattle) (mg/kg DW)
Qs	=	Quantity of soil eaten by the animal (dairy cattle) each day (kg soil/day)
Cs	=	Average soil concentration over exposure duration (mg PB-HAP compound/kg soil)
Bs	=	Soil bioavailability factor (unitless)
Ba_{milk}	=	PB-HAP compound biotransfer factor for milk (day/kg WW tissue)
MF	=	Metabolism factor (unitless)

EPA (1998)[1] recommends the use of Equation 13 to estimate dairy cattle milk PB-HAP compound concentration (A_{milk}). The discussion in Section 4.4 of the variables F_i, Qp_i, P_i, Qs, Cs, and MF for beef cattle generally applies to the corresponding variables for dairy cattle. However, there are some differences in assumptions made for dairy cattle; these differences are summarized in the following subsections.

4.5.1 Fraction of Plant Type *i* Grown on Contaminated Soil and Eaten by the Animal (Dairy Cattle) (F_i)

The calculation of F_i for dairy cattle is identical to that for beef cattle (Section 4.4.1).

4.5.2 Quantity of Plant Type *i* Eaten by the Animal (Dairy Cattle) Per Day (Qp_i)

As discussed in Section 4.4.2, the daily quantity of forage, silage, and grain feed consumed by cattle is estimated for each category of feed material. However, daily ingestion rates for dairy cattle are estimated differently than for beef cattle. The daily quantity of feed consumed by cattle is recommended to be estimated on a dry weight basis for each category of plant feed.

EPA (1998)[1] recommends a default total ingestion rate of 20 kg DW/day for dairy cattle, divided among forage, silage, and grain, as follows:

- Forage = 13.2 kg DW/day;
- Silage = 4.1 kg DW/day; and
- Grain = 3.0 kg DW/day

Uncertainties associated with the estimation of Qp_i include the estimation of forage, grain, and silage ingestion rates, which will vary from site to site. The assumption of uniform contamination of plant materials consumed by cattle also introduces uncertainty.

4.5.3 Concentration of PB-HAP compound in Plant Type *i* Eaten by the Animal (Dairy Cattle) (P_i)

The estimation of P_i for dairy cattle is identical to that for beef cattle (Section 4.4.3).

4.5.4 Quantity of Soil Eaten by the Animal (Dairy Cattle) Per Day (*Qs*)

As discussed in Section 4.4.4, contamination of dairy cattle also results from the ingestion of soil. EPA (1998)[1] recommends a soil ingestion rate of 0.4 kg/day for dairy cattle. Uncertainties associated with *Qs* include the lack of current empirical data to support soil ingestion rates for dairy cattle. The assumption of uniform contamination of soil ingested by cattle also adds uncertainty.

4.5.5 Average Soil Concentration Over Exposure Duration (*Cs*)

The calculation of *Cs* for dairy cattle is the same as for beef cattle (Section 4.4.5).

4.5.6 Soil Bioavailability Factor (*Bs*)

The calculation of *Bs* for dairy cattle is the same as for beef cattle (Section 4.4.6).

4.5.7 Metabolism Factor (*MF*)

The recommended values for *MF* are identical to those recommended for beef cattle (Section 4.4.7).

5.0 Calculation of PB-HAP Compound Concentrations in Pork

PB-HAP compound concentrations in pork tissue are estimated on the basis of the amount of PB-HAP compounds that swine are assumed to consume through their diet; assumed to consist of silage and grain. Additional PB-HAP compound contamination of pork tissue may occur through the ingestion of soil by swine.

5.1 Concentration of PB-HAP compound In Pork

Equation 11 (Section 4.4) describes the calculation of PB-HAP compound concentration in beef cattle (A_{beef}). Equation 11 can be modified to calculate PB-HAP compound concentrations in swine (A_{pork}), as follows:

$$A_{pork} = \left(\sum\left(F_i \cdot Q_{pi} \cdot P_i\right) + Qs \cdot Cs \cdot Bs\right) \cdot Ba_{pork} \cdot MF \qquad \text{(Equation 14)}$$

where

A_{pork} = Concentration of PB-HAP compound in pork (mg PB-HAP compound/kg FW tissue)
F_i = Fraction of plant type *i* grown on contaminated soil and ingested by the animal (swine)(unitless)
Qp_i = Quantity of plant type *i* eaten by the animal (swine) each day (kg DW plant/day)
P_i = Concentration of PB-HAP compound in plant type *i* eaten by the animal (swine) (mg/kg DW)
Qs = Quantity of soil eaten by the animal (swine) (kg/day)
Cs = Average soil concentration over exposure duration (mg PB-HAP compound/kg soil)
Bs = Soil bioavailability factor (unitless)
Ba_{pork} = PB-HAP compound biotransfer factor for pork (day/kg FW tissue)
MF = Metabolism factor (unitless)

EPA (1998)[1] recommends that Equation 14 be used to calculate PB-HAP compound pork concentrations (A_{pork}). The discussion in Section 4.5 of the variables F_i, Qp_i, P_i, Qs, Cs and MF for beef cattle generally applies to the corresponding variables for pork. However, different assumptions are made for pork. These differences are summarized in the following subsections.

5.1.1 Fraction of Plant Type *i* Grown on Contaminated Soil and Eaten by the Animal (Swine) (F_i)

The calculation of F_i for pork is identical to that for beef cattle (Section 4.4.1).

5.1.2 Quantity of Plant Type *i* Eaten by the Animal (Swine) Each Day (Qp_i)

As discussed in Section 4.4.2, the daily quantity of forage, silage, and grain feed consumed by beef cattle is estimated for each category of feed material. However, daily ingestion rates for pork are estimated differently than for beef cattle. Because swine are not grazing animals, they are assumed not to eat forage, and EPA (1998)[1] recommends that the daily quantity of plant feeds (kilograms of DW) consumed by swine be estimated for each category of plant feed.

EPA (1990)[4] and NC DEHNR (1997)[26] did not differentiate between subsistence and typical hog farmers as for cattle. EPA (1990)[4] and NC DEHNR (1997)[26] recommended grain and silage ingestion rates for swine as 3.0 and 1.3 kg DW/day, respectively. NC DEHNR (1997)[26] references EPA (1990)[4] as the source of these ingestion rates. EPA (1990)[4] reported total dry matter ingestion rates for hogs and lactating sows as 3.4 and 5.2 kg DW/day, respectively. EPA (1990)[4] cites Boone, Ng, and Palm (1981)[27] as the source of the ingestion rate for hogs, and NAS (1987)[28] as the source of the ingestion rate for a lactating sow. Boone, Ng, and Palm (1981)[27] reported a grain ingestion rate of 3.4 kg DW/day for a hog. NAS (1987)[28] reported an average ingestion rate of 5.2 kg DW/day for a lactating sow. EPA (1990)[4] recommended using the average of these two rates (4.3 kg DW/day). EPA (1990)[4] assumed that 70 percent of the swine diet is grain and 30 percent silage to obtain the grain ingestion rate of 3.0 kg DW/day and the silage ingestion rate of 1.3 kg DW/day. EPA (1990)[4] cited EPA (1982)[29] as the source of the grain and silage dietary fractions. EPA (1995)[30] recommended an ingestion rate of 4.7 kg DW/day for a swine, referencing NAS (1987).[28] NAS (1987)[28] reported an average daily intake of 4.36 kg DW/day for a gilt (young sow) and a average daily intake of 5.17 kg DW/day for a sow, which averages out to 4.7 kg/DW/day. Assuming the 70 percent grain to 30 percent silage diet noted above, estimated ingestion rates of 3.3 kg DW/day (grain) and 1.4 kg DW/day (silage) are derived.

EPA (1998)[1] recommends the use of the following Qp_i values for pork:

- Grain = 3.3 kg DW/day; and
- Silage = 1.4 kg DW/day.

Uncertainties associated with this variable include the variability of actual grain and silage ingestion rates from site to site. Site-specific data can be used to mitigate this uncertainty. In addition, the assumption of uniform contamination of plant materials consumed by swine produces some uncertainty.

5.1.3 Concentration of PB-HAP compound in Plant Type *i* Eaten by the Animal (Swine) (P_i)

The calculation of P_i for pork is identical to that for beef cattle (Section 4.4.3).

5.1.4 Quantity of Soil Eaten by the Animal (Swine) Each Day (Q_s)

As discussed in Section 4.4.4, additional contamination of swine results from ingestion of soil. EPA (1998)[1] recommends the following soil ingestion rate for swine: 0.37 kg DW/day. Uncertainties associated with this variable include the lack of current empirical data to support soil ingestion rates for swine, and the assumption of uniform contamination of soil ingested by swine.

5.1.5 Average Soil Concentration Over Exposure Duration (*Cs*)

The calculation of *Cs* for pork is the same as for beef cattle (Section 4.4.5).

5.1.6 Soil Bioavailability Factor (*Bs*)

The calculation of *Bs* for pork is the same as for beef cattle (Section 4.4.6)

5.1.7 Metabolism Factor (*MF*)

The recommended values for MF are identical to those recommended for beef cattle (Section 4.4.7).

6.0 Calculation of PB-HAP Compound Concentrations in Chicken and Eggs

Estimates of the PB-HAP compound concentrations in chicken and eggs are based on the amount of PB-HAP compounds that chickens consume through ingestion of grain and soil. The uptake of PB-HAP compounds via inhalation and via ingestion of water is assumed to be insignificant relative to other pathways. Chickens are assumed to be housed in a typical manner that allows contact with soil; and therefore, are assumed to consume 10 percent of their diet as soil. The remainder of the diet (90 percent) is assumed to consist of grain. Grain ingested by chickens is assumed to have originated from the exposure scenario location; therefore, 100 percent of the grain consumed is assumed to be contaminated. The uptake of PB-HAP compounds via ingestion of contaminated insects and other organisms (e.g., worms, etc.), which may also

contribute to the ingestion of PB-HAP compounds, is not accounted for in the equations and may be a limitation depending on the site-specific conditions under which the chickens are raised.

The PB-HAP compound concentration in grain is estimated by using the algorithm for aboveground produce described in Section 3. Grain is considered to be a feed item that is protected from deposition of particles and vapor transfer. As a result, only contamination due to root uptake of PB-HAP compounds is considered in the calculation of PB-HAP compound concentration in grain.

6.1 Concentration of PB-HAP compound in Chicken and Eggs

EPA (1998)[1] recommends the use of Equation 15 to calculate PB-HAP compound concentrations in chicken and eggs. It is recommended that PB-HAP compound concentrations in chicken and eggs be determined separately.

$$A_{chicken} \text{ or } A_{egg} = \left(\sum\left[F_i \cdot Qp_i \cdot P_i\right] + Qs \cdot Cs \cdot Bs\right) \cdot \left(Ba_{egg} \text{ or } Ba_{chicken}\right) \qquad \text{(Equation 15)}$$

where

$A_{chicken}$	=	Concentration of PB-HAP compound in chicken (mg PB-HAP compound/kg FW tissue)
A_{egg}	=	Concentration of PB-HAP compound in eggs (mg PB-HAP compound/kg FW tissue)
F_i	=	Fraction of plant type *i* (grain) grown on contaminated soil and ingested by the animal (chicken)(unitless)
Qp_i	=	Quantity of plant type *i* (grain) eaten by the animal (chicken) each day (kg DW plant/day)
P_i	=	Concentration of PB-HAP compound in plant type *i* (grain) eaten by the animal (chicken) (mg/kg DW)
Qs	=	Quantity of soil eaten by the animal (chicken) (kg/day)
Cs	=	Average soil concentration over exposure duration (mg PB-HAP compound/kg soil)
Bs	=	Soil bioavailability factor (unitless)
$Ba_{chicken}$	=	PB-HAP compound biotransfer factor for chicken (day/kg FW tissue)
Ba_{egg}	=	PB-HAP compound biotransfer factor for eggs (day/kg FW tissue)

EPA (1998)[1] describes determination of compound specific parameters $Ba_{chicken}$ and Ba_{egg}. The remaining parameters are discussed in the following subsections.

6.1.1 Fraction of Plant Type *i* Grown on Contaminated Soil and Eaten by the Animal (Chicken)(F_i)

The calculation of F_i for chicken is identical to that for beef cattle (Section 4.4.1).

6.1.2 Quantity of Plant Type *i* Eaten by the Animal (Chicken) Each Day (Qp_i)

Because chickens are not grazing animals, they are assumed not to eat forage. Chickens are assumed not to consume any silage. The daily quantity of plant feeds (kilograms of DW)

consumed by chicken only should be estimated for grain feed. EPA (1998)[1] recommends the use of the following ingestion rate (Qp_i): Grain = 0.2 kg DW/day. Uncertainties associated with this variable include the variability of actual grain ingestion rates from site to site. In addition, the assumption of uniform contamination of plant materials consumed by chicken produces some uncertainty.

6.1.3 Concentration of PB-HAP compound in Plant Type *i* Eaten by the Animal (Chicken) (P_i)

The total PB-HAP compound concentration is the PB-HAP compound concentration in grain and can be calculated by using Equation 16. Values for *Pr* can be derived by using Equation 10.

$$P_i = \sum_i \left(Pr \right) \qquad \text{(Equation 16)}$$

where

P_i = Concentration of PB-HAP compound in each plant type *i* eaten by the animal (mg PB-HAP compound/kg DW)
Pr = Plant concentration due to root uptake (mg PB-HAP compound/kg DW)

6.1.4 Quantity of Soil Eaten by the Animal (Chicken) Each Day (*Qs*)

PB-HAP compound concentration in chickens also results from intake of soil. As discussed earlier, chickens are assumed to consume 10 percent of their total diet as soil. EPA (1998)[1] recommends the following soil ingestion rate for chicken: 0.022 kg DW/day. Uncertainties associated with this variable include the lack of current empirical data to support soil ingestion rates for chicken, and the assumption of uniform contamination of soil ingested by chicken.

6.1.5 Average Soil Concentration Over Exposure Duration (*Cs*)

The calculation of *Cs* for chicken is the same as for beef cattle (Section 4.4.5).

6.1.6 Soil Bioavailability Factor (*Bs*)

The calculation of *Bs* for chicken is the same as for beef cattle (Section 4.4.6)

7.0 Calculation of PB-HAP Compound Concentrations in Drinking Water and Fish

PB-HAP compound concentrations in surface water are calculated for all water bodies selected for evaluation in the risk assessment; specifically, evaluation of the drinking water and/or fish ingestion exposure pathways. Mechanisms considered for determination of PB-HAP compound loading of the water column are:

(1) Direct deposition,
(2) Runoff from impervious surfaces within the watershed,
(3) Runoff from pervious surfaces within the watershed,
(4) Soil erosion over the total watershed,
(5) Direct diffusion of vapor phase PB-HAP compounds into the surface water, and
(6) Internal transformation of compounds chemically or biologically.

Other potential mechanisms may need consideration on a case-by-case basis (e.g., tidal influences), however, contributions from other potential mechanisms are assumed to be negligible in comparison with those being evaluated.

The USLE and a sediment delivery ratio are used to estimate the rate of soil erosion from the watershed. In the ISCST3 model, surface water concentration algorithms include a sediment mass balance, in which the amount of sediment assumed to be buried and lost from the water body is equal to the difference between the amount of soil introduced to the water body by erosion and the amount of suspended solids lost in downstream flow. As a result, the assumptions are made that sediments do not accumulate in the water body over time, and an equilibrium is maintained between the surficial layer of sediments and the water column. The total water column PB-HAP compound concentration is the sum of the PB-HAP compound concentration dissolved in water and the PB-HAP compound concentration associated with suspended solids. Partitioning between water and sediment varies with the PB-HAP compound. The total concentration of each PB-HAP compound is partitioned between the sediment and the water column. The assumptions for other multimedia models may differ.

To evaluate the PB-HAP compound loading to a water body from its associated watershed, it is recommended that the PB-HAP compound concentration in watershed soils be calculated. As described in Section 2, the equation for PB-HAP compound concentration in soil includes a loss term that considers the loss of contaminants from the soil after deposition. These loss mechanisms all lower the soil concentration associated with a specific deposition rate.

The ISCST3 model approach for modeling PB-HAP compound loading to a water body represents a simple steady-state model to solve for a water column in equilibrium with the upper sediment layer. This approach may be limited in addressing the dynamic exchange of contaminants between the water body and the sediments following changes in external loadings. While appropriate for calculating risk under long-term average conditions, the evaluation of complex water bodies or shorter term loading scenarios may be improved through the use of a dynamic modeling framework [e.g., Exposure Analysis Modeling System (EXAMS)]. Although typically more resource intensive, such analysis may offer the ability to refine modeling of contaminant loading to a water body. Additionally, the computations may better represent the exposure scenario being evaluated.

For example, EXAMS allows computations to be performed for each defined segment or compartment of a water body or stream. These compartments are considered physically homogeneous and are connected via advective and dispersive fluxes. Compartments can be defined as littoral, epilimnion, hypolimnion, or benthic. Such resolution also makes it possible to assign receptor locations specific to certain portions of a water body where evaluation of exposure is of greatest interest.

Some considerations regarding the selection and use of a dynamic modeling framework or simulation model to evaluate water bodies may include the following:

- Will a complex surface water modeling effort provide enhanced results over the use of the more simplistic steady-state equations;

- Are the resources needed to conduct, as well as review, a more complex modeling effort justified in comparison to the refinement to results provided;

- Has the model been used previously for regulatory purposes, and therefore, already has available documentation to support such uses;

- Can the model conduct steady-state and dynamic analysis; and

- Does the model require calibration with field data, and if so, are there sufficient quantity and quality of site-specific data available to support calibration.

7.1 Total PB-HAP compound Load to the Water Body (L_T)

EPA (1998)[1] recommends the use of Equation 17 to calculate the total PB-HAP compound load to a water body (L_T).

$$L_T = L_{DEP} + L_{dif} + L_{RI} + L_R + L_E + L_I \qquad \text{(Equation 17)}$$

where

L_T	=	Total PB-HAP compound load to the water body (including deposition, runoff, and erosion) (g/yr)
L_{DEP}	=	Total (wet and dry) particle phase and vapor phase PB-HAP compound direct deposition load to water body (g/yr)
L_{dif}	=	Vapor phase PB-HAP compound diffusion load to water body (g/yr)
L_{RI}	=	Runoff load from impervious surfaces (g/yr)
L_R	=	Runoff load from pervious surfaces (g/yr)
L_E	=	Soil erosion load (g/yr)
L_I	=	Internal transfer (g/yr)

Due to the limited data and uncertainty associated with the chemical or biological internal transfer, L_I, of compounds into daughter products, EPA (1998)[1] recommends a default value for this variable of zero. However, if a permitting authority determines that site-specific conditions indicate calculation of internal transfer may need to be considered, EPA (1998)[1] recommends following the methodologies described in EPA NCEA document, *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions* (EPA 1998).[12] Calculation of each of the remaining variables (L_{DEP}, L_{dif}, L_{RI}, L_R, and L_E) is discussed in the following subsections.

7.1.1 Total (Wet and Dry) Particle Phase and Vapor Phase PB-HAP compound Direct Deposition Load to Water Body (L_{DEP})

EPA (1998)[1] recommends Equation 18 to calculate the load to the water body from the direct deposition of wet and dry particles and vapors onto the surface of the water body (L_{DEP}).

$$L_{DEP} = Q \cdot \left[F_v \cdot Dytwv + \left(1 - F_v\right) \cdot Dytyp \right] \cdot A_W \qquad \text{(Equation 18)}$$

where

L_{DEP} = Total (wet and dry) particle phase and vapor phase PB-HAP compound direct deposition load to water body (g/yr)
Q = PB-HAP compound emission rate (g/s)
F_v = Fraction of PB-HAP compound air concentration in vapor phase (unitless)
$Dytwv$ = Unitized yearly (water body or watershed) average total (wet and dry) deposition from vapor phase (s/m^2-yr)
$Dytwp$ = Unitized yearly (water body or watershed) average total (wet and dry) deposition from particle phase (s/m^2-yr)
A_W = Water body surface area (m^2)

7.1.2 Vapor Phase PB-HAP compound Diffusion Load to Water Body (L_{dif})

EPA (1998)[1] recommends using Equation 19 to calculate the vapor phase PB-HAP compound diffusion load to the water body (L_{dif}).

$$L_{dif} = \frac{K_v \cdot Q \cdot F_v \cdot Cyvw \cdot A_W \cdot 1 \times 10^{-6}}{\frac{H}{R \cdot T_{wk}}} \qquad \text{(Equation 19)}$$

where

L_{dif} = Vapor phase PB-HAP compound diffusion load to water body (g/yr)
K_v = Overall PB-HAP compound transfer rate coefficient (m/yr)
Q = PB-HAP compound emission rate (g/s)
F_v = Fraction of PB-HAP compound air concentration in vapor phase (unitless)
$Cywv$ = Unitized yearly (water body or watershed) average air concentration from vapor phase (µg-s/g-m^3)
A_W = Water body surface area (m^2)
10^{-6} = Units conversion factor (g/µg)
H = Henry's Law constant (atm-m^3/mol)
R = Universal gas constant (atm-m^3/mol-K)
T_{wk} = Water body temperature (K)

The overall PB-HAP compound transfer rate coefficient (K_v) is calculated by using Equation 29 (see section 7.4.4). EPA (1998)[1] recommends a water body temperature (T_{wk}) of 298 K (or 25°C).

7.1.3 Runoff Load from Impervious Surfaces (L_{RI})

In some watershed soils, a fraction of the total (wet and dry) deposition in the watershed will be to impervious surfaces. This deposition may accumulate and be washed off during rain events. EPA (1998)[1] recommends the use of Equation 20 to calculate impervious runoff load to a water body (L_{RI}).

$$L_{RI} = Q \cdot \left[F_v \cdot Dytwv + \left(1.0 - F_v\right) \cdot Dytwp \right] \cdot A_I \qquad \text{(Equation 20)}$$

where

L_{RI} = Runoff load from impervious surfaces (g/yr)
Q = PB-HAP compound emission rate (g/s)
F_v = Fraction of PB-HAP compound air concentration in vapor phase (unitless)
$Dytwv$ = Unitized yearly (water body or watershed) average total (wet and dry) deposition from vapor phase (s/m^2-yr)
$Dytwp$ = Unitized yearly (water body or watershed) average total (wet and dry) deposition from particle phase (s/m^2-yr)
A_I = Impervious watershed area receiving PB-HAP compound deposition (m^2)

Impervious watershed area receiving PB-HAP compound deposition (A_I) is the portion of the total effective watershed area that is impervious to rainfall (such as roofs, driveways, streets, and parking lots) and drains to the water body.

7.1.4 Runoff Load from Pervious Surfaces (L_R)

EPA (1998)[1] recommends the use of Equation 21 to calculate the runoff dissolved PB-HAP compound load to the water body from pervious soil surfaces in the watershed (L_R).

$$L_R = RO \cdot \left(A_L - A_I\right) \cdot \frac{Cs \cdot BD}{\theta_{sw} + Kd_s + BD} \cdot 0.01 \qquad \text{(Equation 21)}$$

where

L_R = Runoff load from pervious surfaces (g/yr)
RO = Average annual surface runoff from pervious areas (cm/yr)
A_L = Total watershed area receiving PB-HAP compound deposition (m^2)
A_I = Impervious watershed area receiving PB-HAP compound deposition (m^2)
Cs = Average soil concentration over exposure duration (in watershed soils) (mg PB-HAP compound/kg soil)
BD = Soil bulk density (g soil/cm^3 soil)
θ_{sw} = Soil volumetric water content (mL water/cm^3 soil)
Kd_s = Soil-water partition coefficient (cm^3 water/g soil)
0.01 = Units conversion factor (kg-cm^2/mg-m^2)

The calculation of the PB-HAP compound concentration in watershed soils (Cs) are discussed in Section 2.1. Soil bulk density (BD) is described in Section 2.5.2. Soil water content (θ_{sw}) is described in Section 2.5.4.

7.1.5 Soil Erosion Load (L_E)

EPA (1998)[1] recommends the use of Equation 22 to calculate soil erosion load (L_E).

$$L_E = X_e \cdot \left(A_L - A_I\right) \cdot SD \cdot ER \cdot \frac{Cs \cdot Kd_s \cdot BD}{\theta_{sw} + Kd_s + BD} \cdot 0.001 \qquad \text{(Equation 22)}$$

where

L_E	=	Soil erosion load (g/yr)
X_e	=	Unit soil loss (kg/m^2-yr)
A_L	=	Total watershed area (evaluated) receiving PB-HAP compound deposition (m^2)
A_I	=	Impervious watershed area receiving PB-HAP compound deposition (m^2)
SD	=	Sediment delivery ratio (watershed) (unitless)
ER	=	Soil enrichment ratio (unitless)
Cs	=	Average soil concentration over exposure duration (in watershed soils) (mg PB-HAP compound/kg soil)
BD	=	Soil bulk density (g soil/cm^3 soil)
θ_{sw}	=	Soil volumetric water content (mL water/cm^3 soil)
Kd_s	=	Soil-water partition coefficient (mL water/g soil)
0.001	=	Units conversion factor (k-cm^2/mg-m^2)

Unit soil loss (X_e) is described in Section 7.2. Watershed sediment delivery ratio (SD) is calculated as described in Section 7.3. PB-HAP compound concentration in soils (Cs) is described in Section 2.1. Soil bulk density (BD) is described in Section 2.5.2. Soil water content (θ_{sw}) is described in Section 2.5.4.

7.2 Universal Soil Loss Equation - USLE

EPA (1998)[1] recommends that the universal soil loss equation (USLE), Equation 22A, be used to calculate the unit soil loss (X_e) specific to each watershed.

$$X_e = RF \cdot K \cdot LS \cdot C \cdot PF \cdot \frac{907.18}{4047} \qquad \text{(Equation 22A)}$$

where

X_e	=	Unit soil loss (kg/m^2-yr)
RF	=	USLE rainfall (or erosivity) factor (yr^{-1})
K	=	USLE erodibility factor (ton/acre)
LS	=	USLE length-slope factor (unitless)
C	=	USLE cover management factor (unitless)
PF	=	USLE supporting practice factor (unitless)
907.18	=	Units conversion factor (kg/ton)
4047	=	Units conversion factor (m^2/acre)

The USLE *RF* variable, which represents the influence of precipitation on erosion, is derived from data on the frequency and intensity of storms. This value is typically derived on a storm-by-storm basis, but average annual values have been compiled (U.S. Department of Agriculture 1982).[31] Information on determining site-specific values for variables used in calculating X_e is provided in U.S. Department of Agriculture (U.S. Department of Agriculture 1997)[32] and EPA guidance (EPA 1985).[22]

7.3 Sediment Delivery Ratio (*SD*)

EPA (1998)[1] recommends the use of Equation 23 to calculate sediment delivery ratio (*SD*).

$$SD = a \cdot \left(A_L\right)^{-b} \qquad \text{(Equation 23)}$$

where

SD = Sediment delivery ratio (watershed) (unitless)
a = Empirical intercept coefficient (unitless)
b = Empirical slope coefficient (unitless)
A_L = Total watershed area (evaluated) receiving PB-HAP compound deposition (m^2)

A_L is the total watershed surface area evaluated that is affected by deposition and drains to the body of water (see Chapter 2). In assigning values to the watershed surface area affected by deposition, the following may be a consideration:

- Distance from the emission source;
- Location of the area affected by deposition fallout with respect to the point at which drinking water is extracted or fishing occurs; and
- The watershed hydrology.

7.4 Total Water Body PB-HAP compound Concentration (C_{wtot})

EPA (1998)[1] recommends the use of Equation 24 to calculate total water body PB-HAP compound concentration (C_{wtot}). The total water body concentration includes both the water column and the bed sediment.

$$C_{wtot} = \frac{L_T}{Vf_x \cdot f_{wc} \cdot k_{wt} \cdot A_W \cdot \left(d_{wc} + d_{bs}\right)} \qquad \text{(Equation 24)}$$

where

C_{wtot} = Total water body PB-HAP compound concentration (including water column and bed sediment) (g PB-HAP compound/m^3 water body)
L_T = Total PB-HAP compound load to the water body (including deposition, runoff, and erosion) (g/yr)
Vf_x = Average volumetric flow rate through water body (m^3/yr)
f_{wc} = Fraction of total water body PB-HAP compound concentration in the water column (unitless)
k_{wt} = Overall total water body PB-HAP compound dissipation rate constant (yr^{-1})

A_W = Water body surface area (m^2)
d_{wc} = Depth of water column (m)
d_{bs} = Depth of upper benthic sediment layer (m)

The total PB-HAP compound load to the water body (L_T) – including deposition, runoff, and erosion – is described in Section 7.1. The depth of the upper benthic layer (d_{bs}), which represents the portion of the bed that is in equilibrium with the water column, cannot be precisely specified; however, EPA (1998)[1] recommends a default value of 0.03. Issues related to the remaining parameters are summarized in the following subsections.

7.4.1 Fraction of Total Water Body PB-HAP compound Concentration in the Water Column (f_{wc}) and Benthic Sediment (f_{bs})

EPA (1998)[1] recommends using Equation 25A to calculate fraction of total water body PB-HAP compound concentration in the water column (f_{wc}), and Equation 25B to calculate total water body contaminant concentration in benthic sediment (f_{bs}).

$$f_{wc} = \frac{\left(1 + kd_{sw} \cdot TSS \cdot 1 \times 10^{-6}\right) \cdot d_{wc} / d_z}{\left(1 + kd_{sw} \cdot TSS \cdot 10^{-6}\right) \cdot d_{wc} / d_z + \left(\theta_{bs} + Kd_{bs} \cdot C_{BS}\right) \cdot d_{bs} / d_z} \qquad \text{(Equation 25A)}$$

$$f_{bs} = 1 - f_{wc} \qquad \text{(Equation 25B)}$$

where

f_{wc} = Fraction of total water body PB-HAP compound concentration in the water column (unitless)
f_{bs} = Fraction of total water body PB-HAP compound concentration in benthic sediment (unitless)
Kd_{sw} = Suspended sediments/surface water partition coefficient (L water/kg suspended sediment)
TSS = Total suspended solids concentration (mg/L)
1×10^{-6} = Units conversion factor (kg/mg)
d_z = Total water body depth (m)
θ_{bs} = Bed sediment porosity ($L_{water}/L_{sediment}$)
Kd_{bs} = Bed sediment/sediment pore water partition coefficient (L water/kg bottom sediment)
C_{BS} = Bed sediment concentration (g/cm^3 [equivalent to kg/L])
d_{wc} = Depth of water column (m)
d_{bs} = Depth of upper benthic sediment layer (m)

The partition coefficient Kd_{sw} describes the partitioning of a contaminant between sorbing material, such as soil, surface water, suspended solids, and bed sediments. Due to variability in water body specific values, EPA (1998)[1] recommends the use of water body-specific measured total suspended solids (*TSS*) values representative of long-term average annual values for the water body of concern. Average annual values for *TSS* are generally expected to be in the range

of 2 to 300 mg/L; with additional information on anticipated *TSS* values available in the EPA NCEA document, *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions* (EPA 1998).[12] If measured data are not available, or of unacceptable quality, a calculated *TSS* value can be obtained for non-flowing water bodies using Equation 25C.

$$TSS = \frac{X_e \cdot \left(A_L - A_I\right) \cdot SD \cdot 1 \times 10^3}{Vf_x + D_{ss} \cdot A_W} \qquad \text{(Equation)25C}$$

where

TSS	=	Total suspended solids concentration (mg/L)
X_e	=	Unit soil loss (kg/m^2-yr)
A_L	=	Total watershed area (evaluated) receiving PB-HAP compound deposition (m^2)
A_I	=	Impervious watershed area receiving PB-HAP compound deposition (m^2)
SD	=	Sediment delivery ratio (watershed) (unitless)
Vf_x	=	Average volumetric flow rate through water body (value should be 0 for quiescent lakes or ponds) (m^3/yr)
D_{ss}	=	Suspended solids deposition rate (a default value of 1,825 for quiescent lakes or ponds) (m/yr)
A_W	=	Water body surface area (m^2)
1×10^{-3}	=	Units conversion factor (g/kg)

The default value of 1,825 m/yr provided for D_{ss} is characteristic of Stoke's settling velocity for an intermediate (fine to medium) silt.

Also, to evaluate the appropriateness of watershed-specific values used in calculating the unit soil loss (X_e), as described in Section 7.2, the water-body specific measured *TSS* value can be compared to the calculated *TSS* value obtained using Equation 25C. If the measured and calculated *TSS* values differ significantly, parameter values used in calculating X_e can be re-evaluated. This re-evaluation of *TSS* and X_e can also be conducted if the calculated *TSS* value is outside of the normal range expected for average annual measured values, as discussed above.

Bed sediment porosity (θ_{bs}) can be calculated from the bed sediment concentration by using Equation 26 (EPA 1993b)[11]:

$$\theta_{bs} = 1 - \frac{C_{BS}}{\rho_s} \qquad \text{(Equation 26)}$$

where

θ_{bs}	=	Bed sediment porosity ($L_{water}/L_{sediment}$)
ρ_s	=	Bed sediment density (kg/L)
C_{BS}	=	Bed sediment concentration (kg/L)

EPA (1998)[1] recommends the default value of 0.6 $L_{water}/L_{sediment}$ for bed sediment porosity (θ_{bs}). This assumes a bed sediment density (ρ_s) of 2.65 kg/L and a bed sediment concentration (C_{BS}) of 1.0 kg/L.

7.4.2 Overall Total Water Body PB-HAP compound Dissipation Rate Constant (k_{wt})

EPA (1998)[1] recommends the use of Equation 27 to calculate the overall dissipation rate of PB-HAP compounds in surface water, resulting from volatilization and benthic burial.

$$k_{wt} = f_{wc} \cdot k_v + f_{bs} \cdot k_b \qquad \text{(Equation 27)}$$

where

k_{wt} = Overall total water body dissipation rate constant (yr^{-1})
f_{wc} = Fraction of total water body PB-HAP compound concentration in the water column (unitless)
k_v = Water column volatilization rate constant (yr^{-1})
f_{bs} = Fraction of total water body PB-HAP compound concentration in benthic sediment (unitless)
k_b = Benthic burial rate constant (yr^{-1})

The variables f_{wc} and f_{bs} are discussed in Section 7.4.1, and Equations 25A and 25B.

7.4.3 Water Column Volatilization Rate Constant (k_v)

EPA (1998)[1] recommends using Equation 28 to calculate water column volatilization rate constant.

$$k_v = \frac{K_v}{d_z \cdot \left(1 + kd_{sw} \cdot TSS \cdot 1 \times 10^{-6}\right)} \qquad \text{(Equation 28)}$$

where

k_v = Water column volatilization rate constant (yr^{-1})
K_v = Overall PB-HAP compound transfer rate coefficient (m/yr)
d_z = Total water body depth (m)
Kd_{sw} = Suspended sediments/surface water partition coefficient (L water/kg suspended sediments)
TSS = Total suspended solids concentration (mg/L)
1×10^{-6} = Units conversion factor (kg/mg)

Total water body depth (d_z), suspended sediment and surface water partition coefficient (Kd_{sw}), and total suspended solids concentration (TSS), are described in Section 7.4.1. The overall transfer rate coefficient (K_v) is described in Section 7.4.4.

7.4.4 Overall PB-HAP compound Transfer Rate Coefficient (K_v)

Volatile organic chemicals can move between the water column and the overlying air. The overall transfer rate K_v, or conductivity, is determined by a two-layer resistance model that assumes that two "stagnant films" are bounded on either side by well-mixed compartments. Concentration differences serve as the driving force for the water layer diffusion. Pressure differences drive the diffusion for the air layer. From balance considerations, the same mass must pass through both films; the two resistances thereby combine in series, so that the conductivity is the reciprocal of the total resistance.

EPA (1998)[1] recommends the use of Equation 29 to calculate the overall transfer rate coefficient (K_v).

$$K_v = \left(K_L^{-1} + \left(K_G \cdot \frac{H}{R \cdot T_{wk}} \right)^{-1} \right)^{-1} \cdot \theta^{T_{wk}-293} \qquad \text{(Equation 29)}$$

where

K_v	=	Overall PB-HAP compound transfer rate coefficient (m/yr)
K_L	=	Liquid phase transfer coefficient (m/yr)
K_G	=	Gas phase transfer coefficient (m/yr)
H	=	Henry's Law constant (atm-m^3/mol)
R	=	Universal gas constant (atm-m^3/mol-K)
T_{wk}	=	Water body temperature (K)
θ	=	Temperature correction factor (unitless)

The value of the conductivity K_v depends on the intensity of turbulence in the water body and the overlying atmosphere. As Henry's Law constant increases, the conductivity tends to be increasingly influenced by the intensity of turbulence in water. Conversely, as Henry's Law constant decreases, the value of the conductivity tends to be increasingly influenced by the intensity of atmospheric turbulence.

The liquid and gas phase transfer coefficients, K_L and K_G, respectively, vary with the type of water body. The liquid phase transfer coefficient (K_L) is calculated by using Equations 30A and 30B (described in Section 7.4.5). The gas phase transfer coefficient (K_G) is calculated by using Equations 31A and 31B (described in Section 7.4.6).

Henry's Law constants generally increase with increasing vapor pressure of a PB-HAP compound and generally decrease with increasing solubility of a PB-HAP compound. Henry's Law constants are compound-specific and are presented in Appendix D. The universal ideal gas constant, R, is 8.205×10^{-5} atm-m^3/mol-K, at 20°C. The temperature correction factor (θ), which is equal to 1.026, is used to adjust for the actual water temperature. Volatilization is assumed to occur much less readily in lakes and reservoirs than in moving water bodies.

7.4.5 Liquid Phase Transfer Coefficient (K_L)

EPA (1998)[1] recommends using Equations 30A and 30B to calculate liquid phase transfer coefficient. (K_L).

$$K_L = \sqrt{\frac{\left(1 \times 10^{-4}\right) \cdot D_w \cdot u}{d_z}} \cdot 3.1536 \times 10^7 \qquad \text{(Equation 30A)}$$

$$K_L = \left(C_d^{0.5} \cdot W\right) \cdot \left(\frac{\rho_a}{\rho_w}\right)^{0.5} \cdot \frac{k^{0.33}}{\lambda_z} \cdot \frac{\mu_w}{\rho_w \cdot D_w} \cdot 3.1536 \times 10^7 \qquad \text{(Equation 30B)}$$

where

K_L	=	Liquid phase transfer coefficient (m/yr)
D_w	=	Diffusivity of PB-HAP compound in water (cm^2/s)
u	=	Current velocity (m/s)
1×10^{-4}	=	Units conversion factor (m^2/cm^2)
d_z	=	Total water body depth (m)
C_d	=	Drag coefficient (unitless)
W	=	Average annual wind speed (m/s)
ρ_a	=	Density of air (g/cm^3)
ρ_w	=	Density of water (g/cm^3)
k	=	von Karman's constant (unitless)
λ_z	=	Dimensionless viscous sublayer thickness (unitless)
μ_w	=	Viscosity of water corresponding to water temperature (g/cm-s)
3.1536×10^7	=	Units conversion factor (s/yr)

For a flowing stream or river, the transfer coefficients are controlled by flow-induced turbulence. For these systems, the liquid phase transfer coefficient is calculated by using Equation 30A. For a stagnant system (quiescent lake or pond), the transfer coefficient is controlled by wind-induced turbulence, and the liquid phase transfer coefficient can be calculated by using Equation 30B. The total water body depth (d_z) for liquid phase transfer coefficients is discussed in Section 7.4.1. EPA (1998)[1] recommends the use of the following default values:

- A diffusivity of chemical in water ranging (D_w) from 1.0×10^{-5} to 8.5×10^{-2} cm^2/s;
- A dimensionless viscous sublayer thickness (λ_z) of 4;
- A von Karman's constant (k) of 0.4;
- A drag coefficient (C_d) of 0.0011;
- An air density (ρ_a) of 0.0012 g/cm^3 at standard conditions (temperature = 20°C or 293 K, pressure = 1 atm or 760 millimeters of mercury);
- A water density of(ρ_w) of 1 g/cm^3; and
- A water viscosity(μ_w) of a 0.0169 g/cm-s corresponding to water temperature.

7.4.6 Gas Phase Transfer Coefficient (K_G)

EPA (1998)[1] recommends using Equations 31A and 31B to calculate gas phase transfer coefficient (K_G).

For flowing streams or rivers:

$$K_G = 36{,}500\ m/yr \qquad \text{(Equation 31A)}$$

For quiescent lakes or ponds:

$$K_G = \left(C_d^{0.5} \cdot W\right) \cdot \frac{k^{0.33}}{\lambda_z} \cdot \left(\frac{\mu_a}{\rho_a \cdot D_a}\right)^{-0.67} \cdot 3.1536 \times 10^7 \qquad \text{(Equation 31B)}$$

where

K_G	=	Gas phase transfer coefficient (m/yr)
C_d	=	Drag coefficient (unitless)
W	=	Average annual wind speed (m/s)
k	=	von Karman's constant (unitless)
λ_z	=	Dimensionless viscous sublayer thickness (unitless)
μ_a	=	Viscosity of air corresponding to air temperature (g/cm-s)
ρ_a	=	Density of air corresponding to water temperature (g/cm^3)
D_a	=	Diffusivity of PB-HAP compound in air (cm^2/s)
3.1536×10^7	=	Units conversion factor (s/yr)

EPA (1998)[1] recommends 1.81 x 10^{-4} g/cm-s for the viscosity of air corresponding to air temperature.

7.4.7 Benthic Burial Rate Constant (k_b)

EPA (1998)[1] recommends using Equation 32 to calculate benthic burial rate (k_b).

$$k_b = \left(\frac{X_e \cdot A_L \cdot SD \cdot 1 \times 10^3 - Vf_x \cdot TSS}{A_W \cdot TSS}\right) \cdot \left(\frac{TSS \cdot 1 \times 10^{-6}}{C_{BS} \cdot d_{bs}}\right) \qquad \text{(Equation 32)}$$

where

k_b	=	Benthic burial rate constant (yr^{-1})
X_e	=	Unit soil loss (kg/m^2-yr)
A_L	=	Total watershed area (evaluated) receiving deposition (m^2)
SD	=	Sediment delivery ratio (watershed) (unitless)
Vf_x	=	Average volumetric flow rate through water body (m^3/yr)
TSS	=	Total suspended solids concentration (mg/L)
A_W	=	Water body surface area (m^2)

C_{BS} = Bed sediment concentration (g/cm^3)
d_{bs} = Depth of upper benthic sediment layer (m)
1×10^{-6} = Units conversion factor (kg/mg)
1×10^{3} = Units conversion factor (g/kg)

The benthic burial rate constant (k_b), can also be expressed in terms of the rate of burial (Wb) (Equation 33):

$$Wb = k_b \cdot d_{bs} \qquad \text{(Equation 33)}$$

where

Wb = Rate of burial (m/yr)
k_b = Benthic burial rate constant (yr^{-1})
d_{bs} = Depth of upper benthic sediment layer (m)

EPA (1998)[1] recommends the following default value of 1.0 kg/L for bed sediment concentration (C_{BS}).

Section 7.2 discusses the unit soil loss (X_e). Section 7.3 discusses sediment delivery ratio (SD) and watershed area evaluated receiving PB-HAP compound deposition (A_L). Section 7.4 discusses the depth of the upper benthic sediment layer (d_{bs}). Average volumetric flow rate through the water body (Vf_x) and water body surface area (A_w) are discussed further in EPA (1998).[1] Section 7.4.1 discusses total suspended solids concentration (TSS).

The calculated value for k_b is expected to range from 0 to 1.0; with low k_b values expected for water bodies characteristic of no or limited sedimentation (rivers and fast flowing streams), and k_b values closer to 1.0 expected for water bodies characteristic of higher sedimentation (lakes). This range of values is based on the relation between the benthic burial rate and rate of burial expressed in Equation 33; with the depth of upper benthic sediment layer held constant. For k_b values calculated as a negative (water bodies with high average annual volumetric flow rates in comparison to watershed area evaluated), EPA (1998)[1] recommends assigning a k_b value of 0 for use in calculating the total water body PB-HAP compound concentration (C_{wtot}) in Equation 34 (see next section). If the calculated k_b value exceeds 1.0, re-evaluation of the parameter values used in calculating X_e is recommended to be conducted.

7.4.8 Total PB-HAP compound Concentration in Water Column (C_{wctot})

EPA (1998)[1] recommends using Equation 34 to calculate total PB-HAP compound concentration in water column (C_{wctot}).

$$C_{wctot} = f_{wc} \cdot C_{wtot} \cdot \frac{d_{wc} + d_{bs}}{d_{wc}} \qquad \text{(Equation 34)}$$

where

C_{wctot}	=	Total PB-HAP compound concentration in water column (mg PB-HAP compound/L water column)
f_{wc}	=	Fraction of total water body PB-HAP compound concentration in the water column (unitless)
C_{wtot}	=	Total water body PB-HAP compound concentration, including water column and bed sediment (mg PB-HAP compound/L water body)
d_{wc}	=	Depth of water column (m)
d_{bs}	=	Depth of upper benthic sediment layer (m)

Total water body PB-HAP compound concentration – including water column and bed sediment (C_{wtot}) and fraction of total water body PB-HAP compound concentration in the water column (f_{wc}) – can be calculated by using Equation 34 and Equation 35 (see next section). Depth of upper benthic sediment layer (d_{bs}) is discussed in Section 7.4.1.

7.4.9 Dissolved Phase Water Concentration (C_{dw})

EPA (1998)[1] recommends the use of Equation 35 to calculate the concentration of PB-HAP compound dissolved in the water column (C_{dw}).

$$C_{dw} = \frac{C_{wctot}}{1 + Kd_{sw} \cdot TSS \cdot 1 \times 10^{-6}} \qquad \text{(Equation 35)}$$

where

C_{dw}	=	Dissolved phase water concentration (mg PB-HAP compound/L water)
C_{wctot}	=	Total PB-HAP compound concentration in water column (mg PB-HAP compound/L water column)
Kd_{sw}	=	Suspended sediments/surface water partition coefficient (L water/kg suspended sediment)
TSS	=	Total suspended solids concentration (mg/L)
1×10^{-6}	=	Units conversion factor (kg/mg)

The total PB-HAP compound concentration in water column (C_{wctot}) is calculated by using the Equation 34. Section 7.4.1 discusses the surface water partition coefficient (Kd_{sw}) and total suspended solids concentration (TSS).

7.4.10 PB-HAP compound Concentration Sorbed to Bed Sediment (C_{sb})

EPA (1998)[1] recommends the use of Equation 36 to calculate PB-HAP compound concentration sorbed to bed sediment (C_{sb}).

$$C_{sb} = f_{bs} \cdot C_{wtot} \cdot \left(\frac{Kd_{bs}}{\theta_{bs} + Kd_{bs} \cdot C_{BS}} \right) \cdot \left(\frac{d_{wc} + d_{bs}}{d_{bs}} \right) \qquad \text{(Equation 36)}$$

where

C_{sb}	=	PB-HAP compound concentration sorbed to bed sediment (mg PB-HAP compound/kg sediment)
f_{bs}	=	Fraction of total water body PB-HAP compound concentration in benthic sediment (unitless)
C_{wtot}	=	Total water body PB-HAP compound concentration, including water column and bed sediment (mg PB-HAP compound/L water body)
Kd_{bs}	=	Bed sediment/sediment pore water partition coefficient (L PB-HAP compound/kg water body)
θ_{bs}	=	Bed sediment porosity ($L_{pore\ water}/L_{sediment}$)
C_{BS}	=	Bed sediment concentration (g/cm^3)
d_{wc}	=	Depth of water column (m)
d_{bs}	=	Depth of upper benthic sediment layer (m)

Bed sediment porosity (θ_{bs}) and bed sediment concentration (C_{BS}) are discussed in Section 7.4.1. Depth of water column (d_{wc}) and depth of upper benthic layer (d_{bs}) are discussed in Section 7.4.

7.5 Concentration of PB-HAP compound in Fish (C_{fish})

The PB-HAP compound concentration in fish is calculated using either a PB-HAP compound-specific bioconcentration factor (*BCF*), a PB-HAP compound-specific bioaccumulation factor (*BAF*), or a PB-HAP compound-specific biota-sediment accumulation factor (*BSAF*). For compounds with a $log\ K_{ow}$ less than 4.0, *BCF*s are used. Compounds with a $log\ K_{ow}$ greater than 4.0 (except for extremely hydrophobic compounds such as polycyclic organic matter and PCBs), are assumed to have a high tendency to bioaccumulate, therefore, *BAF*s are used. While extremely hydrophobic PB-HAP compounds are also assumed to have a high tendency to bioaccumulate, they are expected to be sorbed to the bed sediments more than associated with the water phase. Therefore, for polycyclic organic matter and PCBs, EPA (1998)[1] recommends using *BSAF*s to calculate concentrations in fish.

BCF and *BAF* values are generally based on dissolved water concentrations. Therefore, when *BCF* or *BAF* values are used, the PB-HAP compound concentration in fish is calculated using dissolved water concentrations. *BSAF* values are based on benthic sediment concentrations. Therefore, when *BSAF* values are used, PB-HAP compound concentration in fish is calculated using benthic sediment concentrations. The equations used to calculate fish concentrations are described in the subsequent subsections.

7.5.1 Fish Concentration (C_{fish}) from Bioconcentration Factors Using Dissolved Phase Water Concentration

EPA (1998)[1] recommends the use of Equation 37 to calculate fish concentration from *BCF*s using dissolved phase water concentration.

$$C_{fish} = C_{dw} \cdot BCF_{fish} \qquad \text{(Equation 37)}$$

where

C_{fish} = Concentration of PB-HAP compound in fish (mg PB-HAP compound/kg FW tissue)
C_{dw} = Dissolved phase water concentration (mg PB-HAP compound/L)
BCF_{fish} = Bioconcentration factor for PB-HAP compound in fish (L/kg)

The dissolved phase water concentration (C_{dw}) is calculated by using Equation 35.

7.5.2 Fish Concentration (C_{fish}) from Bioaccumulation Factors Using Dissolved Phase Water Concentration

EPA (1998)[1] recommends the use of Equation 38 to calculate fish concentration from *BAF*s using dissolved phase water concentration.

$$C_{fish} = C_{dw} \cdot BAF_{fish} \qquad \text{(Equation 38)}$$

where

C_{fish} = Concentration of PB-HAP compound in fish (mg PB-HAP compound/kg FW tissue)
C_{dw} = Dissolved phase water concentration (mg PB-HAP compound/L)
BAF_{fish} = Bioaccumulation factor for PB-HAP compound in fish (L/kg FW tissue)

The dissolved phase water concentration (C_{dw}) is calculated by using Equation 35.

7.5.3 Fish Concentration (C_{fish}) from Biota-To-Sediment Accumulation Factors Using PB-HAP compound Sorbed to Bed Sediment

EPA (1998)[1] recommends the use of Equation 39 to calculate fish concentration from *BSAF*s using PB-HAP compound sorbed to bed sediment for very hydrophobic compounds (polycyclic organic matter and PCBs).

$$C_{fish} = \frac{C_{sb} \cdot f_{lipid} \cdot BSAF}{OC_{sed}} \qquad \text{(Equation 39)}$$

where

C_{fish} = Concentration of PB-HAP compound in fish (mg PB-HAP compound/kg FW tissue)

C_{sb} = Concentration of PB-HAP compound sorbed to bed sediment (mg PB-HAP compound/kg bed sediment)
f_{lipid} = Fish lipid content (unitless)
$BSAF$ = Biota-to-sediment accumulation factor (unitless)
OC_{sed} = Fraction of organic carbon in bottom sediment (unitless)

The concentration of PB-HAP compound sorbed to bed sediment (C_{sb}) is calculated by using Equation 36. EPA recommended default values for the fish lipid content (f_{lipid}) and for the fraction of organic carbon in bottom sediment (OC_{sed}) are given in EPA (1998).[1]

Values for the fraction of organic carbon in bottom sediment recommended by EPA (1993b)[11] range from 0.03 to 0.05 (Oc_{sed}). These values are based on an assumption of a surface soil OC content of 0.01. This document states that the organic carbon content in bottom sediments is higher than the organic carbon content in soils because (1) erosion favors lighter-textured soils with higher organic carbon contents, and (2) bottom sediments are partially comprised of detritus materials.

The fish lipid content (f_{lipid}) value is site-specific and dependent on the type of fish. As stated in EPA (1998)[1], a default range of 0.03 to 0.07 is recommended specific to warm or cold water fish species. EPA (2000)[33] provides information supporting a value of 0.03 (3 percent lipid content of the edible portion). EPA (1993a)[34] recommended a default value of 0.04 for OC_{sed}, which is the midpoint of the specified range. EPA (1993b; 1993a)[11][34] recommended the use of 0.07, which was originally cited in Cook et al. (1991).[35]

8.0 Concentrations of Dioxins in Breast Milk

EPA (1998)[1] recommends the use of Equation 40 to estimate the concentrations of dioxins in breast milk.

$$C_{milkfat} = \frac{m \cdot 1 \times 10^9 \cdot h \cdot f_1}{0.6932 \cdot f_2} \qquad \text{(Equation 40)}$$

where

$C_{milkfat}$ = Concentration of dioxin in milk fat of breast milk for a specific exposure scenario (pg dioxin/kg milk fat)
m = Average maternal intake of dioxin for each adult exposure scenario (mg dioxin/kg BW-day)
1×10^9 = Units conversion factor (pg/mg)
h = Half-life of dioxin in adults (days)
f_1 = Fraction of ingested dioxin that is stored in fat (unitless)
f_2 = Fraction of mother's weight that is fat (unitless)

The values of m, h, f_1, and f_2 are site-specific and dependent on the specific species of dioxin present. EPA (1998)[1] recommends a default value of 2,555 days for h, a default value of 0.9 for f_1, and a default value of 0.3 for f_2 . Additional references for the derivation of this equation and these default values are given in EPA (1998).[1]

Uncertainties associated with this equation include:

- The most significant uncertainties are associated with the variable *m*. Because *m* is calculated as the sum of numerous potential intakes, estimates of *m* incorporate uncertainties associated with each exposure pathway. Therefore, *m* may be under- or over-estimated.

- This equation assumes that the concentration of dioxin in breast milk fat is the same as in maternal fat. To the extent that this is not the case, uncertainty is introduced.

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RUSH

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

SUBJECT: Subpart O - Ethylene Oxide Commercial Sterilization Plant Explosions

FROM: for John Seitz, Director OAQPS Henry Thomas

TO: See Addressees

On June 13 and July 5 explosions occurred at two ethylene oxide plants, one in Virginia and one in Massachusetts. In addition, an explosion occurred June 24 at a facility in Indiana where one worker was killed and 69 other persons were injured. The explosion at the Indiana facility is under investigation by the Chemical Accident Investigation Team of the Chemical Emergency Preparedness and Prevention Office (CEPPO) in conjunction with Region 5 and the State Occupational Safety and Health Administration (OSHA). Apparently, these facilities are not the only ones which have had explosions since promulgation of Subpart O on December 6, 1994. While the causes of these explosions are not yet precisely known, these facilities were using combustion control units to control emissions. It is possible these units could be a factor in these incidents. We alerted the Regional Air Toxic Coordinators on July 16 of this situation.

I recommend the following immediate course of action. Regional Offices/States should inform all ethylene oxide facilities of the recent incidents and the potential safety problem. If possible, they should compile the type of control units plants are using or installing to comply with the standards and let us know as soon as possible. As part of this communication, we recommend you inform the facilities that if they have a safety concern they may disconnect the control units immediately in the short term. Compliance with Subpart O is not required until December 8, 1997. In the meantime, we will develop options to ensure that facilities will not be required to operate combustion control units until EPA can determine that it is safe to do so; such options could include modifying the compliance date, if necessary. I do not want the Subpart O December 8, 1997 compliance date potentially compromising safety.

We will work with all stakeholders to share information about the causes of these incidents, to resolve safety concerns and to enable the plants to ultimately comply with the requirements of the standards. Industry representatives will provide, within the next few days, a list of facilities which have had explosions or difficulties operating new controls systems. I'll forward this information to you as soon as we receive it. If you have any questions regarding the emissions requirements please call David Markwordt, at 919-541-0837. If you have any questions about the accident investigations, please call Craig Matthiessen at 202-260-9781.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
EMISSION STANDARDS DIVISION
RESEARCH TRIANGLE PARK, NC 27711

September 23, 2005

MEMORANDUM

SUBJECT: Residual Risk Assessment for the Ethylene Oxide Commercial Sterilization Source Category

FROM: Mark Morris /signed/
Risk and Exposure Assessment Group (C404-01)

TO: Dave Guinnup, Group Leader
Risk and Exposure Assessment Group (C404-01)

1.0 Introduction - The Residual Risk Program

Section 112(d) of the Clean Air Act (CAA) requires EPA to set technology-based national emissions standards for hazardous air pollutants (NESHAP). These standards are based on the maximum achievable control technology (MACT) for the source category and are sometimes referred to as "MACT standards." The MACT standards for existing sources are based (at a minimum) on average emissions control levels achievable by the best controlled 12 percent of sources in the category. The MACT standards do not consider whether the emission controls reduce risks from the source category to an acceptable level.

Section 112(f) of the CAA directs EPA to evaluate the health and environmental risks remaining after technology-based standards have been promulgated (i.e., residual risks) and requires more stringent regulation if existing standards do not meet certain criteria. Specifically, its focus is to protect the public health with an "ample margin of safety," while also ensuring that "taking into consideration costs, energy, safety, and other relevant factors," residual emissions do not result in "an adverse environmental effect." The CAA defines "adverse environmental effect" as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

The residual risk assessment is performed by EPA as part of the residual risk rule development process, which is generally completed within eight years of the promulgation of

MACT standards. The EPA's 1999 Residual Risk Report to Congress provides more information on the general framework and methods for conducting residual risk assessments. This memo describes the methods and results of the residual risk assessment for the ethylene oxide (EtO) commercial sterilization source category.

1.1 Overview of Risk Assessment Methods

The 1994 National Research Council (NRC) report, *Science and Judgment in Risk Assessment*, and the 1997 Commission on Risk Assessment and Management (CRARM) report, *Framework for Environmental Health Risk Management*, provide recommendations concerning residual risk assessment. Among the recommendations in these two reports is the use of an iterative, or tiered, approach to residual risk assessment. At lower tiers, facilities in a given source category are screened using relatively generic conservative assumptions, and at higher tiers, more site-specific information is used, leading to a more accurate picture of risk. The Residual Risk Report to Congress describes the approach to risk assessment being implemented by EPA in response to the NRC and CRARM recommendations.

In both human health and ecological risk assessments, there is essentially a continuum of possible levels of analysis from the most basic screening approach to the more refined, detailed assessment. Screening level analyses are designed to be relatively simple, inexpensive, and quick. They use existing data, defined decision criteria, and models with simplifying conservative assumptions as inputs. More refined levels of analysis include the refinement of aspects of the analysis that are thought to influence risk most or may contain the greatest uncertainty. Refinements can be made through the use of more sophisticated models and by replacing defaults with more precise estimates. Each refinement requires more effort, but produces results that are less uncertain and less conservative (i.e., less likely to overestimate risk). Under residual risk, an assessment starts at the level considered most appropriate upon examination of the available information during the scoping or problem formulation phase; refined iterations of the assessment occur when necessary.

In residual risk assessments, numerical estimates of the potential for adverse impacts to people are calculated for two categories of adverse health effects:

- Risk of developing cancer
- Potential for developing adverse health effects other than cancer (e.g., reproductive effects) or for cancer if a nonlinear/threshold mode of action is established

To derive estimates of risk, quantitative information on exposure is combined with information on dose-response. This process is typically different for cancer and other effects due to the

underlying assumption that cancer is a nonthreshold phenomenon[1] and that thresholds exist for adverse health effects other than cancer.

For inhalation exposures to carcinogens, individual risk, or the increased lifetime probability of developing cancer as a result of a lifetime of exposure to a HAP, is derived by multiplying the estimated exposure concentration by the cancer unit risk estimate (URE). The URE represents an upper bound of the increased risk of developing cancer for an individual exposed continuously for a lifetime (e.g., 70 years) to a specific concentration (e.g., 1 µg/m3) of that HAP in the air.

For ingestion exposures, the toxicity benchmark, the oral cancer slope factor (CSFo), is used with the appropriate exposure factors (e.g., lifetime, exposure duration, body weight and consumption rate) and media concentrations to arrive at the individual risk from ingestion.

The potential for chronic noncancer effects through inhalation is evaluated by comparing an estimate of the lifetime exposure concentration with an inhalation toxicity benchmark called the reference concentration (RfC). The potential for noncancer effects from ingestion exposures is evaluated by comparing average exposure levels with an oral toxicity value called the reference dose (RfD). The RfC and RfD represent estimates (with uncertainty spanning perhaps an order of magnitude) of daily exposure of the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Values similar to EPA's RfC and RfD (e.g., MRLs derived by the ATSDR) are used where RfC or RfD values are unavailable.

The hazard quotient (HQ), used to express the potential hazard of noncarcinogens to human health, is a ratio of exposure to the toxicity benchmark. It is commonly calculated and used as a surrogate indicator of noncancer risk. Hazard quotient values less than or equal to 1 indicate that exposures are below the RfC or RfD and not likely to cause adverse effects. Hazard quotient values greater than 1 indicate that the potential for adverse effects is increased; however, the HQ should not be interpreted as a probability.

The hazard index (HI), which is the sum of more than one hazard quotient, addresses multiple risks from several chemicals and is the sum of HQ values for individual pollutants to which an individual is exposed. As an initial screen, all individual HQ values can be added. In a more refined analysis, the aggregation of the HQ values is considered on the basis of toxicological similarity, or similarity of target organs among specific chemicals.[2]

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[1] While recognized by the 1986 Guidelines for Carcinogen Risk Assessment, the current Interim Guidelines (USEPA 1999, 2001) more explicitly recognize the potential for the acceptance of a nonlinear or threshold mode of action for cancer. Accordingly, there may be some substances (e.g., chloroform) for which an RfC/RfD is relied on for cancer as well as other effects.

[2] This approach is consistent with the US EPA's 1986 Mixtures Guidelines (U.S. EPA, 1986c) and Supplemental Guidance (USEPA, 2000).

The potential for acute effects through inhalation is evaluated by comparing an estimate of the short-term (1-hour) exposure concentration with available relevant acute reference values.

2.0 Background - Commercial Ethylene Oxide Sterilizers and Fumigators

The commercial EtO sterilizers and fumigators source category covers the use of EtO as a sterilant or fumigant. Commercial sterilization facilities use EtO as a sterilant for heat- and moisture-sensitive products and as a fumigant to control microorganisms or insects. EtO is used to sterilize or fumigate medical equipment (e.g., syringes and surgical gloves), spices, pharmaceuticals, and cosmetics. Libraries and museums also use EtO to fumigate books and other historical items. The MACT standards apply to all of these kinds of uses, with the following exceptions:

- Beehive fumigators;
- Research and laboratory facilities, as defined in section 112(c)(7) of the Act; and
- Medical facilities such as hospitals, doctor's offices, clinics, or other facilities whose primary purpose is providing medical services to humans or animals.

Commercial EtO sterilization encompasses two main types of processes: (1) bulk sterilization and (2) single-item sterilization. For the single-item sterilization procedure, items are placed in a plastic pouch, sterilant gas is injected into the pouch, and the sealed pouch is placed in an aeration cabinet or room for sterilization. Single-item sterilization processes generally use far less than 1 ton of EtO per year per facility. Facilities that use less than 1 ton of EtO per year are only subject to minimal recordkeeping under the MACT standards.

Bulk sterilization is by far the more commonly used EtO sterilization process (i.e., more items sterilized). Using this process, products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas (EtO) at a predetermined temperature, humidity level, and pressure. The typical sterilization cycle consists of six phases:

1. **Presterilization conditioning.** After the products have been loaded into the chamber, a partial vacuum is created. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable gas mixtures are used, the removal of air reduces the potential for ignition. The chamber temperature and humidity also are adjusted during this phase to ensure proper sterilization.
2. **Sterilization.** The EtO, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration. The chamber pressure is maintained for about 4 to 6 hours.
3. **Evacuation.** Following sufficient exposure time, the EtO gas is evacuated from the chamber with a vacuum pump. This postcycle vacuum phase typically lasts about 10 minutes.
4. **Air wash.** The pressure in the chamber is brought to atmospheric pressure by introducing either air, nitrogen, or CO_2. The combination of evacuation and air

wash phases is repeated from two to four times to remove as much of the EtO from the product as possible.

5. **Chamber exhaust.** Prior to unloading the products from the sterilizer, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust is a worker safety system that is responsible for removing EtO from the void space in the sterilizer chamber.
6. **Aeration.** Following their removal from the sterilization chamber, the sterile products are placed in an aeration room and kept there for several hours or days depending on the product. EtO concentrations in the aeration room are maintained at relatively low levels by ventilating the room at a rate of about 20 air changes per hour.

EtO is released during the sterilization cycle from the following primary sources:

- Sterilization chamber vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
- Sterilization chamber vacuum pump drain;
- Chamber exhaust vent(s); and
- Aeration room vent(s).

The MACT standards cover both area and major sources. Major sources are sources that emit 10 or more tons per year (tpy) of any regulated hazardous air pollutant (HAP) or 25 or more tpy of any combination of HAPs. Area sources, or "nonmajor sources," are sources that do not exceed these limits. The emission reductions and limits set forth in the MACT standards are presented in Table 1.

Table 1. Commercial Sterilization MACT Standards

	Emission Standards		
Source Size (annual EtO usage)	Sterilization Chamber vent	Aeration room vent	Chamber exhaust vent
Usage < 1 ton	No control required; minimal recordkeeping requirements only		
1ton ≤ Usage < 10 tons	99% emission reduction	No control	No control
Usage ≥ 10 tons	99% emission reduction	1 ppmv maximum outlet concentration or 99% emission reduction	No control

3.0 Methods

3.1 Scope

Facilities – The residual risk program covers all facilities covered by the MACT standards. However, evaluating the residual risks is only mandatory for major sources and is discretionary for area sources. Both major and area sources were included in this assessment.

Emission sources – All emission points associated with a source category are covered under the residual risk program regardless of whether controls were established under the MACT program. For this source category, all EtO emission points were covered under the MACT and are included in this analysis.

Hazardous Air Pollutants – EtO is the only HAP released by sources in this source category.

Pathway – EtO is a gaseous volatile organic compound. The inhalation pathway is expected to be the primary route of exposure for humans, and the assessment of human health risks via inhalation was the focus of this analysis. Some HAPs which are persistent and bioaccumulative can also pose human health risks via pathways other than inhalation (e.g., by depositing to the ground and entering the food chain). The EPA has developed a list of persistent, bioaccumulative, and toxic (PBT) HAPs based on information from the Pollution Prevention program, the Great Waters program, the Toxics Release Inventory (TRI), and additional analysis conducted by the Office of Air Quality Planning and Standards.[3] Ethylene oxide is not on the list of PBTs. Consequently, we believe the non-inhalation risks to be minimal for this source category, and we conclude that a quantitative risk assessment for multipathway exposures is unnecessary.

Receptor (exposed population) – The residual risk program is concerned with general population exposure associated with ambient releases. Consequently, it is focused on long-term (chronic) and short-term (acute) exposures beyond the fenceline. The EPA is also required to consider adverse impacts to the environment (e.g., ecological risks) as a part of a residual risk assessment. Regarding the inhalation exposure pathway for terrestrial mammals, we contend that human toxicity values for the inhalation pathway are protective of terrestrial mammals. Because EtO is not considered to be persistent and bioaccumulative, we expect risks to mammals via ingestion routes and risks to non-terrestrial animals to be insignificant. Therefore, we conclude that a quantitative ecological risk assessment is unnecessary for this source category.

Endpoints – This risk assessment addressed both cancer and effects other than cancer associated with chronic exposures and non-cancer effects associated with acute or short-term

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[3] Air Toxics Risk Assessment Reference Library, Volume 1. EPA-453/K-04-001A. U.S. Environmental Protection Agency. April 2004.

exposures

3.2 Source Category Characterization

Several sources of data were reviewed for this risk assessment, including the National Emissions Inventory (NEI) point source database, the Toxics Release Inventory (TRI), the Ethylene Oxide Sterilization Association (EOSA), MACT compliance reports, and Title V permits. A total of 76 commercial EtO sterilizer sources were identified.[4] Previous lists of commercial EtO sterilizer sources included approximately 120 sources, but some of these sources subsequently have been found not to be in this source category, are no longer operating, or are duplicates of other sources. There are also many sources that were on previous lists based on older TRI or NEI data that were not in the 2000 TRI. Some of these facilities may still be operating but do not appear in the TRI because they use less than the 10,000 pound (5 ton) reporting threshold amount of EtO. Considering the TRI threshold, we conclude that we have identified all major sources and many of the area sources (sources that use less than 10 tpy). Therefore, we believe that our data is representative of the source category.

Information needed to support the risk assessment include the following:

- Facility location (latitude and longitude);
- Urban/rural classification;
- Emission rate (kilograms/year);
- Exit gas temperature (degrees Kelvin);
- Vent type (vertical or non-vertical);
- Point source stack height (meters);
- Cross-sectional area of nearby building contributing to building downwash (m^2);
- Point source stack diameter (meters);
- Point source exit velocity (meters/second);
- Fugitive source release height (meters); and
- Area of fugitive emissions (m^2).

3.2 Post-MACT Emissions

Post-MACT mass emission rates were available for each of the 76 facilities,[5] but we do not know specifically how emissions were estimated for most sources. The MACT standards do not require continuous emissions monitoring; they require an initial control device performance test and continuous monitoring of control device operating parameters to ensure the device is operating properly. Without continuous emissions monitoring data, the only way to estimate

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[4] A. Koppel, J. Laurenson, M. Fisher and D. Burch, ICF, to M. Morris and D. Markwordt, EPA. *Data and assumptions used for the screening-level residual risk analysis of the commercial ethylene oxide sterilizers and fumigators source category.* July 2004.

[5] A. Koppel, *op. cit.*

emissions is using process knowledge of how much EtO goes through the main vent, rear chamber exhaust, and aeration room vent, and considering the respective MACT control requirements for these emission points.

Background information for the MACT standards indicates that approximately 95% of the EtO goes through the main vent, 1% through the rear chamber exhaust, and 4% through the aeration room vent.[6] Knowing these percentages and considering the emission reductions required by the standards (or achieved in excess of the standards), overall emissions can be estimated. We presume that the emissions included in the emissions inventories and the data supplied by the industry were estimated in this way, and we believe this mass-balance methodology is appropriate for this source category because the sterilization process is relatively simple, EtO is the only HAP, and no chemical transformation occurs during the process.

The relative attribution of emissions discussed above is approximate and varies by source. For example, a source that does more air washes may have more than 95% of the EtO going through the main vent and less than 1% exiting the rear chamber exhaust. Also, products vary in the amount of EtO they retain. For example, a source sterilizing spices may have a higher proportion of EtO going through the aeration room vent because spices tend to retain more EtO than medical products. We conclude that these process variations would not bias the risk assessment. A facility that does more air washes might have lower emissions because the main vent is controlled but the rear chamber exhaust is not. An area source that sterilizes a product that retains a relatively high proportion of EtO may have higher emissions because less of the EtO goes through the main vent and more goes through the aeration room vent, which is not required to be controlled for area sources.

Information on the annual amount of EtO used in commercial sterilization (approximately 4,000 tons)[7] supports our emissions data. Approximately 99 percent of EtO goes through the main vent and aeration room vent, and 1 percent through the rear chamber exhaust. Using the total industry usage amount and applying 99 percent MACT control to the main and aeration vents yields approximately 40 tpy. Combined with the 1 percent, or 40 tpy, from the rear chamber exhaust, the total emissions based on source category usage are about 80 tpy. This compares well with the 82 tpy from our database. This comparsion does not address the accuracy of the emissions estimate of an individual facility, but it does support our estimate for the entire source category.

Acute emissions estimates – For this source category, a small source (about one ton per

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[6] *Ethylene Oxide Emissions From Commercial Sterilization/Fumigation Operations - Background Information Document for Proposed Standards.* EPA-453/D-93-016. U.S. Environmental Protection Agency. October 1992.

[7] K. Steilen, Ethylene Oxide Sterilization Association, to D. Markwordt. *NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations.* June 1998.

year of usage) that has no control requirements under the MACT standards would create a worst-case short-term exposure scenario similar to a large source, which can emit up to 10 tpy after control. The emissions from this source category are directly related to the amount of EtO used. Approximately 99 percent (uncontrolled) of the EtO used is emitted from the main vent and aeration room vent, and these emissions are required to be reduced by 99 percent for all sources using more than 10 tpy of EtO per year. The remaining 1 percent of EtO is emitted from the rear chamber exhaust, which is not required to be controlled at any source.

Considering the usage breakdown described in the previous paragraph, the largest user of EtO in the source category (500 tpy) would have main vent and aeration room vent emissions of approximately 5 tpy. The rear chamber exhaust emissions would also be 5 tpy. The emissions from large sources are essentially continuous because such sources are typically operated with multiple sterilization chambers, with one or two at a time routing EtO to a control device. Therefore, the 10 tons of total emissions from the largest user would be approximately 2 pounds per hour. However, if we are conservative and assume that the emissions are not continuous but instead occur only two hours per day, the total hourly emissions could be as high as 30 pounds.

We estimate that a small source emitting one ton per year would create a higher short-term exposure than a larger source because sources that use less than 1 tpy are not required to control emissions and are likely to operate a single chamber in a batch mode. The highest expected charge of EtO into a chamber at a small source is 40 pounds.[8] At 40 pounds per charge, a 1-tpy source would charge about once per week and, for the purposes of the acute assessment, the entire amount is assumed to be released in 1 hour. Since the 40 pounds per hour estimated to be emitted from a small source exceeds the 30 pounds per hour estimated to be emitted from the largest source in the source category, we based our short-term exposure scenario on a small source. The only reasonable case where a large source could create a higher short-term exposure than a small source would be control device failure. However, the large source does not have to release the EtO in the chamber until the control device is repaired, and even if it had to be released, it could be released slowly.

3.2.2 Source Release Characteristics

Data on source release characteristics (e.g., release height, exit velocity, stack gas temperature) were available for about half of the facilities. Where actual data were not available, a number of assumptions were used to fill data gaps.[9]

Stack Height – Approximately 80% of the facilities were missing release height data for their fugitive emissions, and 60% were missing data for point (or vertical) emissions. For

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[8] J. Hadley, Ethylene Oxide Sterilization Association, to D. Markwordt, EPA. Section 112(f) "what ifs." February 2004.

[9] A. Koppel, *op. cit.*

fugitive release height, we used 75 percent of the height of the average known EtO building to simulate a combination of windows, side-vents, and roof vents. For stacks, we adopted the NEI default of 12 m, which is almost identical to (less than 1 m higher than) the average height of the known EtO stacks.

Area – Approximately 90% of the facilities needed area data for fugitive emissions, and 60% needed data for vertical emissions. For fugitive (or non-vertical) emissions, this is the area of the release, such as impoundment or cumulative vent areas. For vertical emissions, area refers to the vertical (or wind normal) cross-sectional area, or height by width, of the building. The NEI did not contain default values for area. Therefore, for unknown fugitive releases, we estimated a minimum of 20 vents x 5 m^2/vent = 100 m^2 to a maximum of 500 m^2. Most of the area data provided by industry for fugitive emissions appeared to be for building area, not for vent opening area. Therefore, we used the default vent area for fugitive emissions unless otherwise indicated. For unknown vertical emissions area, we used the average of the known height and width (17 facilities had heights; 12 had lengths/widths), or 7.3 m x 74 m = 540 m^2. For facilities that provided horizontal dimensions but not height, we assumed 7.3 m height and the square root of the area for width. If the building area reported for fugitive emissions for a given facility is larger than the area provided for the vertical emissions for that facility, we used the fugitive emissions building area based on the assumption that this building is close to the vertical source such that it dominates the downwash effect for the vertical emissions. Also, per HEM-Screen guidance, we used the largest area to represent the facility even if the building with the stack had a smaller area.

Stack Diameter – This parameter was not used for fugitive emissions, and about 50% of the facilities needed diameter for stacks. The NEI used a default of 1.2 m for stacks, which was similar to the known EtO stacks and thus adopted for this analysis.

Gas Exit Velocity – This parameter was not used for fugitive emissions, and approximately 25% of the facilities needed velocity for stacks. The NEI has a default for general stacks of 4.6 m/s, but 6.8 m/s was used instead for this analysis because it appeared to be the actual NEI default used for EtO facilities. This value is also closer to the average for the known EtO facilities (10 m/s). Supplied data had several mistakes (impossibly high velocities) that had to be corrected. We used data indicating that the exit velocity of the gas must be less than 400 ft/sec (Kumar, 1997). When a data source reported a gas exit velocity of greater than 400 (with or without units), we assumed that the value was reported in ft^3/min and thus converted the value to m/s by (1) dividing by the area of the stack opening (assuming a perfect circle), (2) dividing by 60 to convert minutes to seconds, and (3) converting English units to metric as appropriate.

Gas Exit Temperature – Approximately 95% needed temperature for fugitive, and approximately 50% needed it for stacks. The NEI used ambient temperature as the default for fugitive sources and 162 degrees F as the default for stack, which were thus used here.

The specific release characteristics for each of the 76 facilities used in this assessment can be

found in a separate memorandum.[10]

3.2.3 Environmental Setting

Data on the location of facilities and/or emissions points were available for all facilities. These locations were confirmed using aerial photographs of facilities based on address. The classification of the setting as rural or urban is required for dispersion modeling and is rarely identified by existing data sources, so we examined a map of the location of each facility and conducted a qualitative determination about the surrounding structure and asphalt density (based on a simplified version of EPA's definitions of urban and rural in Guideline on Air Quality Models (40 CFR Part 51, Appendix W)).

Discussion of models, data and assumptions associated with source characterization

The database of facilities is thorough, including all facilities in the TRI at the time of data collection. Considering the TRI reporting threshold of 10,000 pounds per year (5 tpy), we conclude that the database includes all major sources (EtO use ≥ 10 tpy) and a significant number of area sources (EtO use < 10 tpy), particulary the higher-emitting area sources.

We also conclude that the emissions estimates are of high quality. Although we are not certain of the methods of emissions estimation in most cases (the MACT standards do not require continuous emissions monitoring), it is likely that emissions were estimated using a mass-balance approach. This approach is appropriate for this source category because the sterilization process is relatively simple, EtO is the only HAP, and no chemical transformation occurs during the process. The sum of the emissions for each facility in the database compares well (within 3 percent) to an emissions estimate based on mass balance and the known usage of EtO by the entire industry. While this comparison does not address the accuracy of the emissions estimate of an individual facility, it does support our estimate for the entire source category.

Source release parameters were available for some facilities from the NEI and from the industry. In cases where no data were available, we used defaults that were based on the data that were available. The use of defaults introduces uncertainties into modeling and calculating risks because the default values may not represent the actual conditions at a source. However, we conclude that there would be no bias introduced by the defaults because the actual values could be higher or lower than the default values. Facility location data were available from the TRI and NEI. Actual emission point locations could vary from these, but we conclude that it would not introduce bias because the actual locations may be nearer or farther from the receptor.

3.3 Environmental Fate and Transport Modeling

As discussed above, EtO is a gaseous volatile organic compound which is not expected to

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[10] A. Koppel, *op. cit.*

be persistent or bioaccumulative. Therefore, this assessment focuses on the estimation of ground-level air concentration. We conducted two separate dispersion modeling activities to address chronic long-term exposures and acute short-term exposures.

3.3.1 Dispersion Modeling for Chronic Exposures

We selected the EPA Human Exposure Model - Screen (HEM-Screen)[11] for the chronic portion of the residual risk assessment. The HEM-Screen model contains (1) an atmospheric dispersion model with meteorological data, and (2) U.S. Bureau of Census population data for 2000 at the census block level. The number of people within a census block varies, but averages about 40 people.

The HEM-Screen's dispersion model is a Gaussian model (based on the Industrial Source Complex Long Term model, ISCLT2) that has been simplified to improve computational efficiency. Necessary source-related inputs include map coordinates, release heights, exit velocities, stack diameters, temperatures, and annual emission rates. For simplicity, all of the emissions from a source were assumed to originate from a single point (the centroid of the plant site). For this source category, this assumption is not likely to introduce significant uncertainty because the emission points are typically located in the same building or in adjacent buildings.

Specifying the latitude and longitude of the source in HEM-Screen calls the stability array (STAR) summary from the nearest meteorological station for use in the dispersion algorithm. The STAR data are standard climatological frequency-of-occurrence summaries formulated for use in EPA models (obtained from the National Climatic Center, Asheville, NC). A STAR summary is a joint frequency-of-occurrence of wind speed, atmospheric stability, and wind direction, reflecting 5 years of data for 348 U.S. sites. The model produces polar coordinate receptor grid points consisting of 10 downwind distances (extending from 100 or 200 meters to 50 kilometers[12]) located along each of 16 radials. The dispersion model estimates ambient ground-level concentrations for each of the 160 receptor locations on this grid. The model estimates the annual average concentration at these receptor locations which are then used to interpolate for specific locations of an exposed population. The model, therefore, supports the estimation of a maximum off-site ground-level concentration in addition to concentrations specific to an exposed population.

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[11] Supporting documentation is available through the EPA OAQPS *Human Exposure Modeling - Human Exposure Model (HEM)* website at: http://www.epa.gov/ttn/fera/data/human/hemusers-new.pdf.

[12] Fifty kilometers is the nominal distance to which EPA considers most steady-state Gaussian plume models, such as ISCLT2, to be applicable.

We also used a more refined model, HEM-3[13], to model facilities with individual lifetime cancer risk estimates greater than 50 in a million from the HEM-Screen modeling. The HEM-3 model is similar to HEM-Screen in that it is a steady-state Gaussian plume model, but it has some significant differences. The main differences between HEM-3 and HEM-Screen that are relevant to the assessment performed for this source category are:

- HEM-3 estimates cancer risks and exposures, as well as acute and chronic noncancer risks and exposures. HEM-Screen focuses mainly on cancer risks and exposures;
- HEM-3 uses the Industrial Source Complex Short Term model, ISCLT3, and hourly meteorological data whereas HEM-Screen uses ISCLT2 and the frequency-of-occurrence data described above; and
- Both HEM-3 and HEM-Screen calculate risks for individual census blocks, but the two models use different methods for the blocks closest to the facility. The HEM-3 model estimates pollutant concentrations at the census block centroid, whereas HEM-Screen interpolates between receptors on the polar grid to estimate concentration at census block centroids.

In most cases, fenceline data were not available for this source category. Therefore, we used 100 meters as a default value for the first downwind distance at which we modeled ground-level concentrations for the chronic portion of the risk assessment. We have data indicating that fenceline distances for some sources are shorter than 100 meters, which may affect the estimation of maximum offsite concentration. However, the distance to residences (specifically, census block centroids) is the relevant distance for the chronic risk assessment. Attachment 1 shows the effect of the first downwind receptor distance on maximum individual lifetime cancer risk. There are only three facilities where the highest risk occurs at a different census block when the first downwind distance is 20 meters instead of 100 meters, and the risk is not significantly different in these cases. Therefore, 100m as the first downwind receptor distance is reasonable and unlikely to significantly underestimate chronic exposure concentrations or risks.

Discussion of models, data, and assumptions associated with air quality modeling

The use of HEM-Screen and HEM-3, as used for this risk assessment, introduces uncertainties into the results of the assessment. The models include assumptions regarding model algorithms, meteorology, geography, deposition, chemical fate and transport, terrain and building downwash effects, and other components of the models, and there are uncertainties inherent in those assumptions. In the models, meteorologic data are pulled from the built-in set of data for the weather station nearest the source. These data may not be representative of the weather in the area around the source if the weather station is far away or if there are deviations in the weather pattern estimates from the site-specific patterns. Fate and transport characteristics

[13] Supporting documentation is available through the EPA OAQPS *Human Exposure Modeling - Human Exposure Model (HEM)* website at: http://www.epa.gov/ttn/fera/data/hem/hem3_users_guide.pdf

are assumed to be the same for all HAPs (e.g., no chemical transformation to more or less toxic substances; all chemicals assumed to disperse in the same way) and all HAPs are modeled as gases (e.g., no accounting for deposition of pollutants). We do not believe that these assumptions introduce significant uncertainty in this assessment because EtO is a volatile gas that is unlikely to deposit, the half-life in air is long enough (days) so as not to affect modeled concentrations within 50 kilometers of a source, and even if some transformation occurs, the reported transformation products (including formaldehyde and acetaldehyde) either are not HAPs or are less toxic than EtO. More discussion on the limitations of HEM-Screen can be found in a separate memorandum.[14]

A number of studies have been conducted to examine model accuracy, and these studies indicate that: (1) Models are more reliable for estimating longer time-averaged concentrations than for estimating short-term concentrations at specific locations; and (2) the models are reasonably reliable in estimating the magnitude of highest concentrations occurring sometime, somewhere within an area.[15] Errors in highest estimated concentrations of ±10 to 40 percent are typical and well within the factor-of-two accuracy that has long been recognized for these models.

3.3.2 Chronic Exposure Estimation

The estimated annual average concentration at a person's residential location is used as a first approximation or surrogate for their exposure. This is based on the assumption that people spend a majority of their time at home. It is also assumed that the ambient concentration is a surrogate for their exposure and is based on evidence that for many pollutants the long-term indoor concentration closely approximates that found indoors due to penetration and ventilation.

The census data used in HEM-Screen and HEM-3 are at the census block level, which is the smallest defined population unit available. For assessment of population exposures using HEM-Screen and HEM-3, all people within a block are assumed to reside at the centroid of the block (i.e., the area-weighted geographical center of the block). The census block centroid location was used as a surrogate for actual receptor locations and should not bias the results of the assessment because actual residences may be closer to or farther from the source relative to the census block centroid.

<u>Discussion of models, data, and assumptions associated with chronic exposure modeling</u>

In using HEM-Screen and HEM-3, a major assumption of this analysis is that modeled

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[14] *Using the Human Exposure Model (Version 2000) for Residual Risk Tests and Other Risk Screening Assessments.* Memorandum to Maria Pimentel, U.S. Environmental Protection Agency, from Darcie Smith and Phil Norwood, EC/R Incorporated. September 2003.

[15] 40 CFR Part 51, Appendix W.

ambient concentrations at the residential census block centroid are an adequate surrogate for long-term individual exposures. Indoor concentrations of EtO emitted from these facilities will be lower than outdoor levels, as EtO is a relatively reactive pollutant. However, the extent to which these levels are lower depends on a variety of factors, such as the degree and type of ventilation (e.g., air conditioning vs. open windows) and the type of indoor environment (e.g., schools versus residences). Ideally, we would like to model individuals as they move through their communities and undertake different activities, but such modeling is time- and resource-intensive and can only capture a portion of the uncertainty associated with the full range of human activities. Exposure modeling performed as part of the 1999 National Air Toxics Assessment indicates that (at the census tract level) exposure concentrations may be 10 to 15 percent lower than ambient exposure concentrations. In general, we can expect long-term exposures will be overstated for high-end estimates (as most individuals will not spend all their time at their highly affected residences), but may understate the total population exposed (as some individuals living outside the modeled area may regularly commute into the area for work or school).

When looking at long-term, or even lifetime, exposures, it should be noted that relatively few people in the United States reside in one place for their entire lives. For the purposes of this assessment, cancer risk estimates are based on a lifetime exposure at the 2000 census-identified place of residence. While it is impossible to know how this assumption affects the risk experienced by an particular individual (as people can move into higher- or lower-risk areas), we expect this assumption will overstate the exposure to those most exposed (i.e., people already living in high exposure areas are unlikely to move to yet higher exposure areas). However, this assumption will also tend to underestimate the total number of people exposed and population risk (i.e., "incidence") because population levels are generally increasing.

Finally, not all individuals experience the same degree of exposure or internal dose of a given pollutant due to individual-specific parameters such as weight, gender and age. While the health benchmarks used in the analysis crudely account for sensitive populations, a prototypical human (e.g., body weight, ventilation rate) is used to define the benchmark. Because of the variability of these parameters in the population, this factor will result in a degree of uncertainty in the resulting risk estimate.

3.3.3 Dispersion Modeling for Acute Exposures

As a screening assessment of the potential for public health impacts associated with short-term emissions from EtO commercial sterilization sources, a hypothetical 1-hour exposure scenario was constructed from the data available for the chronic assessment. This assessment is constructed in a conservative manner such that the conclusion drawn may be either that there is negligible potential for impacts associated with short-term emissions situations, or that a more sophisticated analysis is needed.

The SCREEN3 air dispersion model was used. The SCREEN3 model is a screening-

level Gaussian dispersion model used to predict maximum 1-hour impacts immediately downwind (plume center-line) from a source.[16] The SCREEN3 model examines a range of stability classes and wind speeds to identify the "worst case" meteorological conditions, which is the combination of wind speed and stability that results in the maximum ground level concentration. Considering engineering knowledge of the process, the release characteristics for the hypothetical source modeled were selected from site-specific source data with the objective of constructing a release scenario that would produce maximum estimates of potential short-term exposure levels. The SCREEN3 model was then used to predict worst-case 1-hour concentrations at locations from 100 meters to 5000 meters downwind from the source. Parameter values used for the SCREEN3 model run are included in Attachment 2.

One hundred meters is the default value in the SCREEN3 model for the first downwind distance at which ground-level concentrations are modeled, and it is the value we used for the acute portion of the risk assessment. Although we have data indicating there are fenceline distances shorter than 100 meters, we conclude that it is appropriate to use the 100 meter distance because it is unlikely that a person would be exposed for one hour at the shortest fenceline distance in the worst-case meteorological conditions. Further, a SCREEN3 modeling run using the same parameters of the hypothetical source but with discrete downwind distances from 10 to 100 meters resulted in a maximum concentration that exceeded the 100-meter concentration by less than 20 percent.

The highest of the modeled concentrations (at or beyond 100 meters) was considered in relation to the available 1-hour reference values pertinent to such an exposure scenario, which included Emergency Response Planning Guidelines developed by the American Industrial Hygiene Association, interim Acute Exposure Guideline Levels developed by the National Advisory Committee, and the Level of Concern (or IDLH/10) per the Agency's *Technical Guidance for Hazards Analysis*.[17]

Discussion of models, data, and assumptions in acute dispersion and exposure modeling

In many ways, modeling acute exposures is more difficult than modeling chronic exposures in that the purpose is usually not to estimate exposure over a typical hour, but rather to estimate exposures where several factors conspire to result in unusually high short-term

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[16] A relatively large degree of conservatism is incorporated in the modeling procedure to provide reasonable assurance that maximum concentrations will not be underestimated *(Screening Procedures for Estimating the Air Quality Impacts of Stationary Sources, Revised*, USEPA 1992). The SCREEN3 model contains a set of generic meteorological conditions (wind speed and atmospheric stability combinations) that are designed to predict maximum one hour ground level conditions at user specified downwind distances (*SCREEN3 Model Users Guide* USEPA 1995).

[17] *Technical Guidance for Hazards Analysis*. EPA-OSWER-86-0001. U.S. Environmental Protection Agency, Federal Emergency Management Agency, U.S. Department of Transportation. December 1987.

exposures. The approach used here is to utilize high-end estimates of various parameters (short-term emission rates, "worst-case" meteorological conditions) to determine an estimate of how high acute exposure might be. While the joint probability of all of these factors happening at any given time is quite low, the purpose here is not to estimate average acute exposures, but to capture rare events that may still affect public health.

3.4 Ethylene Oxide Dose-Response Information

The Integrated Risk Information System (IRIS), EPA's clearinghouse for toxicity information, is our primary source of health effects information. The URE, CSFo, and RfC/RfD values presented in IRIS are consensus values developed by EPA workgroups. However, IRIS does not contain URE, CSFo, and RfC/RfD values for all HAPs, including EtO. Many HAPs have dose-response assessments developed by several environmental agencies or organizations. Because different organizations developed these assessments at different times for purposes that were similar but not identical, it is inevitable that the results are not totally consistent. In some cases interagency differences are substantial, especially between assessments that were done many years apart. In lieu of chemical-specific decisions to resolve these discrepancies, EPA has applied a consistent default priority scheme to the sources of chronic dose-response information.

Hazard identification and dose-response assessment information for chronic exposure was obtained from various sources and prioritized according to (1) consistency with EPA risk assessment guidelines and (2) level of independent review received. The prioritization process is aimed at incorporating into our assessments the best available science with respect to dose-response information. The following four sources were used to select a URE and RfC (or similar values) for use in this assessment (listed in hierarchical order):

- IRIS - EPA's Integrated Risk Information System (U.S. EPA, 2004).
- ATSDR - the Agency for Toxics Substance and Disease Registry's Minimal Risk Levels (ATSDR, 1999a).
- California EPA's Reference Exposure Levels (RELs)(CalEPA, 1999b) and Unit Risk values. (CalEPA, 1999a)
- HEAST - the Health Effects Assessment Tables (U.S. EPA, 1997c).

In residual risk assessments, draft RfCs, RfDs, and UREs under development for the EPA IRIS process are given priority over existing IRIS files on a case-by-case basis, where such assessments have already undergone external peer review and subsequent revision. Consistent with EPA's commitment to sound science, we do not include draft assessments that have not undergone peer review. This practice conforms to the 1996 changes to the IRIS review process requiring such external peer review. Where externally peer reviewed IRIS draft assessments are not available to supersede existing EPA IRIS values, current IRIS information is used. For substances lacking current IRIS assessments, ATSDR chronic MRLs (available only for noncancer effects) receive next preference, followed by CalEPA chronic RELs and UREs. Where ATSDR or CalEPA assessments do not exist, HEAST assessments may be used.

Although no formal prioritization scheme has been developed for the use of acute values in residual risk assessments, the hazard assessment requirements of the Risk Management Program regulation intended to protect the public from accidental releases under CAA section 112(r) include a hierarchy for the consideration of three of the acute reference values included in this analysis.[18] Recognizing variations in the methodologies used in their derivation, the AEGL values are considered preferable to the ERPG values, which are considered preferable to the Levels of Concern for purposes of evaluating potential hazard associated with accidental release conditions. While there may inherent differences between hazard assessment for accidental release conditions and short-term elevations in concentration relevant to residual risk assessments, this hierarchy is considered relevant here because our short-term exposure scenario is similar to an accidental release in that it is expected to occur infrequently, if at all.

A flexible, transparent approach has been employed for evaluation of the potential for acute impacts which is intended to utilize all the available relevant values. The acute scenario developed for the initial level of assessment is designed to be a worst-case scenario. To evaluate the potential for harm associated with this scenario, all the available acute reference values are displayed with it in a comparative manner. The availability of each of the types of reference values is noted along with the relationships among the reference values and with the projected acute exposure. Where the projected acute exposure is similar or greater than any of the reference values, that is noted along with any salient aspects of the projected exposure and the reference value. In recognition of the lack of all acute reference values for all pollutants, this is considered the best, most transparent approach. It is noted, however, that the lack of the same types of reference values for all pollutants assessed injects an inherent inconsistency across pollutants in the robustness of this evaluation.

The use of multiple acute benchmarks gives the reader some notion of the uncertainty in this part of the analysis, though the differences in these values often represents the varying purposes for which these were developed. The use of acute exposure benchmarks is a somewhat less-well-developed program within EPA (relative to the use of chronic benchmarks); therefore a greater degree of uncertainty is associated. The EPA is developing an Acute Reference Exposure (ARE) value for EtO, which could be lower than the acute benchmarks used in the risk assessment. The schedule for the development of the EtO ARE can be found at: http://cfpub.epa.gov/iristrac.

Table 2 presents chronic and acute dose-response values for EtO. These values are described in more detail on EPA's Air Toxics Website at http://www.epa.gov/ttn/atw/toxsource/summary.html.

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[18] 61 FR 31667-31730.

Table 2. Ethylene Oxide Dose-Response Values

Chronic		Acute				
URE[a] (per μg/m^3)	RfC[b] (μg/m^3)	AEGL-2[c] (μg/m^3)	AEGL-3 (μg/m^3)	ERPG-2[d] (μg/m^3)	ERPG-3 (μg/m^3)	IDLH/10[e] (μg/m^3)
8.8 E-05[f]	30	81,000	360,000	90,000	900,000	140,000

[a]Unit risk estimate (URE): The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 μg/m^3 in air. The interpretation of unit risk would be as follows: if URE = 1.5 x 10-6 μg/m^3, up to 1.5 additional people are expected to develop cancer in their lifetime per 1,000,000 people exposed continuously for a lifetime to 1 μg of the chemical per m^3 of air.
[b]Rather than an EPA RfC, this value is a Reference Exposure Level (REL) developed by California EPA. Similar to EPA's RfC, the REL is defined by California EPA as "an airborne level that would pose no significant health risk to individuals exposed to that level for an indefinite period of time".
[c]Acute Exposure Guideline Level (AEGL). The AEGLs for a substance take the form of a matrix, with separate ambient levels above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, non-sensory effects (AEGL-1), irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape(AEGL-2), and life-threatening health effects or death (AEGL-3).
[d]Emergency Response Planning Guideline (ERPG). The ERPGs represent concentrations for exposure of the general population for up to 1 hour associated with effects expected to be mild or transient (ERPG-1), irreversible or serious (ERPG-2), and potentially life-threatening or lethal (ERPG-3).
[e]IDLH: Immediately dangerous to life or health.

The National Institute of Occupational Safety and Health (NIOSH) also recommends a 10 minute ceiling value of 5 ppm (9 mg/m^3).[19] While concerns about mutagenicity and its relationship to both cancer and reproductive effects were recognized in the decision to set a ceiling value for occupational exposures which commonly are experienced in burst-like episode, the magnitude of the value is not quantitatively based on risk of these effects. Rather, the quantitative basis of this ceiling value derives primarily from analytical limits of detection or technological feasibility. In implementing this value as a 15 minute time weighted average excursion limit - along with an 8 hour Permissible Exposure Limit (PEL)- the Occupational Safety and Health Administration focused its discussion of associated risk benefits on the rationale that it would yield a reduction (albeit unquantifiable) in worker daily time weighted average exposures, and associated lifetime cancer risk below that which might be associated with the 8 hour PEL alone.[20] Given this background on its quantitative basis, and implementation of this short-term value as an occupational safety technique rather than as a reference value intended for environmental risk assessment applications, it is not presented along with the acute values relied upon for this assessment.

3.4.1 Carcinogenicity of Ethylene Oxide

Because Agency chronic dose-response values for EtO are not currently available, a dose-response value from the California Environmental Protection Agency (CalEPA) was used in the

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[19] NIOSH. 2004. Appendix of NIOSH Pocket Guide to Chemical Hazards, Government Printing Office. http://www.cdc.gov/niosh/npg/npg.html

[20] USDOL. Occupational Exposure to Ethylene Oxide. Federal Register, Volume: 53, Issue: 66, Page 11515 (53 FR 11414). April 6, 1988.

cancer risk assessment for this source category.[21] The CalEPA unit risk estimate describes the excess cancer risk associated with an inhalation exposure to a concentration of 1 $\mu g/m^3$ of EtO. This estimate was determined using a linearized 95% upper confidence interval. In other words, there is a 95% probability that the actual unit risk is lower than the CalEPA value, and only a 5% probability that it is higher. An EPA assessment for EtO is currently under way. The EPA has not yet completed a full evaluation of the data on which it will determine an EPA cancer unit risk estimate for EtO. The schedule for EPA assessment of EtO can be found at: http://cfpub.epa.gov/iristrac.

3.4.2 Effects Other Than Cancer Associated With Ethylene Oxide

Adverse effects other than cancer observed in workers exposed to ethylene oxide at low levels for several months or years include irritation of the eyes, skin, and mucous membranes and effects on the functioning of the nervous system. There is also some evidence that exposure to ethylene oxide can cause an increased rate of miscarriages in female workers exposed to ethylene oxide.[22] Studies in animals have shown that breathing ethylene oxide at high levels can interfere with their ability to reproduce and, at lower levels, can have adverse effects on the nervous system.[23]

The CalEPA based the derivation of the EtO chronic REL on the finding of neurotoxicity in a subchronic inhalation study of mice.[24] The REL is the concentration at or below which adverse health effects are not likely to occur. The REL was derived from the no-observed-adverse-effect level (NOAEL) from the study and has a cumulative uncertainty factor of 100.

The strengths of the REL for EtO include the use of an animal study with both a LOAEL and a NOAEL and the use of an endpoint seen in both animals and humans. Major areas of uncertainty are the short time-frame of the key study, the lack of an appropriate human study, and the limited number of developmental toxicity studies.

Acute exposure of workers to ethylene oxide at the odor detection level has been associated with eye and upper respiratory tract irritation, as well as effects on the nervous system. Acute exposure at somewhat higher levels has also been associated with hematologic effects and

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[21] http://www.oehha.ca.gov/air/cancer_guide

[22] ATSDR. 1990. Toxicological Profile for Ethylene Oxide. TP-90-16. Agency for Toxic Substances and Disease Registry. http://www.atsdr.cdc.gov/toxprofiles/tp137.html

[23] California Office of Environmental Health and Hazard Assessment. 2000. Determination of Noncancer Chronic Reference Exposure Levels Batch 2A December 2000. Chronic Toxicity Summary for Ethylene Oxide. http://www.oehha.ca.gov/air/chronic_rels/pdf/75218.pdf

[24] Snellings WM, Weil CS, and Maronpot RR. 1984. A subchronic inhalation study on the toxicologic potential of ethylene oxide in $B6C3F_1$ mice. Toxicol. Appl. Pharmacol. 76:510-518

more severe effects on the central nervous system. Additionally, human studies have provided suggestive evidence of reproductive toxicity.[25] Experimental animals exposed acutely to ethylene oxide showed evidence of eye and respiratory tract irritation, effects on the central and peripheral nervous system, and evidence of reproductive, developmental and genetic toxicity.[26] The AEGL-2 values were based on a developmental toxicity study in rats[27] and the application of a cumulative uncertainty factor of 100 to the exposure concentration associated with a decrease in fetal weight. An AEGL-1 was not derived because the odor threshold and concentrations causing mild sensory irritation would be above the AEGL-2 levels.

4.0 Results and Discussion

4.1 Human Health

The estimated ambient concentration at each census block is presumed representative of the air breathed continuously throughout a lifetime (70 years) by people living in that block. The census block concentration estimates were (1) multiplied by the EtO URE to obtain an estimate of individual lifetime cancer risk for each block, and (2) divided by the chronic RfC to quantify the noncancer hazard quotient (HQ) for each block. Finally, potential annual population impact was quantified by multiplying the individual lifetime cancer risk estimates for each census block by the number of people living in that block, dividing by 70, and then summing the individual block values across census blocks. These calculations were performed for every census block within 50 kilometers of the source.

Table 3 summarizes the results of the chronic assessment. There are 44 sources with census block estimates that exceed 1 in 1 million individual lifetime cancer risk, 19 sources with census block estimates that exceed 10 in 1 million individual lifetime cancer risk, and no sources predicted to exceed 100 in a million individual lifetime cancer risk at a census block centroid. Approximately 250,000 people live in areas where the individual lifetime cancer risk estimates are greater than 1 in 1 million, 7,300 people live in areas where the individual lifetime cancer risk estimates exceed 10 in 1 million, and no people live in areas where individual lifetime cancer risk estimates exceed 100 in 1 million. There are no sources with census block estimates that exceed a chronic HQ of 1 (the maximum predicted HQ from any source is 0.03). The HEM-Screen input and output files for all 76 sources modeled are presented in Attachments 3 through 6. Attachment 7 contains the HEM-3 results for the facilities with HEM-Screen cancer risk greater than 50 in a million. The HEM-Screen input and output files for only the major sources

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[25] ATSDR, *op. cit.*

[26] ATSDR, *op. cit.*

[27] Snellings, W. M.; Maronpot, R. R.; Zelenak, J. P.; Laffon, C. P. 1982. Teratology study in Fischer 344 rats exposed to ethylene oxide by inhalation. *Toxicology of Applied Pharmacology.* 64:476-481.

are presented in Attachments 8 through 11.

Table 3. Summary of Chronic Risk Assessment Results for 76 Modeled Sources

Highest census block individual lifetime cancer risk	90 in a million
Number of sources with a census block individual lifetime cancer risk at or above 100 in a million	0
Number of sources with a census block individual lifetime cancer risk at or above 10 in a million	19
Number of sources with a census block individual lifetime cancer risk at or above 1 in a million	44
Number of people residing in census blocks for which individual lifetime cancer risk is at or above 100 in a million	0
Number of people residing in census blocks for which individual lifetime cancer risk is at or above 10 in a million	7,200
Number of people residing in census blocks for which individual lifetime cancer risk is at or above 1 in a million	250,000
Potential population impact (cancer cases/year)	0.04
Total population within 50 km of any source	99 million
Chronic noncancer results	
Highest census block HQ	0.03

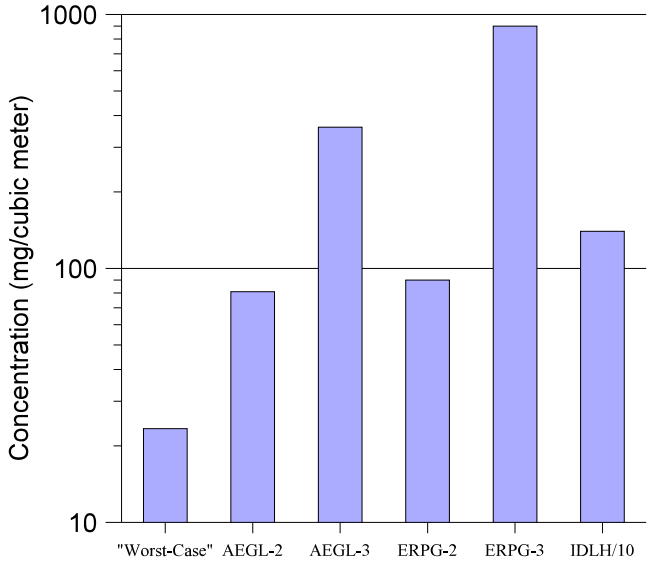
The cancer risk assessment indicates that no source poses a lifetime cancer risk greater than 100 in a million, while approximately half of the modeled sources pose a lifetime cancer risk greater than 1 in a million. The chronic noncancer assessment indicated that no source emitted EtO in quantities that resulted in exposures that approached the inhalation reference concentration, indicating that chronic noncancer effects are unlikely to occur.

Figure 1 illustrates the relationship of the "worst-case" 1- hour concentration estimate derived for this source category to the available acute reference values. As can be seen from the figure, three types of acute reference values are available: interim AEGLs, ERPGs and the IDLH/10. The worst-case concentration estimate is approximately one-third of the lowest of these reference values (the 1-hour interim AEGL-2 value).[28] Details of the inputs used and

[28] The interim AEGL-2 value was derived from the exposure resulting in reduced fetal weight in rats. This interim AEGL-2 value reflects consideration of EPA comment on an earlier draft value that was not based on developmental effects. An AEGL-1 value has not been derived because the odor

results of the acute assessment are presented in Attachment 2.

Figure 1. Short-Term Concentration Comparisons



4.2 Major sources of Uncertainty

No quantitative uncertainty analysis has been performed for this risk assessment, but we can anticipate what are likely to account for the most significant sources of uncertainty in the overall assessment. In the area of source and emissions characterization, we believe that the source coverage and EtO emissions data are relatively strong. For source release characteristics, the defaulting that was necessary for missing data introduces uncertainty, but we conclude that there should be no bias introduced.

The exposure-related uncertainties are generally well documented and are consistent with other residual risk analyses. The assumption of an individual exposed to EtO at their home for 70-years is generally a conservative one; few individuals spend their lifetimes at one residence, to say nothing of indoor/outdoor concentration gradients and commuting patterns. In addition, there are uncertainties related to dispersion modeling, but this is unlikely to create uncertainty larger than a factor of 2.

Generally speaking, cancer UREs are conservative upper-bound estimates of risk. This is

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threshold and concentrations causing mild sensory irritation are higher than the AEGL-2.

tempered somewhat in that the response of potentially sensitive populations (such as children, individuals with auto-immune disorders) are not explicitly modeled. Chronic noncancer benchmarks are designed to identify a level where we do not expect adverse effects in the general population, but this does not necessarily mean that exposures above the benchmarks are certain to cause effects. Given the roughly order of magnitude uncertainty in RfCs and related measures, this does not mean absolutely zero risk either. Finally, the acute benchmarks used in this analyses were adapted for use from other policy needs. Given the varying applications for which these benchmarks were designed (and the inherent uncertainties in their derivation), significant uncertainties remain here as well. Ongoing EPA assessment of EO cancer, noncancer and acute benchmarks should serve to reduce these uncertainties somewhat.

Conclusions

While the potential for acute health effects, chronic non-cancer, and ecological effects appear to be low for this source category, the estimated cancer risks are above one in one million for a significant number of the modeled sources. This analysis is not exhaustive and it is not intended to be. We have used (1) the best emissions data currently available to us, (2) reasonable dispersion models, and (3) exposure locations where receptor populations currently reside. A number of assumptions, modeling choices, and uncertainties are associated with the assessment being presented here. While some of these will tend to overestimate the predicted risk, others will tend to underestimate the predicted risk. On balance, using our scientific judgment and risk assessment experience, we believe the predicted results are health-protective, meaning the predicted risk estimates are likely higher than those which would be expected to actually occur in the exposed population.

cc: Dave Markwordt

Attachments

Attachment 1: Effect of First Downwind Receptor Distance on Maximum Individual Lifetime Cancer Risk

	Distance From Source to First Receptor						
	20m		100m		200m		
Facility	Pop	Risk[a]	Pop	Risk[a]	Pop	Risk[a]	Comments
ETO-18	94	3.08e-04	94	1.48e-04	34	6.85e-05	
ETO-19	3	9.68e-05	3	9.37e-05	3	9.68e-05	
ETO-8	3	7.64e-05	3	7.37e-05	3	7.64e-05	
ETO-27	39	6.90e-05	39	6.61e-05	39	6.90e-05	
ETO-4	49	6.37e-05	49	6.12e-05	49	4.29e-05	
ETO-5	54	6.37e-05	54	6.07e-05	54	6.37e-05	
ETO-57	16	3.19e-05	15	1.31e-05	8	6.36e-06	Census block difference between 20m and 100m distances
ETO-24	1	2.44e-05	1	2.35e-05	1	2.44e-05	
ETO-11	26	2.33e-05	26	2.23e-05	26	2.33e-05	
ETO-22	65	2.17e-05	65	2.14e-05	65	2.17e-05	
ETO-118	28	1.73e-05	28	1.64e-05	28	1.73e-05	
ETO-42	181	1.68e-05	181	1.60e-05	181	1.68e-05	
ETO-12	4	1.66e-05	4	1.66e-05	4	1.66e-05	
ETO-13	7	1.50e-05	7	1.50e-05	7	1.50e-05	
ETO-14	158	1.24e-05	158	9.75e-06	158	1.24e-05	
ETO-91	17	1.23e-05	17	1.23e-05	17	1.23e-05	
ETO-10	3	1.18e-05	3	1.19e-05	3	1.19e-05	
ETO-29	28	1.06e-05	28	1.12e-05	28	1.06e-05	
ETO-3	107	9.86e-06	107	9.86e-06	107	9.86e-06	
ETO-1	322	7.37e-06	322	6.91e-06	322	7.37e-06	
ETO-48	22	6.88e-06	22	5.21e-06	35	4.62e-06	
ETO-9	2	6.69e-06	2	6.69e-06	2	6.69e-06	
ETO-44	16	6.59e-06	6	5.93e-06	16	6.67e-06	Census block difference between 20m and 100m distances
ETO-36	153	5.91e-06	153	5.91e-06	153	5.91e-06	
ETO-35	3	4.89e-06	3	4.76e-06	3	4.89e-06	
ETO-15	1	4.80e-06	1	4.75e-06	1	4.75e-06	
ETO-7	171	4.11e-06	171	3.62e-06	171	4.11e-06	
ETO-20	92	4.02e-06	92	3.22e-06	92	1.33e-06	
ETO-23	111	3.85e-06	111	3.85e-06	111	3.85e-06	
ETO-67	185	3.64e-06	185	3.45e-06	185	2.94e-06	
ETO-61	28	2.36e-06	28	2.21e-06	28	2.19e-06	
ETO-63	16	2.21e-06	16	2.12e-06	16	2.21e-06	
ETO-37	53	2.08e-06	53	2.17e-06	53	2.08e-06	
ETO-26	3	2.02e-06	3	2.01e-06	3	2.02e-06	
ETO-59	926	1.87e-06	926	1.84e-06	926	1.87e-06	
ETO-62	3	1.82e-06	3	1.78e-06	3	1.82e-06	
ETO-49	9	1.59e-06	9	1.55e-06	9	1.59e-06	

ETO-58	51	1.55e-06	51	1.39e-06	51	1.27e-06	
ETO-55	9	1.54e-06	9	1.03e-06	9	4.37e-07	
ETO-33	48	1.48e-06	48	1.48e-06	48	1.48e-06	
ETO-45	35	1.46e-06	35	1.47e-06	35	1.46e-06	
ETO-38	25	1.44e-06	25	1.14e-06	25	1.44e-06	
ETO-56	1,050	1.08e-06	1,050	9.85e-07	1,050	1.08e-06	
ETO-60	71	9.45e-07	71	9.47e-07	71	9.45e-07	
ETO-51	11	9.14e-07	11	8.29e-07	11	9.14e-07	
ETO-108	35	8.64e-07	35	4.29e-07	35	1.27e-07	
ETO-2	4	7.18e-07	4	7.18e-07	4	7.18e-07	
ETO-52	8	6.49e-07	8	6.46e-07	8	3.52e-07	
ETO-41	11	6.35e-07	11	6.35e-07	11	6.35e-07	
ETO-75	19	6.32e-07	19	6.20e-07	19	6.32e-07	
ETO-72	61	6.18e-07	61	5.70e-07	61	4.22e-07	
ETO-68	479	6.11e-07	479	5.97e-07	479	6.11e-07	
ETO-47	462	5.67e-07	462	5.67e-07	462	5.67e-07	
ETO-40	70	5.46e-07	70	5.46e-07	70	5.46e-07	
ETO-66	150	5.25e-07	150	5.21e-07	150	5.25e-07	
ETO-71	6	5.23e-07	6	4.53e-07	6	3.51e-07	
ETO-65	1	4.84e-07	1	4.64e-07	1	4.84e-07	
ETO-39	104	4.19e-07	104	3.94e-07	104	4.19e-07	
ETO-50	535	3.50e-07	535	3.50e-07	535	3.50e-07	
ETO-53	2	3.31e-07	2	3.31e-07	2	3.31e-07	
ETO-99	68	3.20e-07	68	3.01e-07	68	3.20e-07	
ETO-25	22	2.43e-07	22	2.27e-07	22	2.43e-07	
ETO-116	156	2.11e-07	156	2.11e-07	156	2.11e-07	
ETO-119	2	1.80e-07	2	1.81e-07	2	1.80e-07	
ETO-80	23	8.87e-08	23	8.17e-08	23	5.91e-08	
ETO-64	69	4.19e-08	69	4.19e-08	69	4.19e-08	
ETO-43	87	3.80e-08	87	3.80e-08	87	3.80e-08	
ETO-69	49	3.32e-08	49	3.35e-08	49	3.32e-08	
ETO-70	522	2.82e-08	522	2.82e-08	522	2.82e-08	
ETO-32	5	1.13e-08	5	9.41e-09	5	1.13e-08	
ETO-74	2	1.08e-08	2	1.08e-08	2	1.08e-08	
ETO-77	80	6.74e-09	80	5.95e-09	80	6.74e-09	
ETO-46	105	3.27e-09	28	4.74e-09	105	3.00e-09	Census block difference between 20m and 100m distances
ETO-54	1	2.91e-09	1	2.91e-09	1	2.91e-09	
ETO-21		8.80e-43	343	2.37e-06	343	2.37e-06	In HEM-Screen, the only radii set that includes a 20m ring extends out to only 2000m, and there is no census block within 2000m
ETO-117		8.80e-43	49,300	8.80e-43	49,300	8.80e-43	

[a] Risk was estimated using HEM-Screen and does not reflect the more refined assessment of the higher-risk facilities. The purpose of this table is to show the relative effect of varying the distance from the source to the first modeled receptor.

Attachment 2: Acute assessment SCREEN3 run

```
 ***  SCREEN3 MODEL RUN  ***
 *** VERSION DATED 96043 ***

Ethylene Oxide Acute Assessment

SIMPLE TERRAIN INPUTS:
   SOURCE TYPE            =        POINT
   EMISSION RATE (G/S)    =      5.00000
   STACK HEIGHT (M)       =       4.5700
   STK INSIDE DIAM (M)    =        .1000
   STK EXIT VELOCITY (M/S)=       1.4600
   STK GAS EXIT TEMP (K)  =     348.0000
   AMBIENT AIR TEMP (K)   =     293.0000
   RECEPTOR HEIGHT (M)    =        .0000
   URBAN/RURAL OPTION     =        RURAL
   BUILDING HEIGHT (M)    =        .0000
   MIN HORIZ BLDG DIM (M) =        .0000
   MAX HORIZ BLDG DIM (M) =        .0000

THE REGULATORY (DEFAULT) MIXING HEIGHT OPTION WAS SELECTED.
THE REGULATORY (DEFAULT) ANEMOMETER HEIGHT OF 10.0 METERS WAS ENTERED.


BUOY. FLUX =     .006 M**4/S**3;  MOM. FLUX =     .004 M**4/S**2.

*** FULL METEOROLOGY ***

**********************************
*** SCREEN AUTOMATED DISTANCES ***
**********************************

*** TERRAIN HEIGHT OF    0. M ABOVE STACK BASE USED FOR FOLLOWING DISTANCES ***
```

DIST (M)	CONC (UG/M**3)	STAB	U10M (M/S)	USTK (M/S)	MIX HT (M)	PLUME HT (M)	SIGMA Y (M)	SIGMA Z (M)	DWASH
100.	.2339E+05	4	1.0	1.0	320.0	5.00	8.20	4.65	NO
200.	.1012E+05	4	1.0	1.0	320.0	5.00	15.56	8.50	NO
300.	7303.	6	1.0	1.0	10000.0	8.96	11.30	5.76	NO
400.	6919.	6	1.0	1.0	10000.0	8.96	14.69	7.16	NO
500.	5966.	6	1.0	1.0	10000.0	8.96	18.01	8.49	NO
600.	5031.	6	1.0	1.0	10000.0	8.96	21.27	9.77	NO
700.	4241.	6	1.0	1.0	10000.0	8.96	24.49	11.00	NO
800.	3623.	6	1.0	1.0	10000.0	8.96	27.66	12.04	NO
900.	3130.	6	1.0	1.0	10000.0	8.96	30.80	13.04	NO
1000.	2731.	6	1.0	1.0	10000.0	8.96	33.91	14.01	NO
1100.	2414.	6	1.0	1.0	10000.0	8.96	36.98	14.87	NO
1200.	2151.	6	1.0	1.0	10000.0	8.96	40.03	15.71	NO
1300.	1932.	6	1.0	1.0	10000.0	8.96	43.06	16.52	NO
1400.	1746.	6	1.0	1.0	10000.0	8.96	46.06	17.31	NO
1500.	1588.	6	1.0	1.0	10000.0	8.96	49.05	18.07	NO
1600.	1452.	6	1.0	1.0	10000.0	8.96	52.01	18.82	NO
1700.	1334.	6	1.0	1.0	10000.0	8.96	54.95	19.56	NO
1800.	1230.	6	1.0	1.0	10000.0	8.96	57.88	20.27	NO
1900.	1139.	6	1.0	1.0	10000.0	8.96	60.79	20.97	NO
2000.	1059.	6	1.0	1.0	10000.0	8.96	63.69	21.66	NO

2100.	991.1	6	1.0	1.0	10000.0	8.96	66.57	22.25	NO
2200.	930.1	6	1.0	1.0	10000.0	8.96	69.44	22.82	NO
2300.	875.3	6	1.0	1.0	10000.0	8.96	72.29	23.37	NO
2400.	825.7	6	1.0	1.0	10000.0	8.96	75.13	23.92	NO
2500.	780.6	6	1.0	1.0	10000.0	8.96	77.96	24.46	NO
2600.	739.6	6	1.0	1.0	10000.0	8.96	80.77	24.98	NO
2700.	702.0	6	1.0	1.0	10000.0	8.96	83.58	25.50	NO
2800.	667.6	6	1.0	1.0	10000.0	8.96	86.37	26.01	NO
2900.	636.0	6	1.0	1.0	10000.0	8.96	89.16	26.51	NO
3000.	606.8	6	1.0	1.0	10000.0	8.96	91.93	27.01	NO
3500.	495.1	6	1.0	1.0	10000.0	8.96	105.66	29.01	NO
4000.	414.9	6	1.0	1.0	10000.0	8.96	119.18	30.86	NO
4500.	354.8	6	1.0	1.0	10000.0	8.96	132.51	32.60	NO
5000.	308.4	6	1.0	1.0	10000.0	8.96	145.68	34.23	NO

MAXIMUM 1-HR CONCENTRATION AT OR BEYOND 100. M:

100.	.2339E+05	4	1.0	1.0	320.0	5.00	8.20	4.65	NO

DWASH= MEANS NO CALC MADE (CONC = 0.0)
DWASH=NO MEANS NO BUILDING DOWNWASH USED
DWASH=HS MEANS HUBER-SNYDER DOWNWASH USED
DWASH=SS MEANS SCHULMAN-SCIRE DOWNWASH USED
DWASH=NA MEANS DOWNWASH NOT APPLICABLE, X<3*LB

****
*** SUMMARY OF SCREEN MODEL RESULTS ***
****

CALCULATION PROCEDURE	MAX CONC (UG/M**3)	DIST TO MAX (M)	TERRAIN HT (M)
SIMPLE TERRAIN	.2339E+05	100.	0.

Attachment 3: Cancer HEM-Screen input file for all sources

```
00076     ff  0.000088
Ethylene Oxide
ETO-1  EtO Source
175817 661801                    100002
H       206.212.1 5400 1.2  6.8 345
F        22.7 5.2 1001   0    0 293
Ethylene Oxide
ETO-2  EtO Source
402617 743004                    000005
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
H        37.613.7 5400 1.7   12 377
Ethylene Oxide
ETO-3  EtO Source
362132 922317                    100002
F        95.3 5.2 1001   0    0 293
H       907.212.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-4  EtO Source
414452 875638                    000003
F      2848.6 7.6 1001   0  9.1 294
H       127.018.3 5400 2.5100.6 311
H       108.9 9.1 5400 0.2 30.5 311
Ethylene Oxide
ETO-5  EtO Source
425512 721810                    100003
F        11.0 5.2 1001   0    0 293
F      1644.7 5.2 1001   0    0 293
H        46.312.5 5400 1.2  6.8 345
Ethylene Oxide
ETO-7  EtO Source
422020 875347                    000003
H       362.918.3 5670 0.3 30.5 311
H       154.215.2 5670 0.3 44.2 336
H       154.215.2 5670 0.3 44.2 336
Ethylene Oxide
ETO-8  EtO Source
333636 835010                    000002
F      4100.5 5.2 1001   0    0 293
H      1458.819.8 5400 1.4 17.8 500
Ethylene Oxide
ETO-9  EtO Source
421958 880750                    100001
H       884.7 4.9 5400 0.1 68.2 394
Ethylene Oxide
ETO-10  EtO Source
332342 815906                    100002
F      3619.7 5.2 1001   0    0 293
```

H 136.1 9.1 5400 0.8 30.8 366
Ethylene Oxide
ETO-11 EtO Source
364522 863435 100003
F 226.8 5.2 1001 0 14.3 293
H 45.412.2 1820 0.4 14.7 345
F 644.1 7.6 1001 0 14.9 293
Ethylene Oxide
ETO-12 EtO Source
334954 842804 100003
F 63.5 9.1 1001 0 0.6 293
H 108.915.2 5400 0.9 9.1 312
H 1179.3 9.1 5400 0.3 4.9 311
Ethylene Oxide
ETO-13 EtO Source
4046401120130 100003
F 54.4 5.2 1001 0 0 293
H 1297.314.6 3750 0.7 4.3 293
H 1288.212.2 3750 0.3 4.9 293
Ethylene Oxide
ETO-14 EtO Source
415043 873902 000002
H 85.821.3 6960 0.2 4.1 294
H 957.521.3 6960 0.2 4.1 294
Ethylene Oxide
ETO-15 EtO Source
373010 772120 100002
H 1723.713.7 4970 1.1 14.8 405
H 1632.913.7 4970 0.8 20.4 293
Ethylene Oxide
ETO-18 EtO Source
181660 670822 100003
F 10.9 5.2 1001 0 0 293
F 277.6 5.2 1001 0 0 293
H 455.412.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-19 EtO Source
302545 883100 100003
F 1383.5 5.2 1001 0 0 293
F 1383.5 5.2 1001 0 0 293
H 780.212.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-20 EtO Source
404232 740343 000001
H 54.412.287.70 0.1 8.2 322
Ethylene Oxide
ETO-21 EtO Source
3151301064115 100004
H 2023.012.244.50 1.2100.6 450
H 90.718.344.50 0.6 3 294
H 1914.212.244.50 0.3 4.9 293
F 90.710.737.21 0 3 293

```
Ethylene Oxide
ETO-22  EtO Source
350455 900343                    000002
H       684.010.7 4450 1.1  7.4 405
H       756.6 9.8 4450 0.2 10.2 293
Ethylene Oxide
ETO-23  EtO Source
343336 820748                    100002
F       562.5 5.2 1001   0 21.3 389
H       263.115.2 7240   2  3.3 561
Ethylene Oxide
ETO-24  EtO Source
372214 894111                    100002
H      1877.9 7.6 8950 0.8 13.1 316
H      3138.9 7.6 8950 0.8 20.4 318
Ethylene Oxide
ETO-25  EtO Source
414201 713508                    100001
H        90.721.3 5760 0.9 11.2 293
Ethylene Oxide
ETO-26  EtO Source
3400051181316                     000003
H        45.4 5.2 5400 1.2 60.7 293
H       172.412.2 5400 1.2  4.6 345
F        18.1 5.2 1001   0  6.8 293
Ethylene Oxide
ETO-27  EtO Source
350141 820358                    100002
F      1414.3 5.2 1001   0    0 293
H       304.412.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-29  EtO Source
3944051050710                     000001
H      1378.912.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-32  EtO Source
355510 813402                    100001
H         1.412.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-33  EtO Source
333650 965645                    000002
F       412.8 5.2 1001   0    0 293
H       353.812.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-35  EtO Source
403401 795129                    100001
H       340.2 7.9 5400 0.2  0.8 327
Ethylene Oxide
ETO-36  EtO Source
334334 843502                    000002
H       372.910.7 4450 1.1  7.4 405
H       527.5   7 4450 0.8 13.4 293
```

Ethylene Oxide
ETO-37 EtO Source
422015 713800 100002
H 27.2 8.8 6250 1 11 344
H 544.314.9 6250 2 2.3 950
Ethylene Oxide
ETO-38 EtO Source
403405 742546 000002
H 72.618.3 4720 0.2 13.3 293
H 72.618.3 4720 0.3 32.3 293
Ethylene Oxide
ETO-39 EtO Source
3143401061726 100003
H 18.114.9 6750 2 1.9 356
H 27.2 4.9 6750 0.8 13.4 368
H 18.1 4.9 6750 0.8 10.4 356
Ethylene Oxide
ETO-40 EtO Source
391638 763338 000001
H 163.321.3 5760 0.2 3.1 293
Ethylene Oxide
ETO-41 EtO Source
3403251173300 000003
F 113.4 5.2 1001 0 0 293
H 136.112.1 5400 1.2 6.7 345
H 107.0 5.2 5400 1.2 4.6 293
Ethylene Oxide
ETO-42 EtO Source
312022 891853 000002
F 336.1 5.2 1001 0 0 293
H 0.012.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-43 EtO Source
421807 875347 000002
H 0.8 7.6 5400 0.5 0 294
H 8.210.1 5400 0.1 0.1 294
Ethylene Oxide
ETO-44 EtO Source
280211 823938 000001
H 508.017.7 5400 0.5 24.4 289
Ethylene Oxide
ETO-45 EtO Source
432054 733554 100002
H 163.323.8 5400 0.6 13.7 364
H 72.610.7 5400 0.9 0.6 294
Ethylene Oxide
ETO-46 EtO Source
403830 741249 000001
H 0.318.3 4970 0.2 27.7 293
Ethylene Oxide
ETO-47 EtO Source
3128181002310 000003

F 11.1 5.2 1001 0 0 293
F 11.1 5.2 1001 0 0 293
H 381.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-48 EtO Source
385640 951330 000001
H 340.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-49 EtO Source
350748 805702 100003
H 90.718.3 5400 0.9 39.6 355
H 90.712.2 5400 0.9 15.2 311
F 90.7 7.6 1001 0 4.9 294
Ethylene Oxide
ETO-50 EtO Source
450757 931615 000001
H 127.011.3 4130 0.6 4.6 372
Ethylene Oxide
ETO-51 EtO Source
412018 725215 000002
F 2.3 5.2 1001 0 0 293
H 113.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-52 EtO Source
354649 794851 000001
H 27.215.2 9120 1.2 1.9 351
Ethylene Oxide
ETO-53 EtO Source
344419 822230 000001
H 117.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-54 EtO Source
3931151194309 000001
H 0.413.7 5120 0.2 2.3 293
Ethylene Oxide
ETO-55 EtO Source
355517 800146 000002
F 1.4 5.2 1001 0 0 293
H 33.112.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-56 EtO Source
391008 764646 000003
H 56.712.2 5400 0.2 6.1 311
H 56.719.8 5400 0.2 3 297
F 2.3 5.2 1001 0 0 293
Ethylene Oxide
ETO-57 EtO Source
391414 863737 100003
F 51.7 5.2 1001 0 0 293
F 51.7 5.2 1001 0 0 293
H 10.412.2 5400 1.2 6.8 345
Ethylene Oxide

ETO-58 EtO Source
425245 854103 000001
H 199.615.2 3430 1.1 2.4 308
Ethylene Oxide
ETO-59 EtO Source
392430 764550 000001
H 113.4 3.7 5400 0.2 6.8 297
Ethylene Oxide
ETO-60 EtO Source
403806 752008 000001
H 105.712.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-61 EtO Source
3359481181218 000003
F 27.2 5.2 1001 0 0 293
H 54.4 5.2 5400 1.2 4.6 293
H 5.412.2 5400 1.2 7 345
Ethylene Oxide
ETO-62 EtO Source
344615 821751 000002
F 68.9 5.2 1001 0 0 293
H 21.812.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-63 EtO Source
414511 875525 000001
H 90.7 7.2 5400 0.3 6.1 300
Ethylene Oxide
ETO-64 EtO Source
410750 743610 100001
H 18.318.9 5400 0.1 6.8 300
Ethylene Oxide
ETO-65 EtO Source
382410 753424 000001
H 81.615.2 5400 0.1 10.1 298
Ethylene Oxide
ETO-66 EtO Source
350808 805743 000002
H 0.912.1 5400 1.2 6.8 345
F 69.9 5.2 1001 0 0 293
Ethylene Oxide
ETO-67 EtO Source
3120471105719 100002
F 36.3 5.2 1001 0 0 293
H 0.4 8.5 8170 0.7 5.5 345
Ethylene Oxide
ETO-68 EtO Source
420813 875929 000002
H 40.8 6.1 5400 0.1 0.1 294
H 16.3 7.3 5400 0 64.8 311
Ethylene Oxide
ETO-69 EtO Source
450000 922700 000001

H 6.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-70 EtO Source
324756 970250 000001
H 24.518.3 5990 0.3 8.5 293
Ethylene Oxide
ETO-71 EtO Source
362650 833448 100001
H 32.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-72 EtO Source
424111 830722 000001
H 15.715.2 5400 0.1 28 305
Ethylene Oxide
ETO-74 EtO Source
275307 824044 000001
H 9.1 4.6 5400 0.1 1.5 298
Ethylene Oxide
ETO-75 EtO Source
353910 802948 100002
H 18.112.2 7380 1 0.71033
H 9.1 0.9 7380 0.5 17.5 311
Ethylene Oxide
ETO-77 EtO Source
392935 764025 000002
H 0.922.9 5400 0.1 6.1 311
H 0.922.9 5400 0.1 6.1 311
Ethylene Oxide
ETO-80 EtO Source
3243011170933 000001
H 1.818.3 5070 0.3 1.2 293
Ethylene Oxide
ETO-91 EtO Source
4524281223239 000001
H 907.2 0.3 5400 0.5 5 458
Ethylene Oxide
ETO-99 EtO Source
430004 773919 100001
H 21.812.2 3300 0.1 3.7 301
Ethylene Oxide
ETO-108 EtO Source
450506 931508 000001
H 4.5 4.310170 0.3 1.1 339
Ethylene Oxide
ETO-116 EtO Source
3330101171000 000002
H 0.6 8.5 4610 0.8 15.2 408
F 63.5 5.2 1001 0 0 293
Ethylene Oxide
ETO-117 EtO Source
3515351135647 100001
H 0.012.5 2220 0.1 10.4 293

```
Ethylene Oxide
ETO-118  EtO Source
3944051050710                    000003
H       63.5 6.1 5400 0.4  3.1 295
H      132.4 6.1 5400 0.9  4.6 295
H      753.0 8.5 5400 0.9  5.6 295
Ethylene Oxide
ETO-119  EtO Source
3239181143322                    100002
H       18.112.2 5400 1.1  2.6 977
H        9.112.2 5400 0.5 11.7 311
```

Attachment 4: Noncancer HEM-Screen input file for all sources

```
00076     ff  0.033333
Ethylene Oxide
ETO-1  EtO Source
175817 661801                    100002
H       206.212.1 5400 1.2  6.8 345
F        22.7 5.2 1001   0    0 293
Ethylene Oxide
ETO-2  EtO Source
402617 743004                    000005
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
H        37.613.7 5400 1.7   12 377
Ethylene Oxide
ETO-3  EtO Source
362132 922317                    100002
F        95.3 5.2 1001   0    0 293
H       907.212.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-4  EtO Source
414452 875638                    000003
F      2848.6 7.6 1001   0  9.1 294
H       127.018.3 5400 2.5100.6 311
H       108.9 9.1 5400 0.2 30.5 311
Ethylene Oxide
ETO-5  EtO Source
425512 721810                    100003
F        11.0 5.2 1001   0    0 293
F      1644.7 5.2 1001   0    0 293
H        46.312.5 5400 1.2  6.8 345
Ethylene Oxide
ETO-7  EtO Source
422020 875347                    000003
H       362.918.3 5670 0.3 30.5 311
H       154.215.2 5670 0.3 44.2 336
H       154.215.2 5670 0.3 44.2 336
Ethylene Oxide
ETO-8  EtO Source
333636 835010                    000002
F      4100.5 5.2 1001   0    0 293
H      1458.819.8 5400 1.4 17.8 500
Ethylene Oxide
ETO-9  EtO Source
421958 880750                    100001
H       884.7 4.9 5400 0.1 68.2 394
Ethylene Oxide
ETO-10  EtO Source
332342 815906                    100002
F      3619.7 5.2 1001   0    0 293
```

H 136.1 9.1 5400 0.8 30.8 366
Ethylene Oxide
ETO-11 EtO Source
364522 863435 100003
F 226.8 5.2 1001 0 14.3 293
H 45.412.2 1820 0.4 14.7 345
F 644.1 7.6 1001 0 14.9 293
Ethylene Oxide
ETO-12 EtO Source
334954 842804 100003
F 63.5 9.1 1001 0 0.6 293
H 108.915.2 5400 0.9 9.1 312
H 1179.3 9.1 5400 0.3 4.9 311
Ethylene Oxide
ETO-13 EtO Source
4046401120130 100003
F 54.4 5.2 1001 0 0 293
H 1297.314.6 3750 0.7 4.3 293
H 1288.212.2 3750 0.3 4.9 293
Ethylene Oxide
ETO-14 EtO Source
415043 873902 000002
H 85.821.3 6960 0.2 4.1 294
H 957.521.3 6960 0.2 4.1 294
Ethylene Oxide
ETO-15 EtO Source
373010 772120 100002
H 1723.713.7 4970 1.1 14.8 405
H 1632.913.7 4970 0.8 20.4 293
Ethylene Oxide
ETO-18 EtO Source
181660 670822 100003
F 10.9 5.2 1001 0 0 293
F 277.6 5.2 1001 0 0 293
H 455.412.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-19 EtO Source
302545 883100 100003
F 1383.5 5.2 1001 0 0 293
F 1383.5 5.2 1001 0 0 293
H 780.212.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-20 EtO Source
404232 740343 000001
H 54.412.287.70 0.1 8.2 322
Ethylene Oxide
ETO-21 EtO Source
3151301064115 100004
H 2023.012.244.50 1.2100.6 450
H 90.718.344.50 0.6 3 294
H 1914.212.244.50 0.3 4.9 293
F 90.710.737.21 0 3 293

```
Ethylene Oxide
ETO-22  EtO Source
350455 900343                    000002
H       684.010.7 4450 1.1  7.4 405
H       756.6 9.8 4450 0.2 10.2 293
Ethylene Oxide
ETO-23  EtO Source
343336 820748                    100002
F       562.5 5.2 1001   0 21.3 389
H       263.115.2 7240   2  3.3 561
Ethylene Oxide
ETO-24  EtO Source
372214 894111                    100002
H      1877.9 7.6 8950 0.8 13.1 316
H      3138.9 7.6 8950 0.8 20.4 318
Ethylene Oxide
ETO-25  EtO Source
414201 713508                    100001
H        90.721.3 5760 0.9 11.2 293
Ethylene Oxide
ETO-26  EtO Source
3400051181316                     000003
H        45.4 5.2 5400 1.2 60.7 293
H       172.412.2 5400 1.2  4.6 345
F        18.1 5.2 1001   0  6.8 293
Ethylene Oxide
ETO-27  EtO Source
350141 820358                    100002
F      1414.3 5.2 1001   0    0 293
H       304.412.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-29  EtO Source
3944051050710                     000001
H      1378.912.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-32  EtO Source
355510 813402                    100001
H         1.412.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-33  EtO Source
333650 965645                    000002
F       412.8 5.2 1001   0    0 293
H       353.812.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-35  EtO Source
403401 795129                    100001
H       340.2 7.9 5400 0.2  0.8 327
Ethylene Oxide
ETO-36  EtO Source
334334 843502                    000002
H       372.910.7 4450 1.1  7.4 405
H       527.5   7 4450 0.8 13.4 293
```

Ethylene Oxide
ETO-37 EtO Source
422015 713800 100002
H 27.2 8.8 6250 1 11 344
H 544.314.9 6250 2 2.3 950
Ethylene Oxide
ETO-38 EtO Source
403405 742546 000002
H 72.618.3 4720 0.2 13.3 293
H 72.618.3 4720 0.3 32.3 293
Ethylene Oxide
ETO-39 EtO Source
3143401061726 100003
H 18.114.9 6750 2 1.9 356
H 27.2 4.9 6750 0.8 13.4 368
H 18.1 4.9 6750 0.8 10.4 356
Ethylene Oxide
ETO-40 EtO Source
391638 763338 000001
H 163.321.3 5760 0.2 3.1 293
Ethylene Oxide
ETO-41 EtO Source
3403251173300 000003
F 113.4 5.2 1001 0 0 293
H 136.112.1 5400 1.2 6.7 345
H 107.0 5.2 5400 1.2 4.6 293
Ethylene Oxide
ETO-42 EtO Source
312022 891853 000002
F 336.1 5.2 1001 0 0 293
H 0.012.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-43 EtO Source
421807 875347 000002
H 0.8 7.6 5400 0.5 0 294
H 8.210.1 5400 0.1 0.1 294
Ethylene Oxide
ETO-44 EtO Source
280211 823938 000001
H 508.017.7 5400 0.5 24.4 289
Ethylene Oxide
ETO-45 EtO Source
432054 733554 100002
H 163.323.8 5400 0.6 13.7 364
H 72.610.7 5400 0.9 0.6 294
Ethylene Oxide
ETO-46 EtO Source
403830 741249 000001
H 0.318.3 4970 0.2 27.7 293
Ethylene Oxide
ETO-47 EtO Source
3128181002310 000003

F 11.1 5.2 1001 0 0 293
F 11.1 5.2 1001 0 0 293
H 381.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-48 EtO Source
385640 951330 000001
H 340.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-49 EtO Source
350748 805702 100003
H 90.718.3 5400 0.9 39.6 355
H 90.712.2 5400 0.9 15.2 311
F 90.7 7.6 1001 0 4.9 294
Ethylene Oxide
ETO-50 EtO Source
450757 931615 000001
H 127.011.3 4130 0.6 4.6 372
Ethylene Oxide
ETO-51 EtO Source
412018 725215 000002
F 2.3 5.2 1001 0 0 293
H 113.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-52 EtO Source
354649 794851 000001
H 27.215.2 9120 1.2 1.9 351
Ethylene Oxide
ETO-53 EtO Source
344419 822230 000001
H 117.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-54 EtO Source
3931151194309 000001
H 0.413.7 5120 0.2 2.3 293
Ethylene Oxide
ETO-55 EtO Source
355517 800146 000002
F 1.4 5.2 1001 0 0 293
H 33.112.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-56 EtO Source
391008 764646 000003
H 56.712.2 5400 0.2 6.1 311
H 56.719.8 5400 0.2 3 297
F 2.3 5.2 1001 0 0 293
Ethylene Oxide
ETO-57 EtO Source
391414 863737 100003
F 51.7 5.2 1001 0 0 293
F 51.7 5.2 1001 0 0 293
H 10.412.2 5400 1.2 6.8 345
Ethylene Oxide

ETO-58 EtO Source
425245 854103 000001
H 199.615.2 3430 1.1 2.4 308
Ethylene Oxide
ETO-59 EtO Source
392430 764550 000001
H 113.4 3.7 5400 0.2 6.8 297
Ethylene Oxide
ETO-60 EtO Source
403806 752008 000001
H 105.712.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-61 EtO Source
3359481181218 000003
F 27.2 5.2 1001 0 0 293
H 54.4 5.2 5400 1.2 4.6 293
H 5.412.2 5400 1.2 7 345
Ethylene Oxide
ETO-62 EtO Source
344615 821751 000002
F 68.9 5.2 1001 0 0 293
H 21.812.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-63 EtO Source
414511 875525 000001
H 90.7 7.2 5400 0.3 6.1 300
Ethylene Oxide
ETO-64 EtO Source
410750 743610 100001
H 18.318.9 5400 0.1 6.8 300
Ethylene Oxide
ETO-65 EtO Source
382410 753424 000001
H 81.615.2 5400 0.1 10.1 298
Ethylene Oxide
ETO-66 EtO Source
350808 805743 000002
H 0.912.1 5400 1.2 6.8 345
F 69.9 5.2 1001 0 0 293
Ethylene Oxide
ETO-67 EtO Source
3120471105719 100002
F 36.3 5.2 1001 0 0 293
H 0.4 8.5 8170 0.7 5.5 345
Ethylene Oxide
ETO-68 EtO Source
420813 875929 000002
H 40.8 6.1 5400 0.1 0.1 294
H 16.3 7.3 5400 0 64.8 311
Ethylene Oxide
ETO-69 EtO Source
450000 922700 000001

H 6.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-70 EtO Source
324756 970250 000001
H 24.518.3 5990 0.3 8.5 293
Ethylene Oxide
ETO-71 EtO Source
362650 833448 100001
H 32.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-72 EtO Source
424111 830722 000001
H 15.715.2 5400 0.1 28 305
Ethylene Oxide
ETO-74 EtO Source
275307 824044 000001
H 9.1 4.6 5400 0.1 1.5 298
Ethylene Oxide
ETO-75 EtO Source
353910 802948 100002
H 18.112.2 7380 1 0.71033
H 9.1 0.9 7380 0.5 17.5 311
Ethylene Oxide
ETO-77 EtO Source
392935 764025 000002
H 0.922.9 5400 0.1 6.1 311
H 0.922.9 5400 0.1 6.1 311
Ethylene Oxide
ETO-80 EtO Source
3243011170933 000001
H 1.818.3 5070 0.3 1.2 293
Ethylene Oxide
ETO-91 EtO Source
4524281223239 000001
H 907.2 0.3 5400 0.5 5 458
Ethylene Oxide
ETO-99 EtO Source
430004 773919 100001
H 21.812.2 3300 0.1 3.7 301
Ethylene Oxide
ETO-108 EtO Source
450506 931508 000001
H 4.5 4.310170 0.3 1.1 339
Ethylene Oxide
ETO-116 EtO Source
3330101171000 000002
H 0.6 8.5 4610 0.8 15.2 408
F 63.5 5.2 1001 0 0 293
Ethylene Oxide
ETO-117 EtO Source
3515351135647 100001
H 0.012.5 2220 0.1 10.4 293

```
Ethylene Oxide
ETO-118  EtO Source
3944051050710                    000003
H       63.5 6.1 5400 0.4  3.1 295
H      132.4 6.1 5400 0.9  4.6 295
H      753.0 8.5 5400 0.9  5.6 295
Ethylene Oxide
ETO-119  EtO Source
3239181143322                    100002
H       18.112.2 5400 1.1  2.6 977
H        9.112.2 5400 0.5 11.7 311
```

Attachment 5: Cancer HEM-Screen output file for all sources

HUMAN EXPOSURE MODEL
STANDARD SUMMARY REPORT

Date: 12/7/2004 Time: 11:19
Chemical Name: Ethylene Oxide Unit Risk: 8.80E-05

REPORT DESCRIPTION
100m

MODELING OPTIONS

Input File Name:	c:\program files\hem_vb_wrapper_v3\input\etotest.hem
Radii Set:	" 0.1, 0.5, 1.0, 2.0, 5.0,10.0,20.0,30.0,40.0,50.0"
Census Data:	2000
Atmospheric Decay:	No

HEM-SCREEN EXPOSURE RESULTS

	Concentration	Population	Exposure
MAX:	1.68E+00	94	1.58E+02
MIN:	1.00E-38	"98,700,000"	3.27E+04

Level	Concentration	Population	Exposure
1	4.14E+00		0.00E+00
3	1.00E+00	285	3.66E+02
4	5.00E-01	"1,350"	1.11E+03
5	2.50E-01	"3,160"	1.69E+03
6	1.00E-01	"8,530"	2.42E+03
7	5.00E-02	"22,800"	3.44E+03
8	2.50E-02	"75,900"	5.23E+03
9	1.00E-02	"295,000"	8.52E+03
10	5.00E-03	"689,000"	1.13E+04
11	2.50E-03	"1,750,000"	1.49E+04
12	1.00E-03	"6,150,000"	2.13E+04
13	5.00E-04	"14,000,000"	2.68E+04
14	2.50E-04	"20,700,000"	2.93E+04
15	1.00E-04	"33,000,000"	3.12E+04
16	5.00E-05	"43,900,000"	3.20E+04
17	2.50E-05	"55,100,000"	3.24E+04
18	1.00E-05	"71,200,000"	3.27E+04
19	5.00E-06	"80,400,000"	3.27E+04
20	2.50E-06	"87,300,000"	3.27E+04
21	1.00E-06	"91,400,000"	3.27E+04
22	5.00E-07	"94,400,000"	3.27E+04
23	2.50E-07	"96,600,000"	3.27E+04
24	1.00E-07	"97,900,000"	3.27E+04
25	5.00E-08	"98,400,000"	3.27E+04

26	2.50E-08	"98,500,000"	3.27E+04
27	1.00E-08	"98,600,000"	3.27E+04
28	5.00E-09	"98,600,000"	3.27E+04
29	2.50E-09	"98,600,000"	3.27E+04
30	1.00E-09	"98,600,000"	3.27E+04
31	5.00E-10	"98,600,000"	3.27E+04
32	2.50E-10	"98,600,000"	3.27E+04
33	1.00E-10	"98,600,000"	3.27E+04
34	5.00E-11	"98,600,000"	3.27E+04
35	2.50E-11	"98,600,000"	3.27E+04
36	1.00E-11	"98,600,000"	3.27E+04
37	5.00E-12	"98,600,000"	3.27E+04
38	2.50E-12	"98,600,000"	3.27E+04
39	1.00E-12	"98,600,000"	3.27E+04
40	5.00E-13	"98,600,000"	3.27E+04
41	2.50E-13	"98,600,000"	3.27E+04
42	1.00E-13	"98,600,000"	3.27E+04
43	5.00E-14	"98,600,000"	3.27E+04
44	2.50E-14	"98,600,000"	3.27E+04
45	1.00E-14	"98,600,000"	3.27E+04
46	5.00E-15	"98,600,000"	3.27E+04
47	2.50E-15	"98,600,000"	3.27E+04
48	1.00E-15	"98,600,000"	3.27E+04
49	5.00E-16	"98,600,000"	3.27E+04
50	2.50E-16	"98,600,000"	3.27E+04
51	1.00E-16	"98,600,000"	3.27E+04
52	5.00E-17	"98,600,000"	3.27E+04
53	2.50E-17	"98,600,000"	3.27E+04
54	1.00E-17	"98,600,000"	3.27E+04
55	5.00E-18	"98,600,000"	3.27E+04
56	2.50E-18	"98,600,000"	3.27E+04
57	1.00E-18	"98,600,000"	3.27E+04
58	5.00E-19	"98,600,000"	3.27E+04
59	2.50E-19	"98,600,000"	3.27E+04
60	1.00E-19	"98,600,000"	3.27E+04
61	5.00E-20	"98,600,000"	3.27E+04
62	2.50E-20	"98,600,000"	3.27E+04
63	1.00E-20	"98,600,000"	3.27E+04
64	5.00E-21	"98,600,000"	3.27E+04
65	2.50E-21	"98,600,000"	3.27E+04
66	1.00E-21	"98,600,000"	3.27E+04
67	5.00E-22	"98,600,000"	3.27E+04
68	2.50E-22	"98,600,000"	3.27E+04
69	1.00E-22	"98,600,000"	3.27E+04
70	5.00E-23	"98,600,000"	3.27E+04
71	2.50E-23	"98,600,000"	3.27E+04
72	1.00E-23	"98,600,000"	3.27E+04
73	5.00E-24	"98,600,000"	3.27E+04
74	2.50E-24	"98,600,000"	3.27E+04
75	1.00E-24	"98,600,000"	3.27E+04
76	5.00E-25	"98,600,000"	3.27E+04
77	2.50E-25	"98,600,000"	3.27E+04

78	1.00E-25	"98,600,000"	3.27E+04
79	5.00E-26	"98,600,000"	3.27E+04
80	2.50E-26	"98,600,000"	3.27E+04
81	1.00E-26	"98,600,000"	3.27E+04
82	5.00E-27	"98,600,000"	3.27E+04
83	2.50E-27	"98,600,000"	3.27E+04
84	1.00E-27	"98,600,000"	3.27E+04
85	5.00E-28	"98,600,000"	3.27E+04
86	2.50E-28	"98,600,000"	3.27E+04
87	1.00E-28	"98,600,000"	3.27E+04
88	5.00E-29	"98,600,000"	3.27E+04
89	2.50E-29	"98,600,000"	3.27E+04
90	1.00E-29	"98,600,000"	3.27E+04
91	5.00E-30	"98,600,000"	3.27E+04
92	2.50E-30	"98,600,000"	3.27E+04
93	1.00E-30	"98,600,000"	3.27E+04
94	5.00E-31	"98,600,000"	3.27E+04
95	2.50E-31	"98,600,000"	3.27E+04
96	1.00E-31	"98,600,000"	3.27E+04
97	5.00E-32	"98,600,000"	3.27E+04
98	2.50E-32	"98,600,000"	3.27E+04
99	1.00E-32	"98,600,000"	3.27E+04
100	5.00E-33	"98,600,000"	3.27E+04
101	2.50E-33	"98,600,000"	3.27E+04
102	1.00E-33	"98,600,000"	3.27E+04
103	5.00E-34	"98,600,000"	3.27E+04
104	2.50E-34	"98,600,000"	3.27E+04
105	1.00E-34	"98,600,000"	3.27E+04
106	5.00E-35	"98,600,000"	3.27E+04
107	2.50E-35	"98,600,000"	3.27E+04
108	1.00E-35	"98,600,000"	3.27E+04
109	5.00E-36	"98,600,000"	3.27E+04
110	2.50E-36	"98,600,000"	3.27E+04
111	1.00E-36	"98,600,000"	3.27E+04
112	5.00E-37	"98,600,000"	3.27E+04
113	2.50E-37	"98,600,000"	3.27E+04
114	1.00E-37	"98,600,000"	3.27E+04
115	5.00E-38	"98,600,000"	3.27E+04
116	2.50E-38	"98,600,000"	3.27E+04
117	1.00E-38	"98,700,000"	3.27E+04

HEM-SCREEN RISK RESULTS

	Risk Level	Population	Exposure * Risk
MAX:	1.48E-04	47	6.95E-03
MIN:	8.80E-43	"98,700,000"	2.88E+00

Level	Risk Level	Population	Exposure * Unit Risk
1	3.65E-04		0.00E+00
3	1.00E-04	94	1.39E-02
4	5.00E-05	"1,230"	9.18E-02
5	2.50E-05	"2,640"	1.37E-01

6	1.00E-05	"7,230"	2.01E-01
7	5.00E-06	"20,200"	2.90E-01
8	2.50E-06	"62,600"	4.29E-01
9	1.00E-06	"249,000"	7.06E-01
10	5.00E-07	"596,000"	9.47E-01
11	2.50E-07	"1,460,000"	1.24E+00
12	1.00E-07	"5,120,000"	1.78E+00
13	5.00E-08	"12,200,000"	2.28E+00
14	2.50E-08	"19,500,000"	2.55E+00
15	1.00E-08	"31,000,000"	2.73E+00
16	5.00E-09	"42,000,000"	2.81E+00
17	2.50E-09	"52,900,000"	2.85E+00
18	1.00E-09	"69,400,000"	2.87E+00
19	5.00E-10	"78,900,000"	2.88E+00
20	2.50E-10	"86,600,000"	2.88E+00
21	1.00E-10	"90,800,000"	2.88E+00
22	5.00E-11	"93,800,000"	2.88E+00
23	2.50E-11	"96,300,000"	2.88E+00
24	1.00E-11	"97,700,000"	2.88E+00
25	5.00E-12	"98,400,000"	2.88E+00
26	2.50E-12	"98,500,000"	2.88E+00
27	1.00E-12	"98,600,000"	2.88E+00
28	5.00E-13	"98,600,000"	2.88E+00
29	2.50E-13	"98,600,000"	2.88E+00
30	1.00E-13	"98,600,000"	2.88E+00
31	5.00E-14	"98,600,000"	2.88E+00
32	2.50E-14	"98,600,000"	2.88E+00
33	1.00E-14	"98,600,000"	2.88E+00
34	5.00E-15	"98,600,000"	2.88E+00
35	2.50E-15	"98,600,000"	2.88E+00
36	1.00E-15	"98,600,000"	2.88E+00
37	5.00E-16	"98,600,000"	2.88E+00
38	2.50E-16	"98,600,000"	2.88E+00
39	1.00E-16	"98,600,000"	2.88E+00
40	5.00E-17	"98,600,000"	2.88E+00
41	2.50E-17	"98,600,000"	2.88E+00
42	1.00E-17	"98,600,000"	2.88E+00
43	5.00E-18	"98,600,000"	2.88E+00
44	2.50E-18	"98,600,000"	2.88E+00
45	1.00E-18	"98,600,000"	2.88E+00
46	5.00E-19	"98,600,000"	2.88E+00
47	2.50E-19	"98,600,000"	2.88E+00
48	1.00E-19	"98,600,000"	2.88E+00
49	5.00E-20	"98,600,000"	2.88E+00
50	2.50E-20	"98,600,000"	2.88E+00
51	1.00E-20	"98,600,000"	2.88E+00
52	5.00E-21	"98,600,000"	2.88E+00
53	2.50E-21	"98,600,000"	2.88E+00
54	1.00E-21	"98,600,000"	2.88E+00
55	5.00E-22	"98,600,000"	2.88E+00
56	2.50E-22	"98,600,000"	2.88E+00
57	1.00E-22	"98,600,000"	2.88E+00

58	5.00E-23	"98,600,000"	2.88E+00
59	2.50E-23	"98,600,000"	2.88E+00
60	1.00E-23	"98,600,000"	2.88E+00
61	5.00E-24	"98,600,000"	2.88E+00
62	2.50E-24	"98,600,000"	2.88E+00
63	1.00E-24	"98,600,000"	2.88E+00
64	5.00E-25	"98,600,000"	2.88E+00
65	2.50E-25	"98,600,000"	2.88E+00
66	1.00E-25	"98,600,000"	2.88E+00
67	5.00E-26	"98,600,000"	2.88E+00
68	2.50E-26	"98,600,000"	2.88E+00
69	1.00E-26	"98,600,000"	2.88E+00
70	5.00E-27	"98,600,000"	2.88E+00
71	2.50E-27	"98,600,000"	2.88E+00
72	1.00E-27	"98,600,000"	2.88E+00
73	5.00E-28	"98,600,000"	2.88E+00
74	2.50E-28	"98,600,000"	2.88E+00
75	1.00E-28	"98,600,000"	2.88E+00
76	5.00E-29	"98,600,000"	2.88E+00
77	2.50E-29	"98,600,000"	2.88E+00
78	1.00E-29	"98,600,000"	2.88E+00
79	5.00E-30	"98,600,000"	2.88E+00
80	2.50E-30	"98,600,000"	2.88E+00
81	1.00E-30	"98,600,000"	2.88E+00
82	5.00E-31	"98,600,000"	2.88E+00
83	2.50E-31	"98,600,000"	2.88E+00
84	1.00E-31	"98,600,000"	2.88E+00
85	5.00E-32	"98,600,000"	2.88E+00
86	2.50E-32	"98,600,000"	2.88E+00
87	1.00E-32	"98,600,000"	2.88E+00
88	5.00E-33	"98,600,000"	2.88E+00
89	2.50E-33	"98,600,000"	2.88E+00
90	1.00E-33	"98,600,000"	2.88E+00
91	5.00E-34	"98,600,000"	2.88E+00
92	2.50E-34	"98,600,000"	2.88E+00
93	1.00E-34	"98,600,000"	2.88E+00
94	5.00E-35	"98,600,000"	2.88E+00
95	2.50E-35	"98,600,000"	2.88E+00
96	1.00E-35	"98,600,000"	2.88E+00
97	5.00E-36	"98,600,000"	2.88E+00
98	2.50E-36	"98,600,000"	2.88E+00
99	1.00E-36	"98,600,000"	2.88E+00
100	5.00E-37	"98,600,000"	2.88E+00
101	2.50E-37	"98,600,000"	2.88E+00
102	1.00E-37	"98,600,000"	2.88E+00
103	5.00E-38	"98,600,000"	2.88E+00
104	2.50E-38	"98,600,000"	2.88E+00
105	8.80E-43	"98,600,000"	2.88E+00

HEM-SCREEN RESULTS

Source	Max Concentration	People	Max Exposure	Lifetime Incidence	Max Risk	Annual Incid.	Repeat Interval
ETO-18 EtO Source	1.68E+00	94	1.58E+02	1.39E-02	1.48E-04	0.0024	420
ETO-19 EtO Source	1.06E+00	3	3.19E+00	2.81E-04	9.37E-05	0.0015	690
ETO-8 EtO Source	8.38E-01	3	2.51E+00	2.21E-04	7.37E-05	0.0015	670
ETO-27 EtO Source	7.51E-01	39	2.93E+01	2.58E-03	6.61E-05	0.0013	760
ETO-4 EtO Source	6.96E-01	49	3.41E+01	3.00E-03	6.12E-05	0.0042	240
ETO-5 EtO Source	6.90E-01	54	3.72E+01	3.28E-03	6.07E-05	0.0011	880
ETO-24 EtO Source	2.67E-01	1	2.67E-01	2.35E-05	2.35E-05	0.0011	900
ETO-11 EtO Source	2.53E-01	26	6.58E+00	5.79E-04	2.23E-05	0.0003	"3,200.00"
ETO-22 EtO Source	2.43E-01	65	1.58E+01	1.39E-03	2.14E-05	0.0008	"1,200.00"
ETO-12 EtO Source	1.88E-01	4	7.54E-01	6.63E-05	1.66E-05	0.0039	260
ETO-118 EtO Source	1.86E-01	28	5.21E+00	4.59E-04	1.64E-05	0.001	980
ETO-42 EtO Source	1.82E-01	181	3.29E+01	2.90E-03	1.60E-05	0.0002	"5,200.00"
ETO-13 EtO Source	1.70E-01	7	1.19E+00	1.05E-04	1.50E-05	0.0018	540
ETO-57 EtO Source	1.49E-01	15	2.23E+00	1.96E-04	1.31E-05	0.0001	"11,000.00"
ETO-91 EtO Source	1.40E-01	17	2.38E+00	2.09E-04	1.23E-05	0.0007	"1,500.00"
ETO-10 EtO Source	1.35E-01	3	4.05E-01	3.56E-05	1.19E-05	0.0037	270
ETO-29 EtO Source	1.28E-01	28	3.58E+00	3.15E-04	1.12E-05	0.0013	770
ETO-3 EtO Source	1.12E-01	107	1.20E+01	1.05E-03	9.86E-06	0.0002	"5,200.00"
ETO-14 EtO Source	1.11E-01	158	1.75E+01	1.54E-03	9.75E-06	0.0021	470
ETO-1 EtO Source	7.85E-02	322	2.53E+01	2.22E-03	6.91E-06	0.0004	"2,700.00"
ETO-9 EtO Source	7.60E-02	2	1.52E-01	1.34E-05	6.69E-06	0.0012	840
ETO-44 EtO Source	6.74E-02	6	4.05E-01	3.56E-05	5.93E-06	0.0003	"2,900.00"
ETO-36 EtO Source	6.72E-02	153	1.03E+01	9.05E-04	5.91E-06	0.0005	"2,100.00"
ETO-48 EtO Source	5.92E-02	22	1.30E+00	1.15E-04	5.21E-06	0.0002	"6,400.00"
ETO-35 EtO Source	5.40E-02	3	1.62E-01	1.43E-05	4.76E-06	0.0005	"1,800.00"
ETO-15 EtO Source	5.40E-02	1	5.40E-02	4.75E-06	4.75E-06	0.0027	370
ETO-23 EtO Source	4.37E-02	111	4.85E+00	4.27E-04	3.85E-06	0.0002	"4,300.00"
ETO-7 EtO Source	4.11E-02	171	7.03E+00	6.19E-04	3.62E-06	0.0004	"2,600.00"
ETO-67 EtO Source	3.92E-02	185	7.25E+00	6.38E-04	3.45E-06	<0.0001	"43,000.00"
ETO-20 EtO Source	3.66E-02	92	3.37E+00	2.96E-04	3.22E-06	0.0003	"3,700.00"
ETO-21 EtO Source	2.69E-02	343	9.23E+00	8.13E-04	2.37E-06	0.001	"1,000.00"
ETO-61 EtO Source	2.51E-02	28	7.04E-01	6.20E-05	2.21E-06	0.0003	"3,100.00"
ETO-37 EtO Source	2.47E-02	53	1.31E+00	1.15E-04	2.17E-06	0.0007	"1,400.00"
ETO-63 EtO Source	2.41E-02	16	3.85E-01	3.39E-05	2.12E-06	0.0001	"8,000.00"
ETO-26 EtO Source	2.28E-02	3	6.85E-02	6.03E-06	2.01E-06	0.0008	"1,200.00"
ETO-59 EtO Source	2.09E-02	926	1.94E+01	1.71E-03	1.84E-06	0.0001	"9,200.00"
ETO-62 EtO Source	2.02E-02	3	6.06E-02	5.33E-06	1.78E-06	<0.0001	"26,000.00"
ETO-49 EtO Source	1.76E-02	9	1.59E-01	1.40E-05	1.55E-06	0.0003	"3,300.00"
ETO-33 EtO Source	1.69E-02	48	8.10E-01	7.12E-05	1.48E-06	<0.0001	"54,000.00"
ETO-45 EtO Source	1.67E-02	35	5.85E-01	5.15E-05	1.47E-06	<0.0001	"22,000.00"
ETO-58 EtO Source	1.58E-02	51	8.07E-01	7.10E-05	1.39E-06	0.0001	"9,200.00"
ETO-38 EtO Source	1.29E-02	25	3.23E-01	2.84E-05	1.14E-06	0.0002	"5,100.00"
ETO-55 EtO Source	1.17E-02	9	1.05E-01	9.24E-06	1.03E-06	<0.0001	"73,000.00"
ETO-56 EtO Source	1.12E-02	"1,050"	1.18E+01	1.03E-03	9.85E-07	0.0001	"10,000.00"
ETO-60 EtO Source	1.08E-02	71	7.64E-01	6.73E-05	9.47E-07	0.0001	"16,000.00"
ETO-51 EtO Source	9.42E-03	11	1.04E-01	9.12E-06	8.29E-07	<0.0001	"28,000.00"
ETO-2 EtO Source	8.16E-03	4	3.27E-02	2.87E-06	7.18E-07	0.0002	"5,300.00"
ETO-52 EtO Source	7.35E-03	8	5.88E-02	5.17E-06	6.46E-07	<0.0001	"220,000.00"
ETO-41 EtO Source	7.22E-03	11	7.94E-02	6.99E-06	6.35E-07	0.0003	"3,600.00"
ETO-75 EtO Source	7.04E-03	19	1.34E-01	1.18E-05	6.20E-07	<0.0001	"37,000.00"

ETO-68	EtO Source	6.79E-03	479	3.25E+00	2.86E-04	5.97E-07	0.0001 "13,000.00"
ETO-72	EtO Source	6.47E-03	61	3.95E-01	3.48E-05	5.70E-07	<0.0001 "76,000.00"
ETO-47	EtO Source	6.44E-03	462	2.97E+00	2.62E-04	5.67E-07	<0.0001 "28,000.00"
ETO-40	EtO Source	6.21E-03	70	4.35E-01	3.82E-05	5.46E-07	0.0002 "6,200.00"
ETO-66	EtO Source	5.92E-03	150	8.89E-01	7.82E-05	5.21E-07	<0.0001 "29,000.00"
ETO-65	EtO Source	5.27E-03	1	5.27E-03	4.64E-07	4.64E-07	<0.0001 "76,000.00"
ETO-71	EtO Source	5.15E-03	6	3.09E-02	2.72E-06	4.53E-07	<0.0001 "150,000.00"
ETO-108	EtO Source	4.88E-03	35	1.71E-01	1.50E-05	4.29E-07	<0.0001 "210,000.00"
ETO-39	EtO Source	4.47E-03	104	4.65E-01	4.09E-05	3.94E-07	0.0001 "8,600.00"
ETO-50	EtO Source	3.97E-03	535	2.13E+00	1.87E-04	3.50E-07	0.0001 "12,000.00"
ETO-53	EtO Source	3.76E-03	2	7.52E-03	6.61E-07	3.31E-07	<0.0001 "37,000.00"
ETO-99	EtO Source	3.42E-03	68	2.33E-01	2.05E-05	3.01E-07	<0.0001 "38,000.00"
ETO-25	EtO Source	2.58E-03	22	5.67E-02	4.99E-06	2.27E-07	0.0001 "12,000.00"
ETO-116	EtO Source	2.40E-03	156	3.75E-01	3.30E-05	2.11E-07	<0.0001 "36,000.00"
ETO-119	EtO Source	2.06E-03	2	4.12E-03	3.62E-07	1.81E-07	<0.0001 "170,000.00"
ETO-80	EtO Source	9.28E-04	23	2.13E-02	1.88E-06	8.17E-08	<0.0001 "290,000.00"
ETO-64	EtO Source	4.76E-04	69	3.29E-02	2.89E-06	4.19E-08	<0.0001 "100,000.00"
ETO-43	EtO Source	4.31E-04	87	3.75E-02	3.30E-06	3.80E-08	<0.0001 "190,000.00"
ETO-69	EtO Source	3.81E-04	49	1.87E-02	1.64E-06	3.35E-08	<0.0001 **********
ETO-70	EtO Source	3.20E-04	522	1.67E-01	1.47E-05	2.82E-08	<0.0001 "82,000.00"
ETO-74	EtO Source	1.22E-04	2	2.45E-04	2.15E-08	1.08E-08	<0.0001 "140,000.00"
ETO-32	EtO Source	1.07E-04	5	5.35E-04	4.70E-08	9.41E-09	<0.0001 **********
ETO-77	EtO Source	6.76E-05	80	5.41E-03	4.76E-07	5.95E-09	<0.0001 **********
ETO-46	EtO Source	5.39E-05	28	1.51E-03	1.33E-07	4.74E-09	<0.0001 **********
ETO-54	EtO Source	3.31E-05	1	3.31E-05	2.91E-09	2.91E-09	<0.0001 **********
ETO-117	EtO Source	1.00E-38	"49,300"	4.93E-34	4.33E-38	8.80E-43	<0.0001

*** END OF REPORT ***

Attachment 6: Noncancer HEM-Screen output file for all sources

HUMAN EXPOSURE MODEL
STANDARD SUMMARY REPORT

Date: 12/8/2004 Time: 09:14
Chemical Name: Ethylene Oxide Unit Risk: 3.33E-02

REPORT DESCRIPTION
eonc

MODELING OPTIONS

Input File Name:	c:\program files\hem_vb_wrapper_v3\input\eonctest.hem
Radii Set:	" 0.1, 0.5, 1.0, 2.0, 5.0,10.0,20.0,30.0,40.0,50.0"
Census Data:	2000
Atmospheric Decay:	No

HEM-SCREEN EXPOSURE RESULTS

	Concentration	Population	Exposure
MAX:	1.68E+00	94	1.58E+02
MIN:	1.00E-38	"98,700,000"	3.27E+04

Level	Concentration	Population	Exposure
1	4.14E+00		0.00E+00
3	1.00E+00	285	3.66E+02
4	5.00E-01	"1,350"	1.11E+03
5	2.50E-01	"3,160"	1.69E+03
6	1.00E-01	"8,530"	2.42E+03
7	5.00E-02	"22,800"	3.44E+03
8	2.50E-02	"75,900"	5.23E+03
9	1.00E-02	"295,000"	8.52E+03
10	5.00E-03	"689,000"	1.13E+04
11	2.50E-03	"1,750,000"	1.49E+04
12	1.00E-03	"6,150,000"	2.13E+04
13	5.00E-04	"14,000,000"	2.68E+04
14	2.50E-04	"20,700,000"	2.93E+04
15	1.00E-04	"33,000,000"	3.12E+04
16	5.00E-05	"43,900,000"	3.20E+04
17	2.50E-05	"55,100,000"	3.24E+04
18	1.00E-05	"71,200,000"	3.27E+04
19	5.00E-06	"80,400,000"	3.27E+04
20	2.50E-06	"87,300,000"	3.27E+04
21	1.00E-06	"91,400,000"	3.27E+04
22	5.00E-07	"94,400,000"	3.27E+04
23	2.50E-07	"96,600,000"	3.27E+04
24	1.00E-07	"97,900,000"	3.27E+04
25	5.00E-08	"98,400,000"	3.27E+04

26	2.50E-08	"98,500,000"	3.27E+04
27	1.00E-08	"98,600,000"	3.27E+04
28	5.00E-09	"98,600,000"	3.27E+04
29	2.50E-09	"98,600,000"	3.27E+04
30	1.00E-09	"98,600,000"	3.27E+04
31	5.00E-10	"98,600,000"	3.27E+04
32	2.50E-10	"98,600,000"	3.27E+04
33	1.00E-10	"98,600,000"	3.27E+04
34	5.00E-11	"98,600,000"	3.27E+04
35	2.50E-11	"98,600,000"	3.27E+04
36	1.00E-11	"98,600,000"	3.27E+04
37	5.00E-12	"98,600,000"	3.27E+04
38	2.50E-12	"98,600,000"	3.27E+04
39	1.00E-12	"98,600,000"	3.27E+04
40	5.00E-13	"98,600,000"	3.27E+04
41	2.50E-13	"98,600,000"	3.27E+04
42	1.00E-13	"98,600,000"	3.27E+04
43	5.00E-14	"98,600,000"	3.27E+04
44	2.50E-14	"98,600,000"	3.27E+04
45	1.00E-14	"98,600,000"	3.27E+04
46	5.00E-15	"98,600,000"	3.27E+04
47	2.50E-15	"98,600,000"	3.27E+04
48	1.00E-15	"98,600,000"	3.27E+04
49	5.00E-16	"98,600,000"	3.27E+04
50	2.50E-16	"98,600,000"	3.27E+04
51	1.00E-16	"98,600,000"	3.27E+04
52	5.00E-17	"98,600,000"	3.27E+04
53	2.50E-17	"98,600,000"	3.27E+04
54	1.00E-17	"98,600,000"	3.27E+04
55	5.00E-18	"98,600,000"	3.27E+04
56	2.50E-18	"98,600,000"	3.27E+04
57	1.00E-18	"98,600,000"	3.27E+04
58	5.00E-19	"98,600,000"	3.27E+04
59	2.50E-19	"98,600,000"	3.27E+04
60	1.00E-19	"98,600,000"	3.27E+04
61	5.00E-20	"98,600,000"	3.27E+04
62	2.50E-20	"98,600,000"	3.27E+04
63	1.00E-20	"98,600,000"	3.27E+04
64	5.00E-21	"98,600,000"	3.27E+04
65	2.50E-21	"98,600,000"	3.27E+04
66	1.00E-21	"98,600,000"	3.27E+04
67	5.00E-22	"98,600,000"	3.27E+04
68	2.50E-22	"98,600,000"	3.27E+04
69	1.00E-22	"98,600,000"	3.27E+04
70	5.00E-23	"98,600,000"	3.27E+04
71	2.50E-23	"98,600,000"	3.27E+04
72	1.00E-23	"98,600,000"	3.27E+04
73	5.00E-24	"98,600,000"	3.27E+04
74	2.50E-24	"98,600,000"	3.27E+04
75	1.00E-24	"98,600,000"	3.27E+04
76	5.00E-25	"98,600,000"	3.27E+04
77	2.50E-25	"98,600,000"	3.27E+04

78	1.00E-25	"98,600,000"	3.27E+04
79	5.00E-26	"98,600,000"	3.27E+04
80	2.50E-26	"98,600,000"	3.27E+04
81	1.00E-26	"98,600,000"	3.27E+04
82	5.00E-27	"98,600,000"	3.27E+04
83	2.50E-27	"98,600,000"	3.27E+04
84	1.00E-27	"98,600,000"	3.27E+04
85	5.00E-28	"98,600,000"	3.27E+04
86	2.50E-28	"98,600,000"	3.27E+04
87	1.00E-28	"98,600,000"	3.27E+04
88	5.00E-29	"98,600,000"	3.27E+04
89	2.50E-29	"98,600,000"	3.27E+04
90	1.00E-29	"98,600,000"	3.27E+04
91	5.00E-30	"98,600,000"	3.27E+04
92	2.50E-30	"98,600,000"	3.27E+04
93	1.00E-30	"98,600,000"	3.27E+04
94	5.00E-31	"98,600,000"	3.27E+04
95	2.50E-31	"98,600,000"	3.27E+04
96	1.00E-31	"98,600,000"	3.27E+04
97	5.00E-32	"98,600,000"	3.27E+04
98	2.50E-32	"98,600,000"	3.27E+04
99	1.00E-32	"98,600,000"	3.27E+04
100	5.00E-33	"98,600,000"	3.27E+04
101	2.50E-33	"98,600,000"	3.27E+04
102	1.00E-33	"98,600,000"	3.27E+04
103	5.00E-34	"98,600,000"	3.27E+04
104	2.50E-34	"98,600,000"	3.27E+04
105	1.00E-34	"98,600,000"	3.27E+04
106	5.00E-35	"98,600,000"	3.27E+04
107	2.50E-35	"98,600,000"	3.27E+04
108	1.00E-35	"98,600,000"	3.27E+04
109	5.00E-36	"98,600,000"	3.27E+04
110	2.50E-36	"98,600,000"	3.27E+04
111	1.00E-36	"98,600,000"	3.27E+04
112	5.00E-37	"98,600,000"	3.27E+04
113	2.50E-37	"98,600,000"	3.27E+04
114	1.00E-37	"98,600,000"	3.27E+04
115	5.00E-38	"98,600,000"	3.27E+04
116	2.50E-38	"98,600,000"	3.27E+04
117	1.00E-38	"98,700,000"	3.27E+04

HEM-SCREEN RISK RESULTS

	Risk Level	Population	Exposure * Risk
MAX:	5.60E-02	47	2.63E+00
MIN:	3.33E-40	"98,700,000"	1.09E+03

Level	Risk Level	Population	Exposure * Unit Risk
1	1.38E-01		0.00E+00
3	5.00E-02	94	5.26E+00
4	2.50E-02	401	1.54E+01
5	1.00E-02	"2,100"	4.67E+01

6	5.00E-03	"4,390"	6.38E+01
7	2.50E-03	"14,900"	9.84E+01
8	1.00E-03	"57,300"	1.57E+02
9	5.00E-04	"167,000"	2.32E+02
10	2.50E-04	"428,000"	3.22E+02
11	1.00E-04	"1,360,000"	4.60E+02
12	5.00E-05	"3,440,000"	6.02E+02
13	2.50E-05	"8,960,000"	7.92E+02
14	1.00E-05	"19,000,000"	9.61E+02
15	5.00E-06	"26,800,000"	1.02E+03
16	2.50E-06	"37,400,000"	1.05E+03
17	1.00E-06	"52,000,000"	1.08E+03
18	5.00E-07	"65,600,000"	1.09E+03
19	2.50E-07	"75,100,000"	1.09E+03
20	1.00E-07	"86,100,000"	1.09E+03
21	5.00E-08	"89,500,000"	1.09E+03
22	2.50E-08	"92,600,000"	1.09E+03
23	1.00E-08	"96,200,000"	1.09E+03
24	5.00E-09	"97,500,000"	1.09E+03
25	2.50E-09	"98,200,000"	1.09E+03
26	1.00E-09	"98,500,000"	1.09E+03
27	5.00E-10	"98,600,000"	1.09E+03
28	2.50E-10	"98,600,000"	1.09E+03
29	1.00E-10	"98,600,000"	1.09E+03
30	5.00E-11	"98,600,000"	1.09E+03
31	2.50E-11	"98,600,000"	1.09E+03
32	1.00E-11	"98,600,000"	1.09E+03
33	5.00E-12	"98,600,000"	1.09E+03
34	2.50E-12	"98,600,000"	1.09E+03
35	1.00E-12	"98,600,000"	1.09E+03
36	5.00E-13	"98,600,000"	1.09E+03
37	2.50E-13	"98,600,000"	1.09E+03
38	1.00E-13	"98,600,000"	1.09E+03
39	5.00E-14	"98,600,000"	1.09E+03
40	2.50E-14	"98,600,000"	1.09E+03
41	1.00E-14	"98,600,000"	1.09E+03
42	5.00E-15	"98,600,000"	1.09E+03
43	2.50E-15	"98,600,000"	1.09E+03
44	1.00E-15	"98,600,000"	1.09E+03
45	5.00E-16	"98,600,000"	1.09E+03
46	2.50E-16	"98,600,000"	1.09E+03
47	1.00E-16	"98,600,000"	1.09E+03
48	5.00E-17	"98,600,000"	1.09E+03
49	2.50E-17	"98,600,000"	1.09E+03
50	1.00E-17	"98,600,000"	1.09E+03
51	5.00E-18	"98,600,000"	1.09E+03
52	2.50E-18	"98,600,000"	1.09E+03
53	1.00E-18	"98,600,000"	1.09E+03
54	5.00E-19	"98,600,000"	1.09E+03
55	2.50E-19	"98,600,000"	1.09E+03
56	1.00E-19	"98,600,000"	1.09E+03
57	5.00E-20	"98,600,000"	1.09E+03

58	2.50E-20	"98,600,000"	1.09E+03
59	1.00E-20	"98,600,000"	1.09E+03
60	5.00E-21	"98,600,000"	1.09E+03
61	2.50E-21	"98,600,000"	1.09E+03
62	1.00E-21	"98,600,000"	1.09E+03
63	5.00E-22	"98,600,000"	1.09E+03
64	2.50E-22	"98,600,000"	1.09E+03
65	1.00E-22	"98,600,000"	1.09E+03
66	5.00E-23	"98,600,000"	1.09E+03
67	2.50E-23	"98,600,000"	1.09E+03
68	1.00E-23	"98,600,000"	1.09E+03
69	5.00E-24	"98,600,000"	1.09E+03
70	2.50E-24	"98,600,000"	1.09E+03
71	1.00E-24	"98,600,000"	1.09E+03
72	5.00E-25	"98,600,000"	1.09E+03
73	2.50E-25	"98,600,000"	1.09E+03
74	1.00E-25	"98,600,000"	1.09E+03
75	5.00E-26	"98,600,000"	1.09E+03
76	2.50E-26	"98,600,000"	1.09E+03
77	1.00E-26	"98,600,000"	1.09E+03
78	5.00E-27	"98,600,000"	1.09E+03
79	2.50E-27	"98,600,000"	1.09E+03
80	1.00E-27	"98,600,000"	1.09E+03
81	5.00E-28	"98,600,000"	1.09E+03
82	2.50E-28	"98,600,000"	1.09E+03
83	1.00E-28	"98,600,000"	1.09E+03
84	5.00E-29	"98,600,000"	1.09E+03
85	2.50E-29	"98,600,000"	1.09E+03
86	1.00E-29	"98,600,000"	1.09E+03
87	5.00E-30	"98,600,000"	1.09E+03
88	2.50E-30	"98,600,000"	1.09E+03
89	1.00E-30	"98,600,000"	1.09E+03
90	5.00E-31	"98,600,000"	1.09E+03
91	2.50E-31	"98,600,000"	1.09E+03
92	1.00E-31	"98,600,000"	1.09E+03
93	5.00E-32	"98,600,000"	1.09E+03
94	2.50E-32	"98,600,000"	1.09E+03
95	1.00E-32	"98,600,000"	1.09E+03
96	5.00E-33	"98,600,000"	1.09E+03
97	2.50E-33	"98,600,000"	1.09E+03
98	1.00E-33	"98,600,000"	1.09E+03
99	5.00E-34	"98,600,000"	1.09E+03
100	2.50E-34	"98,600,000"	1.09E+03
101	1.00E-34	"98,600,000"	1.09E+03
102	5.00E-35	"98,600,000"	1.09E+03
103	2.50E-35	"98,600,000"	1.09E+03
104	1.00E-35	"98,600,000"	1.09E+03
105	5.00E-36	"98,600,000"	1.09E+03
106	2.50E-36	"98,600,000"	1.09E+03
107	1.00E-36	"98,600,000"	1.09E+03
108	5.00E-37	"98,600,000"	1.09E+03
109	2.50E-37	"98,600,000"	1.09E+03

110	1.00E-37	"98,600,000"	1.09E+03
111	5.00E-38	"98,600,000"	1.09E+03
112	2.50E-38	"98,600,000"	1.09E+03
113	3.33E-40	"98,700,000"	1.09E+03

HEM-SCREEN RESULTS

Source	Max Concentration	People	Max Exposure	Lifetime Incidence	Max Risk	Annual Incid.	Repeat Interval
ETO-18 EtO Source	1.68E+00	94	1.58E+02	5.26E+00	5.60E-02	0.91	1.1
ETO-19 EtO Source	1.06E+00	3	3.19E+00	1.06E-01	3.55E-02	0.55	1.8
ETO-8 EtO Source	8.38E-01	3	2.51E+00	8.38E-02	2.79E-02	0.56	1.8
ETO-27 EtO Source	7.51E-01	39	2.93E+01	9.76E-01	2.50E-02	0.5	2
ETO-4 EtO Source	6.96E-01	49	3.41E+01	1.14E+00	2.32E-02	1.6	0.63
ETO-5 EtO Source	6.90E-01	54	3.72E+01	1.24E+00	2.30E-02	0.43	2.3
ETO-24 EtO Source	2.67E-01	1	2.67E-01	8.91E-03	8.91E-03	0.42	2.4
ETO-11 EtO Source	2.53E-01	26	6.58E+00	2.19E-01	8.43E-03	0.12	8.5
ETO-22 EtO Source	2.43E-01	65	1.58E+01	5.27E-01	8.11E-03	0.32	3.1
ETO-12 EtO Source	1.88E-01	4	7.54E-01	2.51E-02	6.28E-03	1.5	0.68
ETO-118 EtO Source	1.86E-01	28	5.21E+00	1.74E-01	6.21E-03	0.38	2.6
ETO-42 EtO Source	1.82E-01	181	3.29E+01	1.10E+00	6.07E-03	0.073	14
ETO-13 EtO Source	1.70E-01	7	1.19E+00	3.97E-02	5.68E-03	0.7	1.4
ETO-57 EtO Source	1.49E-01	15	2.23E+00	7.43E-02	4.95E-03	0.034	29
ETO-91 EtO Source	1.40E-01	17	2.38E+00	7.93E-02	4.66E-03	0.26	3.9
ETO-10 EtO Source	1.35E-01	3	4.05E-01	1.35E-02	4.50E-03	1.4	0.71
ETO-29 EtO Source	1.28E-01	28	3.58E+00	1.19E-01	4.26E-03	0.49	2
ETO-3 EtO Source	1.12E-01	107	1.20E+01	4.00E-01	3.73E-03	0.073	14
ETO-14 EtO Source	1.11E-01	158	1.75E+01	5.84E-01	3.69E-03	0.81	1.2
ETO-1 EtO Source	7.85E-02	322	2.53E+01	8.43E-01	2.62E-03	0.14	7.1
ETO-9 EtO Source	7.60E-02	2	1.52E-01	5.07E-03	2.53E-03	0.45	2.2
ETO-44 EtO Source	6.74E-02	6	4.05E-01	1.35E-02	2.25E-03	0.13	7.6
ETO-36 EtO Source	6.72E-02	153	1.03E+01	3.43E-01	2.24E-03	0.18	5.5
ETO-48 EtO Source	5.92E-02	22	1.30E+00	4.34E-02	1.97E-03	0.059	17
ETO-15 EtO Source	5.40E-02	1	5.40E-02	1.80E-03	1.80E-03	1	0.98
ETO-35 EtO Source	5.40E-02	3	1.62E-01	5.40E-03	1.80E-03	0.21	4.9
ETO-23 EtO Source	4.37E-02	111	4.85E+00	1.62E-01	1.46E-03	0.088	11
ETO-7 EtO Source	4.11E-02	171	7.03E+00	2.34E-01	1.37E-03	0.15	6.8
ETO-67 EtO Source	3.92E-02	185	7.25E+00	2.42E-01	1.31E-03	0.0089	110
ETO-20 EtO Source	3.66E-02	92	3.37E+00	1.12E-01	1.22E-03	0.1	9.9
ETO-21 EtO Source	2.69E-02	343	9.23E+00	3.08E-01	8.97E-04	0.38	2.6
ETO-61 EtO Source	2.51E-02	28	7.04E-01	2.35E-02	8.38E-04	0.12	8.2
ETO-37 EtO Source	2.47E-02	53	1.31E+00	4.36E-02	8.23E-04	0.26	3.8
ETO-63 EtO Source	2.41E-02	16	3.85E-01	1.28E-02	8.02E-04	0.047	21
ETO-26 EtO Source	2.28E-02	3	6.85E-02	2.28E-03	7.61E-04	0.31	3.3
ETO-59 EtO Source	2.09E-02	926	1.94E+01	6.46E-01	6.98E-04	0.041	24
ETO-62 EtO Source	2.02E-02	3	6.06E-02	2.02E-03	6.73E-04	0.015	67
ETO-49 EtO Source	1.76E-02	9	1.59E-01	5.29E-03	5.88E-04	0.12	8.7
ETO-33 EtO Source	1.69E-02	48	8.10E-01	2.70E-02	5.62E-04	0.0071	140
ETO-45 EtO Source	1.67E-02	35	5.85E-01	1.95E-02	5.57E-04	0.018	57
ETO-58 EtO Source	1.58E-02	51	8.07E-01	2.69E-02	5.27E-04	0.041	24
ETO-38 EtO Source	1.29E-02	25	3.23E-01	1.08E-02	4.31E-04	0.074	14

ETO-55 EtO Source	1.17E-02	9	1.05E-01	3.50E-03	3.89E-04	0.0052	190
ETO-56 EtO Source	1.12E-02	"1,050"	1.18E+01	3.92E-01	3.73E-04	0.037	27
ETO-60 EtO Source	1.08E-02	71	7.64E-01	2.55E-02	3.59E-04	0.024	42
ETO-51 EtO Source	9.42E-03	11	1.04E-01	3.45E-03	3.14E-04	0.013	74
ETO-2 EtO Source	8.16E-03	4	3.27E-02	1.09E-03	2.72E-04	0.072	14
ETO-52 EtO Source	7.35E-03	8	5.88E-02	1.96E-03	2.45E-04	0.0017	570
ETO-41 EtO Source	7.22E-03	11	7.94E-02	2.65E-03	2.41E-04	0.11	9.5
ETO-75 EtO Source	7.04E-03	19	1.34E-01	4.46E-03	2.35E-04	0.01	98
ETO-68 EtO Source	6.79E-03	479	3.25E+00	1.08E-01	2.26E-04	0.029	34
ETO-72 EtO Source	6.47E-03	61	3.95E-01	1.32E-02	2.16E-04	0.005	200
ETO-47 EtO Source	6.44E-03	462	2.97E+00	9.91E-02	2.15E-04	0.013	74
ETO-40 EtO Source	6.21E-03	70	4.35E-01	1.45E-02	2.07E-04	0.061	16
ETO-66 EtO Source	5.92E-03	150	8.89E-01	2.96E-02	1.97E-04	0.013	76
ETO-65 EtO Source	5.27E-03	1	5.27E-03	1.76E-04	1.76E-04	0.005	200
ETO-71 EtO Source	5.15E-03	6	3.09E-02	1.03E-03	1.72E-04	0.0025	400
ETO-108 EtO Source	4.88E-03	35	1.71E-01	5.69E-03	1.63E-04	0.0018	550
ETO-39 EtO Source	4.47E-03	104	4.65E-01	1.55E-02	1.49E-04	0.044	23
ETO-50 EtO Source	3.97E-03	535	2.13E+00	7.09E-02	1.32E-04	0.03	33
ETO-53 EtO Source	3.76E-03	2	7.52E-03	2.51E-04	1.25E-04	0.01	98
ETO-99 EtO Source	3.42E-03	68	2.33E-01	7.76E-03	1.14E-04	0.0098	100
ETO-25 EtO Source	2.58E-03	22	5.67E-02	1.89E-03	8.59E-05	0.031	33
ETO-116 EtO Source	2.40E-03	156	3.75E-01	1.25E-02	8.00E-05	0.011	95
ETO-119 EtO Source	2.06E-03	2	4.12E-03	1.37E-04	6.86E-05	0.0022	460
ETO-80 EtO Source	9.28E-04	23	2.13E-02	7.11E-04	3.09E-05	0.0013	760
ETO-64 EtO Source	4.76E-04	69	3.29E-02	1.10E-03	1.59E-05	0.0037	270
ETO-43 EtO Source	4.31E-04	87	3.75E-02	1.25E-03	1.44E-05	0.002	490
ETO-69 EtO Source	3.81E-04	49	1.87E-02	6.22E-04	1.27E-05	0.0001	"9,300.00"
ETO-70 EtO Source	3.20E-04	522	1.67E-01	5.57E-03	1.07E-05	0.0046	220
ETO-74 EtO Source	1.22E-04	2	2.45E-04	8.16E-06	4.08E-06	0.0027	370
ETO-32 EtO Source	1.07E-04	5	5.35E-04	1.78E-05	3.56E-06	0.0002	"5,200.00"
ETO-77 EtO Source	6.76E-05	80	5.41E-03	1.80E-04	2.25E-06	0.0002	"4,900.00"
ETO-46 EtO Source	5.39E-05	28	1.51E-03	5.03E-05	1.80E-06	0.0003	"3,400.00"
ETO-54 EtO Source	3.31E-05	1	3.31E-05	1.10E-06	1.10E-06	0.0001	"18,000.00"
ETO-117 EtO Source	1.00E-38	"49,300"	4.93E-34	1.64E-35	3.33E-40	<0.0001	

*** END OF REPORT ***

Attachment 7: HEM-3 results for facilities with HEM-Screen cancer risks > 50 in a million

Facility	Maximum Individual Lifetime Cancer Risk	Maximum Hazard Index
ETO-18	8E-5	0.03
ETO-19	9E-5	0.03
ETO-8	7E-5	0.03
ETO-27	5E-5	0.02
ETO-4	6E-5	0.02
ETO-5	3E-5	0.01

Attachment 8: Cancer HEM-Screen input file for major sources

```
          00061     ff  0.000088
Ethylene Oxide
ETO-1  EtO Source
175817 661801                    100002
H       206.212.1 5400 1.2  6.8 345
F        22.7 5.2 1001   0    0 293
Ethylene Oxide
ETO-2  EtO Source
402617 743004                    000005
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
H        37.613.7 5400 1.7   12 377
Ethylene Oxide
ETO-3  EtO Source
362132 922317                    100002
F        95.3 5.2 1001   0    0 293
H       907.212.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-4  EtO Source
414452 875638                    000003
F      2848.6 7.6 1001   0  9.1 294
H       127.018.3 5400 2.5100.6 311
H       108.9 9.1 5400 0.2 30.5 311
Ethylene Oxide
ETO-5  EtO Source
425512 721810                    100003
F        11.0 5.2 1001   0    0 293
F      1644.7 5.2 1001   0    0 293
H        46.312.5 5400 1.2  6.8 345
Ethylene Oxide
ETO-7  EtO Source
422020 875347                    000003
H       362.918.3 5670 0.3 30.5 311
H       154.215.2 5670 0.3 44.2 336
H       154.215.2 5670 0.3 44.2 336
Ethylene Oxide
ETO-8  EtO Source
333636 835010                    000002
F      4100.5 5.2 1001   0    0 293
H      1458.819.8 5400 1.4 17.8 500
Ethylene Oxide
ETO-9  EtO Source
421958 880750                    100001
H       884.7 4.9 5400 0.1 68.2 394
Ethylene Oxide
ETO-10  EtO Source
332342 815906                    100002
F      3619.7 5.2 1001   0    0 293
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H       136.1 9.1 5400 0.8 30.8 366
Ethylene Oxide
ETO-11  EtO Source
364522 863435                    100003
F       226.8 5.2 1001   0 14.3 293
H        45.412.2 1820 0.4 14.7 345
F       644.1 7.6 1001   0 14.9 293
Ethylene Oxide
ETO-12  EtO Source
334954 842804                    100003
F        63.5 9.1 1001   0  0.6 293
H       108.915.2 5400 0.9  9.1 312
H      1179.3 9.1 5400 0.3  4.9 311
Ethylene Oxide
ETO-13  EtO Source
4046401120130                    100003
F        54.4 5.2 1001   0    0 293
H      1297.314.6 3750 0.7  4.3 293
H      1288.212.2 3750 0.3  4.9 293
Ethylene Oxide
ETO-14  EtO Source
415043 873902                    000002
H        85.821.3 6960 0.2  4.1 294
H       957.521.3 6960 0.2  4.1 294
Ethylene Oxide
ETO-15  EtO Source
373010 772120                    100002
H      1723.713.7 4970 1.1 14.8 405
H      1632.913.7 4970 0.8 20.4 293
Ethylene Oxide
ETO-18  EtO Source
181660 670822                    100003
F        10.9 5.2 1001   0    0 293
F       277.6 5.2 1001   0    0 293
H       455.412.2 5400 1.2  6.8 345
Ethylene Oxide
ETO-19  EtO Source
302545 883100                    100003
F      1383.5 5.2 1001   0    0 293
F      1383.5 5.2 1001   0    0 293
H       780.212.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-20  EtO Source
404232 740343                    000001
H        54.412.287.70 0.1  8.2 322
Ethylene Oxide
ETO-21  EtO Source
3151301064115                    100004
H      2023.012.244.50 1.2100.6 450
H        90.718.344.50 0.6    3 294
H      1914.212.244.50 0.3  4.9 293
F        90.710.737.21   0    3 293
```

Ethylene Oxide
ETO-22 EtO Source
350455 900343 000002
H 684.010.7 4450 1.1 7.4 405
H 756.6 9.8 4450 0.2 10.2 293
Ethylene Oxide
ETO-23 EtO Source
343336 820748 100002
F 562.5 5.2 1001 0 21.3 389
H 263.115.2 7240 2 3.3 561
Ethylene Oxide
ETO-24 EtO Source
372214 894111 100002
H 1877.9 7.6 8950 0.8 13.1 316
H 3138.9 7.6 8950 0.8 20.4 318
Ethylene Oxide
ETO-25 EtO Source
414201 713508 100001
H 90.721.3 5760 0.9 11.2 293
Ethylene Oxide
ETO-26 EtO Source
3400051181316 000003
H 45.4 5.2 5400 1.2 60.7 293
H 172.412.2 5400 1.2 4.6 345
F 18.1 5.2 1001 0 6.8 293
Ethylene Oxide
ETO-27 EtO Source
350141 820358 100002
F 1414.3 5.2 1001 0 0 293
H 304.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-29 EtO Source
3944051050710 000001
H 1378.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-32 EtO Source
355510 813402 100001
H 1.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-33 EtO Source
333650 965645 000002
F 412.8 5.2 1001 0 0 293
H 353.812.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-35 EtO Source
403401 795129 100001
H 340.2 7.9 5400 0.2 0.8 327
Ethylene Oxide
ETO-36 EtO Source
334334 843502 000002
H 372.910.7 4450 1.1 7.4 405
H 527.5 7 4450 0.8 13.4 293

Ethylene Oxide
ETO-37 EtO Source
422015 713800 100002
H 27.2 8.8 6250 1 11 344
H 544.314.9 6250 2 2.3 950
Ethylene Oxide
ETO-38 EtO Source
403405 742546 000002
H 72.618.3 4720 0.2 13.3 293
H 72.618.3 4720 0.3 32.3 293
Ethylene Oxide
ETO-39 EtO Source
3143401061726 100003
H 18.114.9 6750 2 1.9 356
H 27.2 4.9 6750 0.8 13.4 368
H 18.1 4.9 6750 0.8 10.4 356
Ethylene Oxide
ETO-40 EtO Source
391638 763338 000001
H 163.321.3 5760 0.2 3.1 293
Ethylene Oxide
ETO-41 EtO Source
3403251173300 000003
F 113.4 5.2 1001 0 0 293
H 136.112.1 5400 1.2 6.7 345
H 107.0 5.2 5400 1.2 4.6 293
Ethylene Oxide
ETO-44 EtO Source
280211 823938 000001
H 508.017.7 5400 0.5 24.4 289
Ethylene Oxide
ETO-45 EtO Source
432054 733554 100002
H 163.323.8 5400 0.6 13.7 364
H 72.610.7 5400 0.9 0.6 294
Ethylene Oxide
ETO-46 EtO Source
403830 741249 000001
H 0.318.3 4970 0.2 27.7 293
Ethylene Oxide
ETO-47 EtO Source
3128181002310 000003
F 11.1 5.2 1001 0 0 293
F 11.1 5.2 1001 0 0 293
H 381.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-48 EtO Source
385640 951330 000001
H 340.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-49 EtO Source
350748 805702 100003

H 90.718.3 5400 0.9 39.6 355
H 90.712.2 5400 0.9 15.2 311
F 90.7 7.6 1001 0 4.9 294
Ethylene Oxide
ETO-50 EtO Source
450757 931615 000001
H 127.011.3 4130 0.6 4.6 372
Ethylene Oxide
ETO-51 EtO Source
412018 725215 000002
F 2.3 5.2 1001 0 0 293
H 113.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-52 EtO Source
354649 794851 000001
H 27.215.2 9120 1.2 1.9 351
Ethylene Oxide
ETO-54 EtO Source
3931151194309 000001
H 0.413.7 5120 0.2 2.3 293
Ethylene Oxide
ETO-55 EtO Source
355517 800146 000002
F 1.4 5.2 1001 0 0 293
H 33.112.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-56 EtO Source
391008 764646 000003
H 56.712.2 5400 0.2 6.1 311
H 56.719.8 5400 0.2 3 297
F 2.3 5.2 1001 0 0 293
Ethylene Oxide
ETO-57 EtO Source
391414 863737 100003
F 51.7 5.2 1001 0 0 293
F 51.7 5.2 1001 0 0 293
H 10.412.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-58 EtO Source
425245 854103 000001
H 199.615.2 3430 1.1 2.4 308
Ethylene Oxide
ETO-59 EtO Source
392430 764550 000001
H 113.4 3.7 5400 0.2 6.8 297
Ethylene Oxide
ETO-60 EtO Source
403806 752008 000001
H 105.712.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-61 EtO Source
3359481181218 000003

F 27.2 5.2 1001 0 0 293
H 54.4 5.2 5400 1.2 4.6 293
H 5.412.2 5400 1.2 7 345
Ethylene Oxide
ETO-62 EtO Source
344615 821751 000002
F 68.9 5.2 1001 0 0 293
H 21.812.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-67 EtO Source
3120471105719 100002
F 36.3 5.2 1001 0 0 293
H 0.4 8.5 8170 0.7 5.5 345
Ethylene Oxide
ETO-70 EtO Source
324756 970250 000001
H 24.518.3 5990 0.3 8.5 293
Ethylene Oxide
ETO-71 EtO Source
362650 833448 100001
H 32.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-75 EtO Source
353910 802948 100002
H 18.112.2 7380 1 0.71033
H 9.1 0.9 7380 0.5 17.5 311
Ethylene Oxide
ETO-80 EtO Source
3243011170933 000001
H 1.818.3 5070 0.3 1.2 293
Ethylene Oxide
ETO-91 EtO Source
4524281223239 000001
H 907.2 0.3 5400 0.5 5 458
Ethylene Oxide
ETO-117 EtO Source
3515351135647 100001
H 0.012.5 2220 0.1 10.4 293
Ethylene Oxide
ETO-118 EtO Source
3944051050710 000003
H 63.5 6.1 5400 0.4 3.1 295
H 132.4 6.1 5400 0.9 4.6 295
H 753.0 8.5 5400 0.9 5.6 295
Ethylene Oxide
ETO-119 EtO Source
3239181143322 100002
H 18.112.2 5400 1.1 2.6 977
H 9.112.2 5400 0.5 11.7 311

Attachment 9: Noncancer HEM-Screen input file for major sources

```
00061     ff  0.03333
Ethylene Oxide
ETO-1  EtO Source
175817 661801                    100002
H       206.212.1 5400 1.2  6.8 345
F        22.7 5.2 1001   0    0 293
Ethylene Oxide
ETO-2  EtO Source
402617 743004                    000005
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
F        46.5 5.2 1001   0    0 293
H        37.612.1 5400 1.2  6.8 345
H        37.613.7 5400 1.7   12 377
Ethylene Oxide
ETO-3  EtO Source
362132 922317                    100002
F        95.3 5.2 1001   0    0 293
H       907.212.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-4  EtO Source
414452 875638                    000003
F      2848.6 7.6 1001   0  9.1 294
H       127.018.3 5400 2.5100.6 311
H       108.9 9.1 5400 0.2 30.5 311
Ethylene Oxide
ETO-5  EtO Source
425512 721810                    100003
F        11.0 5.2 1001   0    0 293
F      1644.7 5.2 1001   0    0 293
H        46.312.5 5400 1.2  6.8 345
Ethylene Oxide
ETO-7  EtO Source
422020 875347                    000003
H       362.918.3 5670 0.3 30.5 311
H       154.215.2 5670 0.3 44.2 336
H       154.215.2 5670 0.3 44.2 336
Ethylene Oxide
ETO-8  EtO Source
333636 835010                    000002
F      4100.5 5.2 1001   0    0 293
H      1458.819.8 5400 1.4 17.8 500
Ethylene Oxide
ETO-9  EtO Source
421958 880750                    100001
H       884.7 4.9 5400 0.1 68.2 394
Ethylene Oxide
ETO-10  EtO Source
332342 815906                    100002
F      3619.7 5.2 1001   0    0 293
```

```
H       136.1 9.1 5400 0.8 30.8 366
Ethylene Oxide
ETO-11  EtO Source
364522 863435                    100003
F       226.8 5.2 1001   0 14.3 293
H        45.412.2 1820 0.4 14.7 345
F       644.1 7.6 1001   0 14.9 293
Ethylene Oxide
ETO-12  EtO Source
334954 842804                    100003
F        63.5 9.1 1001   0  0.6 293
H       108.915.2 5400 0.9  9.1 312
H      1179.3 9.1 5400 0.3  4.9 311
Ethylene Oxide
ETO-13  EtO Source
4046401120130                    100003
F        54.4 5.2 1001   0    0 293
H      1297.314.6 3750 0.7  4.3 293
H      1288.212.2 3750 0.3  4.9 293
Ethylene Oxide
ETO-14  EtO Source
415043 873902                    000002
H        85.821.3 6960 0.2  4.1 294
H       957.521.3 6960 0.2  4.1 294
Ethylene Oxide
ETO-15  EtO Source
373010 772120                    100002
H      1723.713.7 4970 1.1 14.8 405
H      1632.913.7 4970 0.8 20.4 293
Ethylene Oxide
ETO-18  EtO Source
181660 670822                    100003
F        10.9 5.2 1001   0    0 293
F       277.6 5.2 1001   0    0 293
H       455.412.2 5400 1.2  6.8 345
Ethylene Oxide
ETO-19  EtO Source
302545 883100                    100003
F      1383.5 5.2 1001   0    0 293
F      1383.5 5.2 1001   0    0 293
H       780.212.1 5400 1.2  6.8 345
Ethylene Oxide
ETO-20  EtO Source
404232 740343                    000001
H        54.412.287.70 0.1  8.2 322
Ethylene Oxide
ETO-21  EtO Source
3151301064115                    100004
H      2023.012.244.50 1.2100.6 450
H        90.718.344.50 0.6    3 294
H      1914.212.244.50 0.3  4.9 293
F        90.710.737.21   0    3 293
```

Ethylene Oxide
ETO-22 EtO Source
350455 900343 000002
H 684.010.7 4450 1.1 7.4 405
H 756.6 9.8 4450 0.2 10.2 293
Ethylene Oxide
ETO-23 EtO Source
343336 820748 100002
F 562.5 5.2 1001 0 21.3 389
H 263.115.2 7240 2 3.3 561
Ethylene Oxide
ETO-24 EtO Source
372214 894111 100002
H 1877.9 7.6 8950 0.8 13.1 316
H 3138.9 7.6 8950 0.8 20.4 318
Ethylene Oxide
ETO-25 EtO Source
414201 713508 100001
H 90.721.3 5760 0.9 11.2 293
Ethylene Oxide
ETO-26 EtO Source
3400051181316 000003
H 45.4 5.2 5400 1.2 60.7 293
H 172.412.2 5400 1.2 4.6 345
F 18.1 5.2 1001 0 6.8 293
Ethylene Oxide
ETO-27 EtO Source
350141 820358 100002
F 1414.3 5.2 1001 0 0 293
H 304.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-29 EtO Source
3944051050710 000001
H 1378.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-32 EtO Source
355510 813402 100001
H 1.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-33 EtO Source
333650 965645 000002
F 412.8 5.2 1001 0 0 293
H 353.812.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-35 EtO Source
403401 795129 100001
H 340.2 7.9 5400 0.2 0.8 327
Ethylene Oxide
ETO-36 EtO Source
334334 843502 000002
H 372.910.7 4450 1.1 7.4 405
H 527.5 7 4450 0.8 13.4 293

Ethylene Oxide
ETO-37 EtO Source
422015 713800 100002
H 27.2 8.8 6250 1 11 344
H 544.314.9 6250 2 2.3 950
Ethylene Oxide
ETO-38 EtO Source
403405 742546 000002
H 72.618.3 4720 0.2 13.3 293
H 72.618.3 4720 0.3 32.3 293
Ethylene Oxide
ETO-39 EtO Source
3143401061726 100003
H 18.114.9 6750 2 1.9 356
H 27.2 4.9 6750 0.8 13.4 368
H 18.1 4.9 6750 0.8 10.4 356
Ethylene Oxide
ETO-40 EtO Source
391638 763338 000001
H 163.321.3 5760 0.2 3.1 293
Ethylene Oxide
ETO-41 EtO Source
3403251173300 000003
F 113.4 5.2 1001 0 0 293
H 136.112.1 5400 1.2 6.7 345
H 107.0 5.2 5400 1.2 4.6 293
Ethylene Oxide
ETO-44 EtO Source
280211 823938 000001
H 508.017.7 5400 0.5 24.4 289
Ethylene Oxide
ETO-45 EtO Source
432054 733554 100002
H 163.323.8 5400 0.6 13.7 364
H 72.610.7 5400 0.9 0.6 294
Ethylene Oxide
ETO-46 EtO Source
403830 741249 000001
H 0.318.3 4970 0.2 27.7 293
Ethylene Oxide
ETO-47 EtO Source
3128181002310 000003
F 11.1 5.2 1001 0 0 293
F 11.1 5.2 1001 0 0 293
H 381.912.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-48 EtO Source
385640 951330 000001
H 340.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-49 EtO Source
350748 805702 100003

H 90.718.3 5400 0.9 39.6 355
H 90.712.2 5400 0.9 15.2 311
F 90.7 7.6 1001 0 4.9 294
Ethylene Oxide
ETO-50 EtO Source
450757 931615 000001
H 127.011.3 4130 0.6 4.6 372
Ethylene Oxide
ETO-51 EtO Source
412018 725215 000002
F 2.3 5.2 1001 0 0 293
H 113.412.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-52 EtO Source
354649 794851 000001
H 27.215.2 9120 1.2 1.9 351
Ethylene Oxide
ETO-54 EtO Source
3931151194309 000001
H 0.413.7 5120 0.2 2.3 293
Ethylene Oxide
ETO-55 EtO Source
355517 800146 000002
F 1.4 5.2 1001 0 0 293
H 33.112.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-56 EtO Source
391008 764646 000003
H 56.712.2 5400 0.2 6.1 311
H 56.719.8 5400 0.2 3 297
F 2.3 5.2 1001 0 0 293
Ethylene Oxide
ETO-57 EtO Source
391414 863737 100003
F 51.7 5.2 1001 0 0 293
F 51.7 5.2 1001 0 0 293
H 10.412.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-58 EtO Source
425245 854103 000001
H 199.615.2 3430 1.1 2.4 308
Ethylene Oxide
ETO-59 EtO Source
392430 764550 000001
H 113.4 3.7 5400 0.2 6.8 297
Ethylene Oxide
ETO-60 EtO Source
403806 752008 000001
H 105.712.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-61 EtO Source
3359481181218 000003

F 27.2 5.2 1001 0 0 293
H 54.4 5.2 5400 1.2 4.6 293
H 5.412.2 5400 1.2 7 345
Ethylene Oxide
ETO-62 EtO Source
344615 821751 000002
F 68.9 5.2 1001 0 0 293
H 21.812.1 5400 1.2 6.8 345
Ethylene Oxide
ETO-67 EtO Source
3120471105719 100002
F 36.3 5.2 1001 0 0 293
H 0.4 8.5 8170 0.7 5.5 345
Ethylene Oxide
ETO-70 EtO Source
324756 970250 000001
H 24.518.3 5990 0.3 8.5 293
Ethylene Oxide
ETO-71 EtO Source
362650 833448 100001
H 32.212.2 5400 1.2 6.8 345
Ethylene Oxide
ETO-75 EtO Source
353910 802948 100002
H 18.112.2 7380 1 0.71033
H 9.1 0.9 7380 0.5 17.5 311
Ethylene Oxide
ETO-80 EtO Source
3243011170933 000001
H 1.818.3 5070 0.3 1.2 293
Ethylene Oxide
ETO-91 EtO Source
4524281223239 000001
H 907.2 0.3 5400 0.5 5 458
Ethylene Oxide
ETO-117 EtO Source
3515351135647 100001
H 0.012.5 2220 0.1 10.4 293
Ethylene Oxide
ETO-118 EtO Source
3944051050710 000003
H 63.5 6.1 5400 0.4 3.1 295
H 132.4 6.1 5400 0.9 4.6 295
H 753.0 8.5 5400 0.9 5.6 295
Ethylene Oxide
ETO-119 EtO Source
3239181143322 100002
H 18.112.2 5400 1.1 2.6 977
H 9.112.2 5400 0.5 11.7 311

Attachment 10: Cancer HEM-Screen output file for major sources

HUMAN EXPOSURE MODEL
STANDARD SUMMARY REPORT

Date: 12/14/2004 Time: 10:49
Chemical Name: Ethylene Oxide Unit Risk: 8.80E-05

REPORT DESCRIPTION
majors

MODELING OPTIONS
Input File Name: c:\program files\hem_vb_wrapper_v3\input\eotestmj.hem
Radii Set: " 0.1, 0.5, 1.0, 2.0, 5.0,10.0,20.0,30.0,40.0,50.0"
Census Data: 2000
Atmospheric Decay: No

HEM-SCREEN EXPOSURE RESULTS

	Concentration	Population	Exposure
MAX:	1.68E+00	94	1.58E+02
MIN:	1.00E-38	"91,300,000"	3.23E+04

Level	Concentration	Population	Exposure
1	4.14E+00		0.00E+00
3	1.00E+00	285	3.66E+02
4	5.00E-01	"1,350"	1.11E+03
5	2.50E-01	"3,160"	1.69E+03
6	1.00E-01	"8,350"	2.39E+03
7	5.00E-02	"22,600"	3.40E+03
8	2.50E-02	"74,900"	5.17E+03
9	1.00E-02	"292,000"	8.44E+03
10	5.00E-03	"681,000"	1.11E+04
11	2.50E-03	"1,720,000"	1.47E+04
12	1.00E-03	"6,040,000"	2.11E+04
13	5.00E-04	"13,700,000"	2.64E+04
14	2.50E-04	"20,600,000"	2.89E+04
15	1.00E-04	"32,600,000"	3.08E+04
16	5.00E-05	"43,500,000"	3.16E+04
17	2.50E-05	"54,300,000"	3.20E+04
18	1.00E-05	"69,500,000"	3.22E+04
19	5.00E-06	"77,600,000"	3.23E+04
20	2.50E-06	"83,800,000"	3.23E+04
21	1.00E-06	"85,700,000"	3.23E+04
22	5.00E-07	"87,500,000"	3.23E+04
23	2.50E-07	"89,200,000"	3.23E+04
24	1.00E-07	"90,400,000"	3.23E+04
25	5.00E-08	"91,000,000"	3.23E+04

26	2.50E-08	"91,200,000"	3.23E+04
27	1.00E-08	"91,300,000"	3.23E+04
28	5.00E-09	"91,300,000"	3.23E+04
29	2.50E-09	"91,300,000"	3.23E+04
30	1.00E-09	"91,300,000"	3.23E+04
31	5.00E-10	"91,300,000"	3.23E+04
32	2.50E-10	"91,300,000"	3.23E+04
33	1.00E-10	"91,300,000"	3.23E+04
34	5.00E-11	"91,300,000"	3.23E+04
35	2.50E-11	"91,300,000"	3.23E+04
36	1.00E-11	"91,300,000"	3.23E+04
37	5.00E-12	"91,300,000"	3.23E+04
38	2.50E-12	"91,300,000"	3.23E+04
39	1.00E-12	"91,300,000"	3.23E+04
40	5.00E-13	"91,300,000"	3.23E+04
41	2.50E-13	"91,300,000"	3.23E+04
42	1.00E-13	"91,300,000"	3.23E+04
43	5.00E-14	"91,300,000"	3.23E+04
44	2.50E-14	"91,300,000"	3.23E+04
45	1.00E-14	"91,300,000"	3.23E+04
46	5.00E-15	"91,300,000"	3.23E+04
47	2.50E-15	"91,300,000"	3.23E+04
48	1.00E-15	"91,300,000"	3.23E+04
49	5.00E-16	"91,300,000"	3.23E+04
50	2.50E-16	"91,300,000"	3.23E+04
51	1.00E-16	"91,300,000"	3.23E+04
52	5.00E-17	"91,300,000"	3.23E+04
53	2.50E-17	"91,300,000"	3.23E+04
54	1.00E-17	"91,300,000"	3.23E+04
55	5.00E-18	"91,300,000"	3.23E+04
56	2.50E-18	"91,300,000"	3.23E+04
57	1.00E-18	"91,300,000"	3.23E+04
58	5.00E-19	"91,300,000"	3.23E+04
59	2.50E-19	"91,300,000"	3.23E+04
60	1.00E-19	"91,300,000"	3.23E+04
61	5.00E-20	"91,300,000"	3.23E+04
62	2.50E-20	"91,300,000"	3.23E+04
63	1.00E-20	"91,300,000"	3.23E+04
64	5.00E-21	"91,300,000"	3.23E+04
65	2.50E-21	"91,300,000"	3.23E+04
66	1.00E-21	"91,300,000"	3.23E+04
67	5.00E-22	"91,300,000"	3.23E+04
68	2.50E-22	"91,300,000"	3.23E+04
69	1.00E-22	"91,300,000"	3.23E+04
70	5.00E-23	"91,300,000"	3.23E+04
71	2.50E-23	"91,300,000"	3.23E+04
72	1.00E-23	"91,300,000"	3.23E+04
73	5.00E-24	"91,300,000"	3.23E+04
74	2.50E-24	"91,300,000"	3.23E+04
75	1.00E-24	"91,300,000"	3.23E+04
76	5.00E-25	"91,300,000"	3.23E+04
77	2.50E-25	"91,300,000"	3.23E+04

78	1.00E-25	"91,300,000"	3.23E+04
79	5.00E-26	"91,300,000"	3.23E+04
80	2.50E-26	"91,300,000"	3.23E+04
81	1.00E-26	"91,300,000"	3.23E+04
82	5.00E-27	"91,300,000"	3.23E+04
83	2.50E-27	"91,300,000"	3.23E+04
84	1.00E-27	"91,300,000"	3.23E+04
85	5.00E-28	"91,300,000"	3.23E+04
86	2.50E-28	"91,300,000"	3.23E+04
87	1.00E-28	"91,300,000"	3.23E+04
88	5.00E-29	"91,300,000"	3.23E+04
89	2.50E-29	"91,300,000"	3.23E+04
90	1.00E-29	"91,300,000"	3.23E+04
91	5.00E-30	"91,300,000"	3.23E+04
92	2.50E-30	"91,300,000"	3.23E+04
93	1.00E-30	"91,300,000"	3.23E+04
94	5.00E-31	"91,300,000"	3.23E+04
95	2.50E-31	"91,300,000"	3.23E+04
96	1.00E-31	"91,300,000"	3.23E+04
97	5.00E-32	"91,300,000"	3.23E+04
98	2.50E-32	"91,300,000"	3.23E+04
99	1.00E-32	"91,300,000"	3.23E+04
100	5.00E-33	"91,300,000"	3.23E+04
101	2.50E-33	"91,300,000"	3.23E+04
102	1.00E-33	"91,300,000"	3.23E+04
103	5.00E-34	"91,300,000"	3.23E+04
104	2.50E-34	"91,300,000"	3.23E+04
105	1.00E-34	"91,300,000"	3.23E+04
106	5.00E-35	"91,300,000"	3.23E+04
107	2.50E-35	"91,300,000"	3.23E+04
108	1.00E-35	"91,300,000"	3.23E+04
109	5.00E-36	"91,300,000"	3.23E+04
110	2.50E-36	"91,300,000"	3.23E+04
111	1.00E-36	"91,300,000"	3.23E+04
112	5.00E-37	"91,300,000"	3.23E+04
113	2.50E-37	"91,300,000"	3.23E+04
114	1.00E-37	"91,300,000"	3.23E+04
115	5.00E-38	"91,300,000"	3.23E+04
116	2.50E-38	"91,300,000"	3.23E+04
117	1.00E-38	"91,300,000"	3.23E+04

HEM-SCREEN RISK RESULTS

	Risk Level	Population	Exposure * Risk
MAX:	1.48E-04	47	6.95E-03
MIN:	8.80E-43	"91,300,000"	2.84E+00

Level	Risk Level	Population	Exposure * Unit Risk
1	3.65E-04		0.00E+00
3	1.00E-04	94	1.39E-02
4	5.00E-05	"1,230"	9.18E-02
5	2.50E-05	"2,640"	1.37E-01

6	1.00E-05	"7,050"	1.98E-01
7	5.00E-06	"20,000"	2.87E-01
8	2.50E-06	"62,100"	4.25E-01
9	1.00E-06	"247,000"	7.00E-01
10	5.00E-07	"590,000"	9.37E-01
11	2.50E-07	"1,440,000"	1.23E+00
12	1.00E-07	"5,030,000"	1.76E+00
13	5.00E-08	"11,900,000"	2.24E+00
14	2.50E-08	"19,400,000"	2.52E+00
15	1.00E-08	"30,700,000"	2.69E+00
16	5.00E-09	"41,700,000"	2.77E+00
17	2.50E-09	"52,200,000"	2.81E+00
18	1.00E-09	"67,700,000"	2.83E+00
19	5.00E-10	"76,300,000"	2.84E+00
20	2.50E-10	"83,200,000"	2.84E+00
21	1.00E-10	"85,400,000"	2.84E+00
22	5.00E-11	"87,200,000"	2.84E+00
23	2.50E-11	"88,900,000"	2.84E+00
24	1.00E-11	"90,200,000"	2.84E+00
25	5.00E-12	"90,900,000"	2.84E+00
26	2.50E-12	"91,200,000"	2.84E+00
27	1.00E-12	"91,300,000"	2.84E+00
28	5.00E-13	"91,300,000"	2.84E+00
29	2.50E-13	"91,300,000"	2.84E+00
30	1.00E-13	"91,300,000"	2.84E+00
31	5.00E-14	"91,300,000"	2.84E+00
32	2.50E-14	"91,300,000"	2.84E+00
33	1.00E-14	"91,300,000"	2.84E+00
34	5.00E-15	"91,300,000"	2.84E+00
35	2.50E-15	"91,300,000"	2.84E+00
36	1.00E-15	"91,300,000"	2.84E+00
37	5.00E-16	"91,300,000"	2.84E+00
38	2.50E-16	"91,300,000"	2.84E+00
39	1.00E-16	"91,300,000"	2.84E+00
40	5.00E-17	"91,300,000"	2.84E+00
41	2.50E-17	"91,300,000"	2.84E+00
42	1.00E-17	"91,300,000"	2.84E+00
43	5.00E-18	"91,300,000"	2.84E+00
44	2.50E-18	"91,300,000"	2.84E+00
45	1.00E-18	"91,300,000"	2.84E+00
46	5.00E-19	"91,300,000"	2.84E+00
47	2.50E-19	"91,300,000"	2.84E+00
48	1.00E-19	"91,300,000"	2.84E+00
49	5.00E-20	"91,300,000"	2.84E+00
50	2.50E-20	"91,300,000"	2.84E+00
51	1.00E-20	"91,300,000"	2.84E+00
52	5.00E-21	"91,300,000"	2.84E+00
53	2.50E-21	"91,300,000"	2.84E+00
54	1.00E-21	"91,300,000"	2.84E+00
55	5.00E-22	"91,300,000"	2.84E+00
56	2.50E-22	"91,300,000"	2.84E+00
57	1.00E-22	"91,300,000"	2.84E+00

58	5.00E-23	"91,300,000"	2.84E+00
59	2.50E-23	"91,300,000"	2.84E+00
60	1.00E-23	"91,300,000"	2.84E+00
61	5.00E-24	"91,300,000"	2.84E+00
62	2.50E-24	"91,300,000"	2.84E+00
63	1.00E-24	"91,300,000"	2.84E+00
64	5.00E-25	"91,300,000"	2.84E+00
65	2.50E-25	"91,300,000"	2.84E+00
66	1.00E-25	"91,300,000"	2.84E+00
67	5.00E-26	"91,300,000"	2.84E+00
68	2.50E-26	"91,300,000"	2.84E+00
69	1.00E-26	"91,300,000"	2.84E+00
70	5.00E-27	"91,300,000"	2.84E+00
71	2.50E-27	"91,300,000"	2.84E+00
72	1.00E-27	"91,300,000"	2.84E+00
73	5.00E-28	"91,300,000"	2.84E+00
74	2.50E-28	"91,300,000"	2.84E+00
75	1.00E-28	"91,300,000"	2.84E+00
76	5.00E-29	"91,300,000"	2.84E+00
77	2.50E-29	"91,300,000"	2.84E+00
78	1.00E-29	"91,300,000"	2.84E+00
79	5.00E-30	"91,300,000"	2.84E+00
80	2.50E-30	"91,300,000"	2.84E+00
81	1.00E-30	"91,300,000"	2.84E+00
82	5.00E-31	"91,300,000"	2.84E+00
83	2.50E-31	"91,300,000"	2.84E+00
84	1.00E-31	"91,300,000"	2.84E+00
85	5.00E-32	"91,300,000"	2.84E+00
86	2.50E-32	"91,300,000"	2.84E+00
87	1.00E-32	"91,300,000"	2.84E+00
88	5.00E-33	"91,300,000"	2.84E+00
89	2.50E-33	"91,300,000"	2.84E+00
90	1.00E-33	"91,300,000"	2.84E+00
91	5.00E-34	"91,300,000"	2.84E+00
92	2.50E-34	"91,300,000"	2.84E+00
93	1.00E-34	"91,300,000"	2.84E+00
94	5.00E-35	"91,300,000"	2.84E+00
95	2.50E-35	"91,300,000"	2.84E+00
96	1.00E-35	"91,300,000"	2.84E+00
97	5.00E-36	"91,300,000"	2.84E+00
98	2.50E-36	"91,300,000"	2.84E+00
99	1.00E-36	"91,300,000"	2.84E+00
100	5.00E-37	"91,300,000"	2.84E+00
101	2.50E-37	"91,300,000"	2.84E+00
102	1.00E-37	"91,300,000"	2.84E+00
103	5.00E-38	"91,300,000"	2.84E+00
104	2.50E-38	"91,300,000"	2.84E+00
105	8.80E-43	"91,300,000"	2.84E+00

HEM-SCREEN RESULTS

Source	Max Concentration	People	Max Exposure	Lifetime Incidence	Max Risk	Annual Incid.	Repeat Interval
ETO-18 EtO Source	1.68E+00	94	1.58E+02	1.39E-02	1.48E-04	0.0024	420
ETO-19 EtO Source	1.06E+00	3	3.19E+00	2.81E-04	9.37E-05	0.0015	690
ETO-8 EtO Source	8.38E-01	3	2.51E+00	2.21E-04	7.37E-05	0.0015	670
ETO-27 EtO Source	7.51E-01	39	2.93E+01	2.58E-03	6.61E-05	0.0013	760
ETO-4 EtO Source	6.96E-01	49	3.41E+01	3.00E-03	6.12E-05	0.0042	240
ETO-5 EtO Source	6.90E-01	54	3.72E+01	3.28E-03	6.07E-05	0.0011	880
ETO-24 EtO Source	2.67E-01	1	2.67E-01	2.35E-05	2.35E-05	0.0011	900
ETO-11 EtO Source	2.53E-01	26	6.58E+00	5.79E-04	2.23E-05	0.0003	"3,200.00"
ETO-22 EtO Source	2.43E-01	65	1.58E+01	1.39E-03	2.14E-05	0.0008	"1,200.00"
ETO-12 EtO Source	1.88E-01	4	7.54E-01	6.63E-05	1.66E-05	0.0039	260
ETO-118 EtO Source	1.86E-01	28	5.21E+00	4.59E-04	1.64E-05	0.001	980
ETO-13 EtO Source	1.70E-01	7	1.19E+00	1.05E-04	1.50E-05	0.0018	540
ETO-57 EtO Source	1.49E-01	15	2.23E+00	1.96E-04	1.31E-05	0.0001	"11,000.00"
ETO-91 EtO Source	1.40E-01	17	2.38E+00	2.09E-04	1.23E-05	0.0007	"1,500.00"
ETO-10 EtO Source	1.35E-01	3	4.05E-01	3.56E-05	1.19E-05	0.0037	270
ETO-29 EtO Source	1.28E-01	28	3.58E+00	3.15E-04	1.12E-05	0.0013	770
ETO-3 EtO Source	1.12E-01	107	1.20E+01	1.05E-03	9.86E-06	0.0002	"5,200.00"
ETO-14 EtO Source	1.11E-01	158	1.75E+01	1.54E-03	9.75E-06	0.0021	470
ETO-1 EtO Source	7.85E-02	322	2.53E+01	2.22E-03	6.91E-06	0.0004	"2,700.00"
ETO-9 EtO Source	7.60E-02	2	1.52E-01	1.34E-05	6.69E-06	0.0012	840
ETO-44 EtO Source	6.74E-02	6	4.05E-01	3.56E-05	5.93E-06	0.0003	"2,900.00"
ETO-36 EtO Source	6.72E-02	153	1.03E+01	9.05E-04	5.91E-06	0.0005	"2,100.00"
ETO-48 EtO Source	5.92E-02	22	1.30E+00	1.15E-04	5.21E-06	0.0002	"6,400.00"
ETO-35 EtO Source	5.40E-02	3	1.62E-01	1.43E-05	4.76E-06	0.0005	"1,800.00"
ETO-15 EtO Source	5.40E-02	1	5.40E-02	4.75E-06	4.75E-06	0.0027	370
ETO-23 EtO Source	4.37E-02	111	4.85E+00	4.27E-04	3.85E-06	0.0002	"4,300.00"
ETO-7 EtO Source	4.11E-02	171	7.03E+00	6.19E-04	3.62E-06	0.0004	"2,600.00"
ETO-67 EtO Source	3.92E-02	185	7.25E+00	6.38E-04	3.45E-06	<0.0001	"43,000.00"
ETO-20 EtO Source	3.66E-02	92	3.37E+00	2.96E-04	3.22E-06	0.0003	"3,700.00"
ETO-21 EtO Source	2.69E-02	343	9.23E+00	8.13E-04	2.37E-06	0.001	"1,000.00"
ETO-61 EtO Source	2.51E-02	28	7.04E-01	6.20E-05	2.21E-06	0.0003	"3,100.00"
ETO-37 EtO Source	2.47E-02	53	1.31E+00	1.15E-04	2.17E-06	0.0007	"1,400.00"
ETO-26 EtO Source	2.28E-02	3	6.85E-02	6.03E-06	2.01E-06	0.0008	"1,200.00"
ETO-59 EtO Source	2.09E-02	926	1.94E+01	1.71E-03	1.84E-06	0.0001	"9,200.00"
ETO-62 EtO Source	2.02E-02	3	6.06E-02	5.33E-06	1.78E-06	<0.0001	"26,000.00"
ETO-49 EtO Source	1.76E-02	9	1.59E-01	1.40E-05	1.55E-06	0.0003	"3,300.00"
ETO-33 EtO Source	1.69E-02	48	8.10E-01	7.12E-05	1.48E-06	<0.0001	"54,000.00"
ETO-45 EtO Source	1.67E-02	35	5.85E-01	5.15E-05	1.47E-06	<0.0001	"22,000.00"
ETO-58 EtO Source	1.58E-02	51	8.07E-01	7.10E-05	1.39E-06	0.0001	"9,200.00"
ETO-38 EtO Source	1.29E-02	25	3.23E-01	2.84E-05	1.14E-06	0.0002	"5,100.00"
ETO-55 EtO Source	1.17E-02	9	1.05E-01	9.24E-06	1.03E-06	<0.0001	"73,000.00"
ETO-56 EtO Source	1.12E-02	"1,050"	1.18E+01	1.03E-03	9.85E-07	0.0001	"10,000.00"
ETO-60 EtO Source	1.08E-02	71	7.64E-01	6.73E-05	9.47E-07	0.0001	"16,000.00"
ETO-51 EtO Source	9.42E-03	11	1.04E-01	9.12E-06	8.29E-07	<0.0001	"28,000.00"
ETO-2 EtO Source	8.16E-03	4	3.27E-02	2.87E-06	7.18E-07	0.0002	"5,300.00"
ETO-52 EtO Source	7.35E-03	8	5.88E-02	5.17E-06	6.46E-07	<0.0001	"220,000.00"
ETO-41 EtO Source	7.22E-03	11	7.94E-02	6.99E-06	6.35E-07	0.0003	"3,600.00"
ETO-75 EtO Source	7.04E-03	19	1.34E-01	1.18E-05	6.20E-07	<0.0001	"37,000.00"
ETO-47 EtO Source	6.44E-03	462	2.97E+00	2.62E-04	5.67E-07	<0.0001	"28,000.00"
ETO-40 EtO Source	6.21E-03	70	4.35E-01	3.82E-05	5.46E-07	0.0002	"6,200.00"

ETO-71	EtO Source	5.15E-03	6	3.09E-02	2.72E-06	4.53E-07	<0.0001 "150,000.00"
ETO-39	EtO Source	4.47E-03	104	4.65E-01	4.09E-05	3.94E-07	0.0001 "8,600.00"
ETO-50	EtO Source	3.97E-03	535	2.13E+00	1.87E-04	3.50E-07	0.0001 "12,000.00"
ETO-25	EtO Source	2.58E-03	22	5.67E-02	4.99E-06	2.27E-07	0.0001 "12,000.00"
ETO-119	EtO Source	2.06E-03	2	4.12E-03	3.62E-07	1.81E-07	<0.0001 "170,000.00"
ETO-80	EtO Source	9.28E-04	23	2.13E-02	1.88E-06	8.17E-08	<0.0001 "290,000.00"
ETO-70	EtO Source	3.20E-04	522	1.67E-01	1.47E-05	2.82E-08	<0.0001 "82,000.00"
ETO-32	EtO Source	1.07E-04	5	5.35E-04	4.70E-08	9.41E-09	<0.0001 **********
ETO-46	EtO Source	5.39E-05	28	1.51E-03	1.33E-07	4.74E-09	<0.0001 **********
ETO-54	EtO Source	3.31E-05	1	3.31E-05	2.91E-09	2.91E-09	<0.0001 **********
ETO-117	EtO Source	1.00E-38	"49,300"	4.93E-34	4.33E-38	8.80E-43	<0.0001

*** END OF REPORT ***

Attachment 11: Noncancer HEM-Screen output file for major sources

HUMAN EXPOSURE MODEL
STANDARD SUMMARY REPORT

Date: 12/15/2004 Time: 08:30
Chemical Name: Ethylene Oxide Unit Risk: 3.33E-02

REPORT DESCRIPTION

MODELING OPTIONS
Input File Name: c:\program files\hem_vb_wrapper_v3\input\eoncmj.hem
Radii Set: " 0.1, 0.5, 1.0, 2.0, 5.0,10.0,20.0,30.0,40.0,50.0"
Census Data: 2000
Atmospheric Decay: No

HEM-SCREEN EXPOSURE RESULTS

	Concentration	Population	Exposure
MAX:	1.68E+00	94	1.58E+02
MIN:	1.00E-38	"91,300,000"	3.23E+04

Level	Concentration	Population	Exposure
1	4.14E+00		0.00E+00
3	1.00E+00	285	3.66E+02
4	5.00E-01	"1,350"	1.11E+03
5	2.50E-01	"3,160"	1.69E+03
6	1.00E-01	"8,350"	2.39E+03
7	5.00E-02	"22,600"	3.40E+03
8	2.50E-02	"74,900"	5.17E+03
9	1.00E-02	"292,000"	8.44E+03
10	5.00E-03	"681,000"	1.11E+04
11	2.50E-03	"1,720,000"	1.47E+04
12	1.00E-03	"6,040,000"	2.11E+04
13	5.00E-04	"13,700,000"	2.64E+04
14	2.50E-04	"20,600,000"	2.89E+04
15	1.00E-04	"32,600,000"	3.08E+04
16	5.00E-05	"43,500,000"	3.16E+04
17	2.50E-05	"54,300,000"	3.20E+04
18	1.00E-05	"69,500,000"	3.22E+04
19	5.00E-06	"77,600,000"	3.23E+04
20	2.50E-06	"83,800,000"	3.23E+04
21	1.00E-06	"85,700,000"	3.23E+04
22	5.00E-07	"87,500,000"	3.23E+04
23	2.50E-07	"89,200,000"	3.23E+04
24	1.00E-07	"90,400,000"	3.23E+04

25	5.00E-08	"91,000,000"	3.23E+04
26	2.50E-08	"91,200,000"	3.23E+04
27	1.00E-08	"91,300,000"	3.23E+04
28	5.00E-09	"91,300,000"	3.23E+04
29	2.50E-09	"91,300,000"	3.23E+04
30	1.00E-09	"91,300,000"	3.23E+04
31	5.00E-10	"91,300,000"	3.23E+04
32	2.50E-10	"91,300,000"	3.23E+04
33	1.00E-10	"91,300,000"	3.23E+04
34	5.00E-11	"91,300,000"	3.23E+04
35	2.50E-11	"91,300,000"	3.23E+04
36	1.00E-11	"91,300,000"	3.23E+04
37	5.00E-12	"91,300,000"	3.23E+04
38	2.50E-12	"91,300,000"	3.23E+04
39	1.00E-12	"91,300,000"	3.23E+04
40	5.00E-13	"91,300,000"	3.23E+04
41	2.50E-13	"91,300,000"	3.23E+04
42	1.00E-13	"91,300,000"	3.23E+04
43	5.00E-14	"91,300,000"	3.23E+04
44	2.50E-14	"91,300,000"	3.23E+04
45	1.00E-14	"91,300,000"	3.23E+04
46	5.00E-15	"91,300,000"	3.23E+04
47	2.50E-15	"91,300,000"	3.23E+04
48	1.00E-15	"91,300,000"	3.23E+04
49	5.00E-16	"91,300,000"	3.23E+04
50	2.50E-16	"91,300,000"	3.23E+04
51	1.00E-16	"91,300,000"	3.23E+04
52	5.00E-17	"91,300,000"	3.23E+04
53	2.50E-17	"91,300,000"	3.23E+04
54	1.00E-17	"91,300,000"	3.23E+04
55	5.00E-18	"91,300,000"	3.23E+04
56	2.50E-18	"91,300,000"	3.23E+04
57	1.00E-18	"91,300,000"	3.23E+04
58	5.00E-19	"91,300,000"	3.23E+04
59	2.50E-19	"91,300,000"	3.23E+04
60	1.00E-19	"91,300,000"	3.23E+04
61	5.00E-20	"91,300,000"	3.23E+04
62	2.50E-20	"91,300,000"	3.23E+04
63	1.00E-20	"91,300,000"	3.23E+04
64	5.00E-21	"91,300,000"	3.23E+04
65	2.50E-21	"91,300,000"	3.23E+04
66	1.00E-21	"91,300,000"	3.23E+04
67	5.00E-22	"91,300,000"	3.23E+04
68	2.50E-22	"91,300,000"	3.23E+04
69	1.00E-22	"91,300,000"	3.23E+04
70	5.00E-23	"91,300,000"	3.23E+04
71	2.50E-23	"91,300,000"	3.23E+04
72	1.00E-23	"91,300,000"	3.23E+04
73	5.00E-24	"91,300,000"	3.23E+04
74	2.50E-24	"91,300,000"	3.23E+04
75	1.00E-24	"91,300,000"	3.23E+04
76	5.00E-25	"91,300,000"	3.23E+04

77	2.50E-25	"91,300,000"	3.23E+04
78	1.00E-25	"91,300,000"	3.23E+04
79	5.00E-26	"91,300,000"	3.23E+04
80	2.50E-26	"91,300,000"	3.23E+04
81	1.00E-26	"91,300,000"	3.23E+04
82	5.00E-27	"91,300,000"	3.23E+04
83	2.50E-27	"91,300,000"	3.23E+04
84	1.00E-27	"91,300,000"	3.23E+04
85	5.00E-28	"91,300,000"	3.23E+04
86	2.50E-28	"91,300,000"	3.23E+04
87	1.00E-28	"91,300,000"	3.23E+04
88	5.00E-29	"91,300,000"	3.23E+04
89	2.50E-29	"91,300,000"	3.23E+04
90	1.00E-29	"91,300,000"	3.23E+04
91	5.00E-30	"91,300,000"	3.23E+04
92	2.50E-30	"91,300,000"	3.23E+04
93	1.00E-30	"91,300,000"	3.23E+04
94	5.00E-31	"91,300,000"	3.23E+04
95	2.50E-31	"91,300,000"	3.23E+04
96	1.00E-31	"91,300,000"	3.23E+04
97	5.00E-32	"91,300,000"	3.23E+04
98	2.50E-32	"91,300,000"	3.23E+04
99	1.00E-32	"91,300,000"	3.23E+04
100	5.00E-33	"91,300,000"	3.23E+04
101	2.50E-33	"91,300,000"	3.23E+04
102	1.00E-33	"91,300,000"	3.23E+04
103	5.00E-34	"91,300,000"	3.23E+04
104	2.50E-34	"91,300,000"	3.23E+04
105	1.00E-34	"91,300,000"	3.23E+04
106	5.00E-35	"91,300,000"	3.23E+04
107	2.50E-35	"91,300,000"	3.23E+04
108	1.00E-35	"91,300,000"	3.23E+04
109	5.00E-36	"91,300,000"	3.23E+04
110	2.50E-36	"91,300,000"	3.23E+04
111	1.00E-36	"91,300,000"	3.23E+04
112	5.00E-37	"91,300,000"	3.23E+04
113	2.50E-37	"91,300,000"	3.23E+04
114	1.00E-37	"91,300,000"	3.23E+04
115	5.00E-38	"91,300,000"	3.23E+04
116	2.50E-38	"91,300,000"	3.23E+04
117	1.00E-38	"91,300,000"	3.23E+04

HEM-SCREEN RISK RESULTS

	Risk Level	Population	Exposure * Risk
MAX:	5.60E-02	47	2.63E+00
MIN:	3.33E-40	"91,300,000"	1.08E+03

Level	Risk Level	Population	Exposure * Unit Risk
1	1.38E-01		0.00E+00
3	5.00E-02	94	5.26E+00
4	2.50E-02	401	1.54E+01

5	1.00E-02	"2,100"	4.67E+01
6	5.00E-03	"4,210"	6.27E+01
7	2.50E-03	"14,700"	9.73E+01
8	1.00E-03	"56,800"	1.56E+02
9	5.00E-04	"166,000"	2.30E+02
10	2.50E-04	"423,000"	3.19E+02
11	1.00E-04	"1,340,000"	4.55E+02
12	5.00E-05	"3,390,000"	5.95E+02
13	2.50E-05	"8,690,000"	7.78E+02
14	1.00E-05	"18,900,000"	9.49E+02
15	5.00E-06	"26,500,000"	1.00E+03
16	2.50E-06	"37,000,000"	1.04E+03
17	1.00E-06	"51,400,000"	1.06E+03
18	5.00E-07	"64,200,000"	1.07E+03
19	2.50E-07	"73,100,000"	1.08E+03
20	1.00E-07	"82,900,000"	1.08E+03
21	5.00E-08	"84,900,000"	1.08E+03
22	2.50E-08	"86,300,000"	1.08E+03
23	1.00E-08	"88,800,000"	1.08E+03
24	5.00E-09	"90,000,000"	1.08E+03
25	2.50E-09	"90,600,000"	1.08E+03
26	1.00E-09	"91,100,000"	1.08E+03
27	5.00E-10	"91,200,000"	1.08E+03
28	2.50E-10	"91,300,000"	1.08E+03
29	1.00E-10	"91,300,000"	1.08E+03
30	5.00E-11	"91,300,000"	1.08E+03
31	2.50E-11	"91,300,000"	1.08E+03
32	1.00E-11	"91,300,000"	1.08E+03
33	5.00E-12	"91,300,000"	1.08E+03
34	2.50E-12	"91,300,000"	1.08E+03
35	1.00E-12	"91,300,000"	1.08E+03
36	5.00E-13	"91,300,000"	1.08E+03
37	2.50E-13	"91,300,000"	1.08E+03
38	1.00E-13	"91,300,000"	1.08E+03
39	5.00E-14	"91,300,000"	1.08E+03
40	2.50E-14	"91,300,000"	1.08E+03
41	1.00E-14	"91,300,000"	1.08E+03
42	5.00E-15	"91,300,000"	1.08E+03
43	2.50E-15	"91,300,000"	1.08E+03
44	1.00E-15	"91,300,000"	1.08E+03
45	5.00E-16	"91,300,000"	1.08E+03
46	2.50E-16	"91,300,000"	1.08E+03
47	1.00E-16	"91,300,000"	1.08E+03
48	5.00E-17	"91,300,000"	1.08E+03
49	2.50E-17	"91,300,000"	1.08E+03
50	1.00E-17	"91,300,000"	1.08E+03
51	5.00E-18	"91,300,000"	1.08E+03
52	2.50E-18	"91,300,000"	1.08E+03
53	1.00E-18	"91,300,000"	1.08E+03
54	5.00E-19	"91,300,000"	1.08E+03
55	2.50E-19	"91,300,000"	1.08E+03
56	1.00E-19	"91,300,000"	1.08E+03

57	5.00E-20	"91,300,000"	1.08E+03
58	2.50E-20	"91,300,000"	1.08E+03
59	1.00E-20	"91,300,000"	1.08E+03
60	5.00E-21	"91,300,000"	1.08E+03
61	2.50E-21	"91,300,000"	1.08E+03
62	1.00E-21	"91,300,000"	1.08E+03
63	5.00E-22	"91,300,000"	1.08E+03
64	2.50E-22	"91,300,000"	1.08E+03
65	1.00E-22	"91,300,000"	1.08E+03
66	5.00E-23	"91,300,000"	1.08E+03
67	2.50E-23	"91,300,000"	1.08E+03
68	1.00E-23	"91,300,000"	1.08E+03
69	5.00E-24	"91,300,000"	1.08E+03
70	2.50E-24	"91,300,000"	1.08E+03
71	1.00E-24	"91,300,000"	1.08E+03
72	5.00E-25	"91,300,000"	1.08E+03
73	2.50E-25	"91,300,000"	1.08E+03
74	1.00E-25	"91,300,000"	1.08E+03
75	5.00E-26	"91,300,000"	1.08E+03
76	2.50E-26	"91,300,000"	1.08E+03
77	1.00E-26	"91,300,000"	1.08E+03
78	5.00E-27	"91,300,000"	1.08E+03
79	2.50E-27	"91,300,000"	1.08E+03
80	1.00E-27	"91,300,000"	1.08E+03
81	5.00E-28	"91,300,000"	1.08E+03
82	2.50E-28	"91,300,000"	1.08E+03
83	1.00E-28	"91,300,000"	1.08E+03
84	5.00E-29	"91,300,000"	1.08E+03
85	2.50E-29	"91,300,000"	1.08E+03
86	1.00E-29	"91,300,000"	1.08E+03
87	5.00E-30	"91,300,000"	1.08E+03
88	2.50E-30	"91,300,000"	1.08E+03
89	1.00E-30	"91,300,000"	1.08E+03
90	5.00E-31	"91,300,000"	1.08E+03
91	2.50E-31	"91,300,000"	1.08E+03
92	1.00E-31	"91,300,000"	1.08E+03
93	5.00E-32	"91,300,000"	1.08E+03
94	2.50E-32	"91,300,000"	1.08E+03
95	1.00E-32	"91,300,000"	1.08E+03
96	5.00E-33	"91,300,000"	1.08E+03
97	2.50E-33	"91,300,000"	1.08E+03
98	1.00E-33	"91,300,000"	1.08E+03
99	5.00E-34	"91,300,000"	1.08E+03
100	2.50E-34	"91,300,000"	1.08E+03
101	1.00E-34	"91,300,000"	1.08E+03
102	5.00E-35	"91,300,000"	1.08E+03
103	2.50E-35	"91,300,000"	1.08E+03
104	1.00E-35	"91,300,000"	1.08E+03
105	5.00E-36	"91,300,000"	1.08E+03
106	2.50E-36	"91,300,000"	1.08E+03
107	1.00E-36	"91,300,000"	1.08E+03
108	5.00E-37	"91,300,000"	1.08E+03

109	2.50E-37	"91,300,000"	1.08E+03
110	1.00E-37	"91,300,000"	1.08E+03
111	5.00E-38	"91,300,000"	1.08E+03
112	2.50E-38	"91,300,000"	1.08E+03
113	3.33E-40	"91,300,000"	1.08E+03

HEM-SCREEN RESULTS

Source	Max Concentration	People	Max Exposure	Lifetime Incidence	Max Risk	Annual Incid.	Repeat Interval
ETO-18 EtO Source	1.68E+00	94	1.58E+02	5.26E+00	5.60E-02	0.91	1.1
ETO-19 EtO Source	1.06E+00	3	3.19E+00	1.06E-01	3.55E-02	0.55	1.8
ETO-8 EtO Source	8.38E-01	3	2.51E+00	8.38E-02	2.79E-02	0.56	1.8
ETO-27 EtO Source	7.51E-01	39	2.93E+01	9.76E-01	2.50E-02	0.5	2
ETO-4 EtO Source	6.96E-01	49	3.41E+01	1.14E+00	2.32E-02	1.6	0.63
ETO-5 EtO Source	6.90E-01	54	3.72E+01	1.24E+00	2.30E-02	0.43	2.3
ETO-24 EtO Source	2.67E-01	1	2.67E-01	8.91E-03	8.91E-03	0.42	2.4
ETO-11 EtO Source	2.53E-01	26	6.58E+00	2.19E-01	8.43E-03	0.12	8.5
ETO-22 EtO Source	2.43E-01	65	1.58E+01	5.27E-01	8.11E-03	0.32	3.1
ETO-12 EtO Source	1.88E-01	4	7.54E-01	2.51E-02	6.28E-03	1.5	0.68
ETO-118 EtO Source	1.86E-01	28	5.21E+00	1.74E-01	6.21E-03	0.38	2.6
ETO-13 EtO Source	1.70E-01	7	1.19E+00	3.97E-02	5.68E-03	0.7	1.4
ETO-57 EtO Source	1.49E-01	15	2.23E+00	7.43E-02	4.95E-03	0.034	29
ETO-91 EtO Source	1.40E-01	17	2.38E+00	7.93E-02	4.66E-03	0.26	3.9
ETO-10 EtO Source	1.35E-01	3	4.05E-01	1.35E-02	4.50E-03	1.4	0.71
ETO-29 EtO Source	1.28E-01	28	3.58E+00	1.19E-01	4.26E-03	0.49	2
ETO-3 EtO Source	1.12E-01	107	1.20E+01	4.00E-01	3.73E-03	0.073	14
ETO-14 EtO Source	1.11E-01	158	1.75E+01	5.84E-01	3.69E-03	0.81	1.2
ETO-1 EtO Source	7.85E-02	322	2.53E+01	8.43E-01	2.62E-03	0.14	7.1
ETO-9 EtO Source	7.60E-02	2	1.52E-01	5.07E-03	2.53E-03	0.45	2.2
ETO-44 EtO Source	6.74E-02	6	4.05E-01	1.35E-02	2.25E-03	0.13	7.6
ETO-36 EtO Source	6.72E-02	153	1.03E+01	3.43E-01	2.24E-03	0.18	5.5
ETO-48 EtO Source	5.92E-02	22	1.30E+00	4.34E-02	1.97E-03	0.059	17
ETO-15 EtO Source	5.40E-02	1	5.40E-02	1.80E-03	1.80E-03	1	0.98
ETO-35 EtO Source	5.40E-02	3	1.62E-01	5.40E-03	1.80E-03	0.21	4.9
ETO-23 EtO Source	4.37E-02	111	4.85E+00	1.62E-01	1.46E-03	0.088	11
ETO-7 EtO Source	4.11E-02	171	7.03E+00	2.34E-01	1.37E-03	0.15	6.8
ETO-67 EtO Source	3.92E-02	185	7.25E+00	2.42E-01	1.31E-03	0.0089	110
ETO-20 EtO Source	3.66E-02	92	3.37E+00	1.12E-01	1.22E-03	0.1	9.9
ETO-21 EtO Source	2.69E-02	343	9.23E+00	3.08E-01	8.97E-04	0.38	2.6
ETO-61 EtO Source	2.51E-02	28	7.04E-01	2.35E-02	8.38E-04	0.12	8.2
ETO-37 EtO Source	2.47E-02	53	1.31E+00	4.36E-02	8.23E-04	0.26	3.8
ETO-26 EtO Source	2.28E-02	3	6.85E-02	2.28E-03	7.61E-04	0.31	3.3
ETO-59 EtO Source	2.09E-02	926	1.94E+01	6.46E-01	6.98E-04	0.041	24
ETO-62 EtO Source	2.02E-02	3	6.06E-02	2.02E-03	6.73E-04	0.015	67
ETO-49 EtO Source	1.76E-02	9	1.59E-01	5.29E-03	5.88E-04	0.12	8.7
ETO-33 EtO Source	1.69E-02	48	8.10E-01	2.70E-02	5.62E-04	0.0071	140
ETO-45 EtO Source	1.67E-02	35	5.85E-01	1.95E-02	5.57E-04	0.018	57
ETO-58 EtO Source	1.58E-02	51	8.07E-01	2.69E-02	5.27E-04	0.041	24
ETO-38 EtO Source	1.29E-02	25	3.23E-01	1.08E-02	4.31E-04	0.074	14
ETO-55 EtO Source	1.17E-02	9	1.05E-01	3.50E-03	3.89E-04	0.0052	190

ETO-56 EtO Source	1.12E-02	"1,050"	1.18E+01	3.92E-01	3.73E-04	0.037	27
ETO-60 EtO Source	1.08E-02	71	7.64E-01	2.55E-02	3.59E-04	0.024	42
ETO-51 EtO Source	9.42E-03	11	1.04E-01	3.45E-03	3.14E-04	0.013	74
ETO-2 EtO Source	8.16E-03	4	3.27E-02	1.09E-03	2.72E-04	0.072	14
ETO-52 EtO Source	7.35E-03	8	5.88E-02	1.96E-03	2.45E-04	0.0017	570
ETO-41 EtO Source	7.22E-03	11	7.94E-02	2.65E-03	2.41E-04	0.11	9.5
ETO-75 EtO Source	7.04E-03	19	1.34E-01	4.46E-03	2.35E-04	0.01	98
ETO-47 EtO Source	6.44E-03	462	2.97E+00	9.91E-02	2.15E-04	0.013	74
ETO-40 EtO Source	6.21E-03	70	4.35E-01	1.45E-02	2.07E-04	0.061	16
ETO-71 EtO Source	5.15E-03	6	3.09E-02	1.03E-03	1.72E-04	0.0025	400
ETO-39 EtO Source	4.47E-03	104	4.65E-01	1.55E-02	1.49E-04	0.044	23
ETO-50 EtO Source	3.97E-03	535	2.13E+00	7.09E-02	1.32E-04	0.03	33
ETO-25 EtO Source	2.58E-03	22	5.67E-02	1.89E-03	8.59E-05	0.031	33
ETO-119 EtO Source	2.06E-03	2	4.12E-03	1.37E-04	6.86E-05	0.0022	460
ETO-80 EtO Source	9.28E-04	23	2.13E-02	7.11E-04	3.09E-05	0.0013	760
ETO-70 EtO Source	3.20E-04	522	1.67E-01	5.57E-03	1.07E-05	0.0046	220
ETO-32 EtO Source	1.07E-04	5	5.35E-04	1.78E-05	3.56E-06	0.0002	"5,200.00"
ETO-46 EtO Source	5.39E-05	28	1.51E-03	5.03E-05	1.80E-06	0.0003	"3,400.00"
ETO-54 EtO Source	3.31E-05	1	3.31E-05	1.10E-06	1.10E-06	0.0001	"18,000.00"
ETO-117 EtO Source	1.00E-38	"49,300"	4.93E-34	1.64E-35	3.33E-40	<0.0001	

*** END OF REPORT ***