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Alternative Control Technology Document – Ethylene Oxide Sterilization/Fumigation Operations

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Alternative Control Technology Document – Ethylene Oxide Sterilization/Fumigation Operations

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Office of Air and Radiation
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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.[4]

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[4]

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.

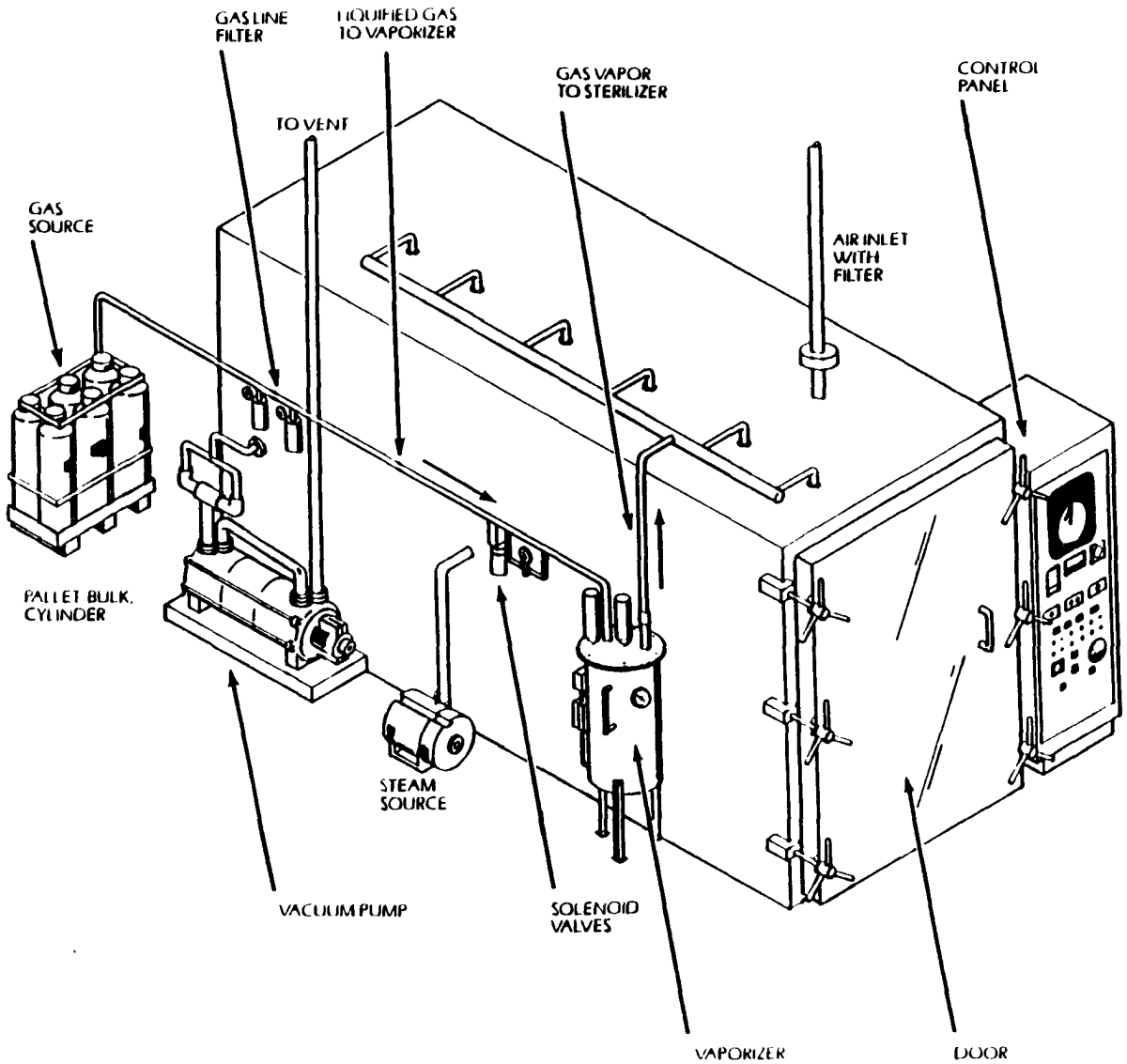


Figure 3-1. Schematic of a gas sterilizer. (Courtesy of Union Carbide Corporation, Linde Division.)[12]

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]

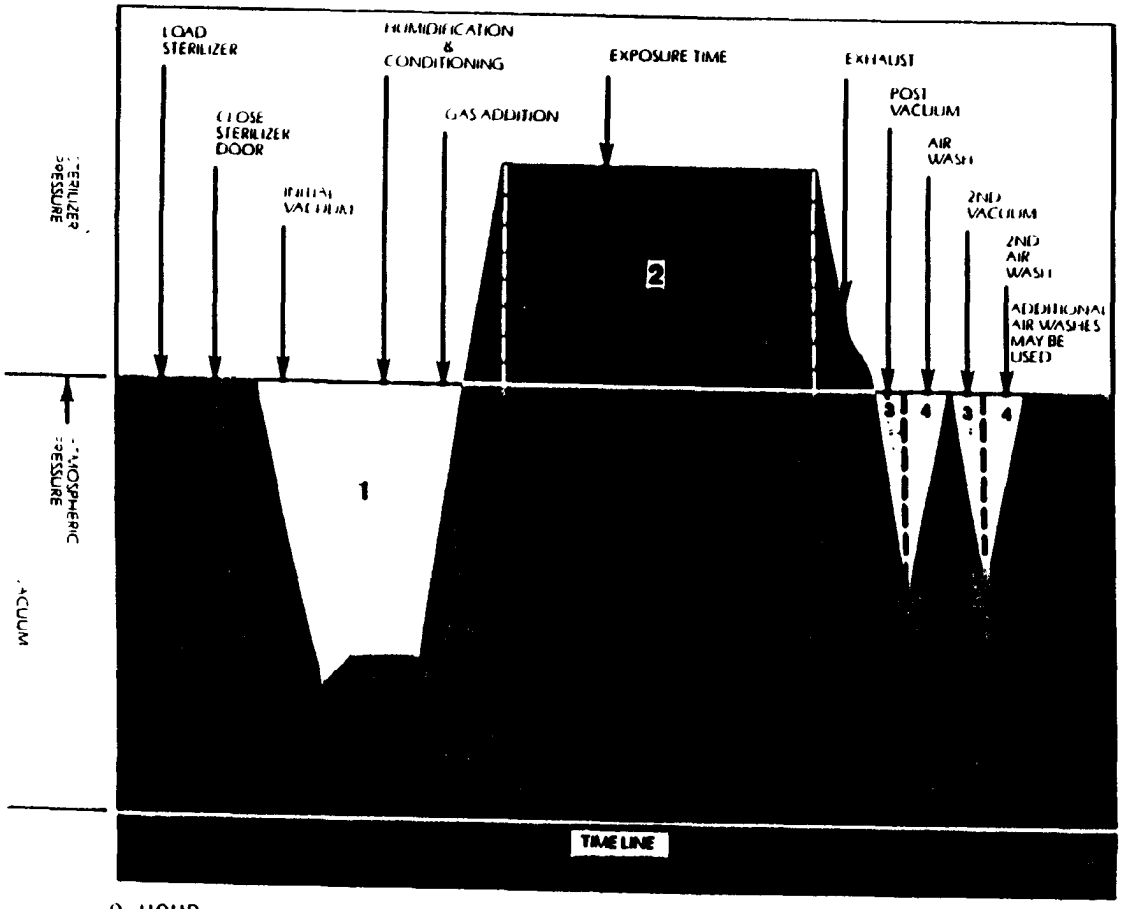
Sterilant gas	No. of facilities[a b]	Percent of facilities	No. of chambers[c]	Percent of chambers	EO use, Mg/yr[d]	Percent of total EO use
12/88 (EO/CFC-12)	154	76	295	68	720	30
Pure EO	44	22	122	28	1,350	60
10/90 (EO/CO_2)	14	7	19	4	4	<0.01
Other mixtures[e]	16	8	25	6	190	10

[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



0 HOUR

8 HOUR

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]

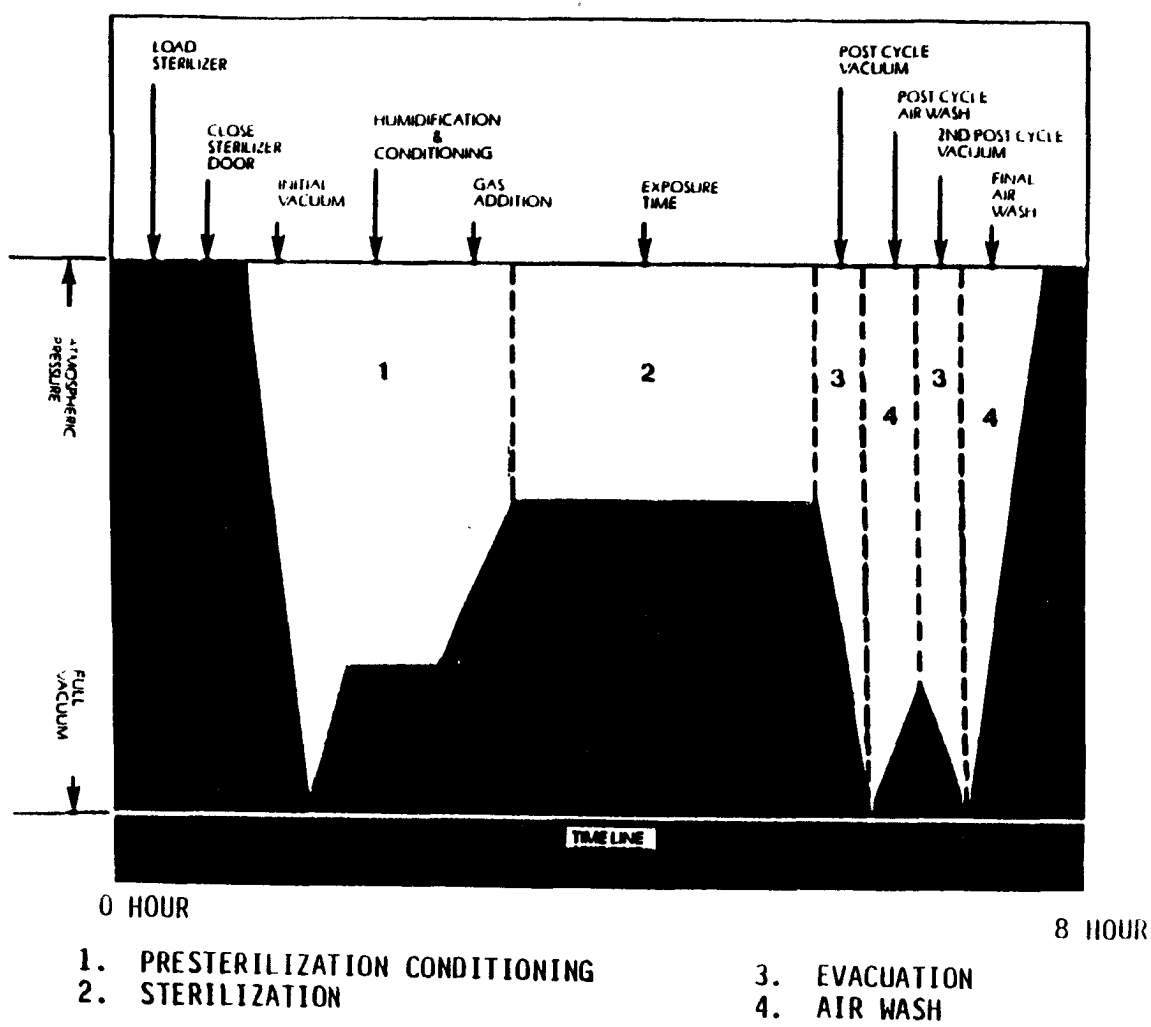


Figure 3-3. Sterilization cycle for pure EO. (Courtesy of Union Carbide Corporation, Linde Division.)[12]

about 45 percent by injecting steam. Proper numidification 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

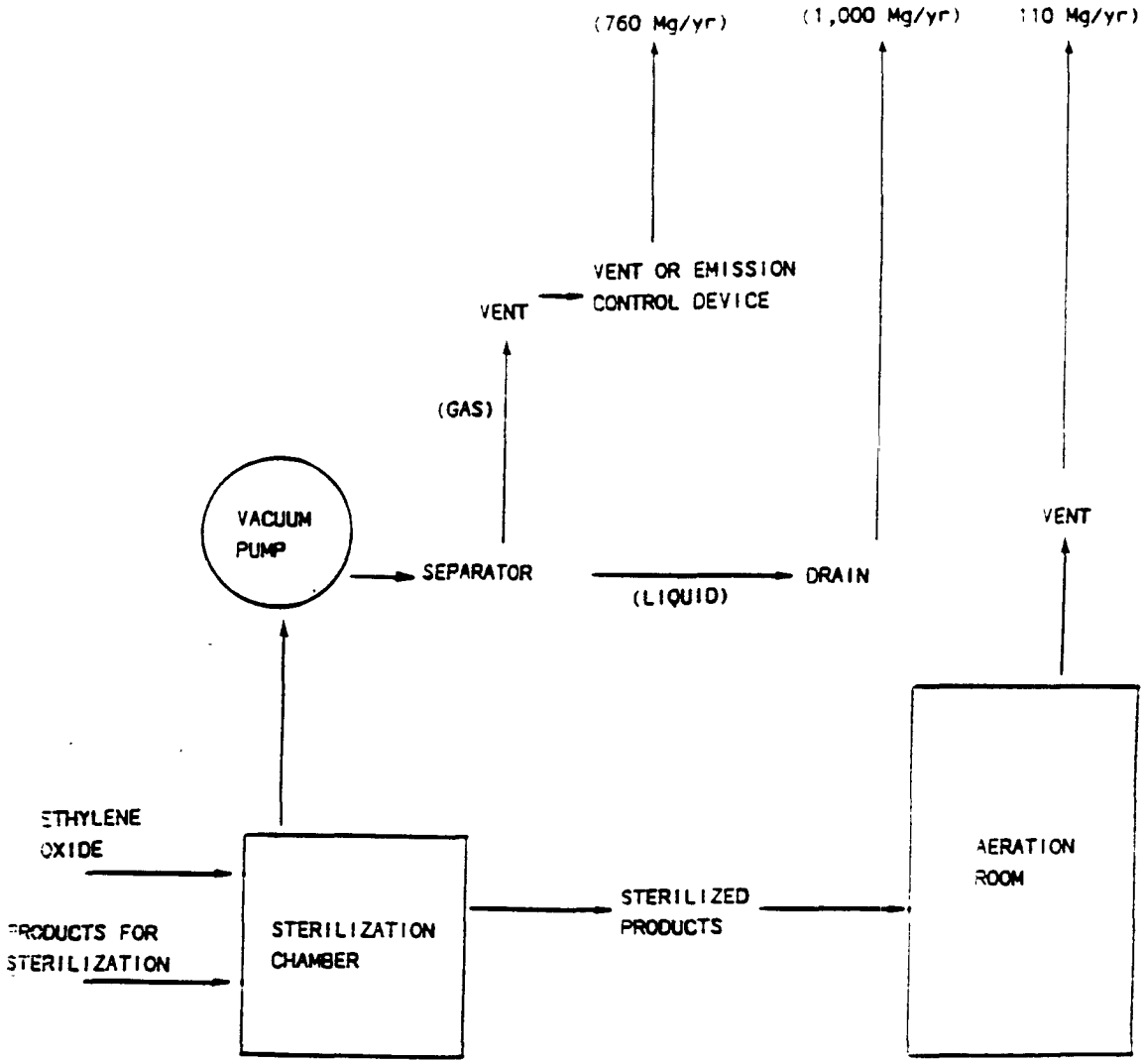


Figure 3-4. Schematic of emission sources at commercial sterilization facilities. (Does not include hospitals).

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

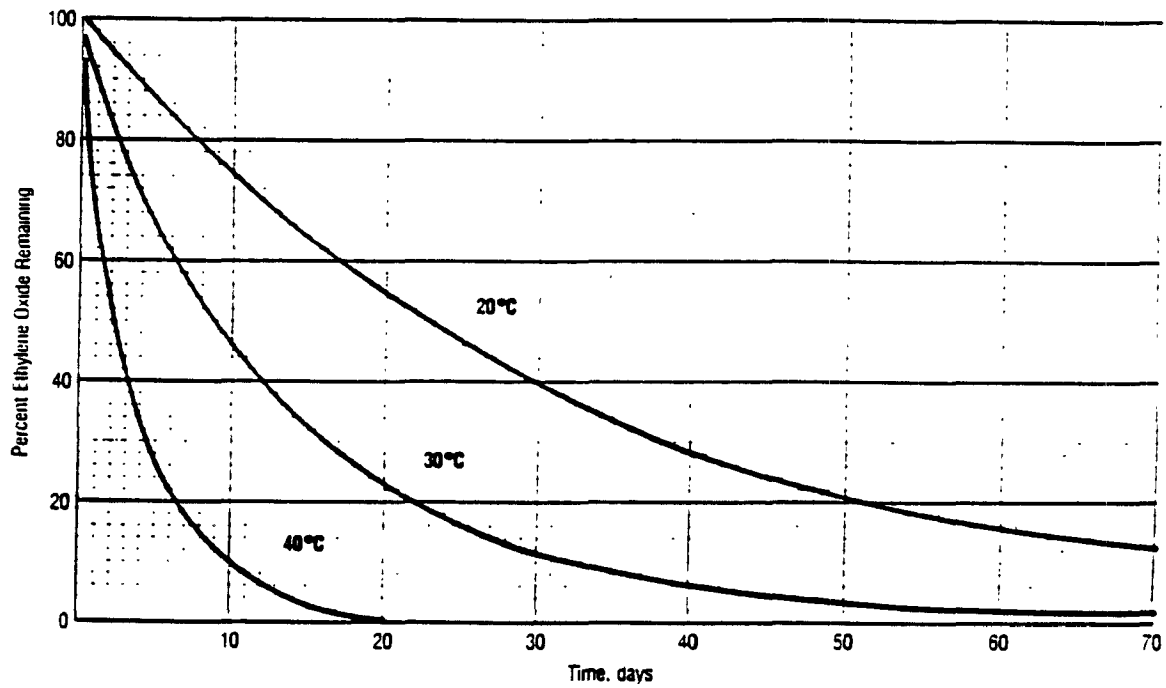


Figure 3-5. Hydrolysis rates of dilute, neutral aqueous solutions of ethylene oxide.
(Courtesy of Union Carbide Corporation, Ethylene Oxide/Glycol Division.)[8]

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_3 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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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

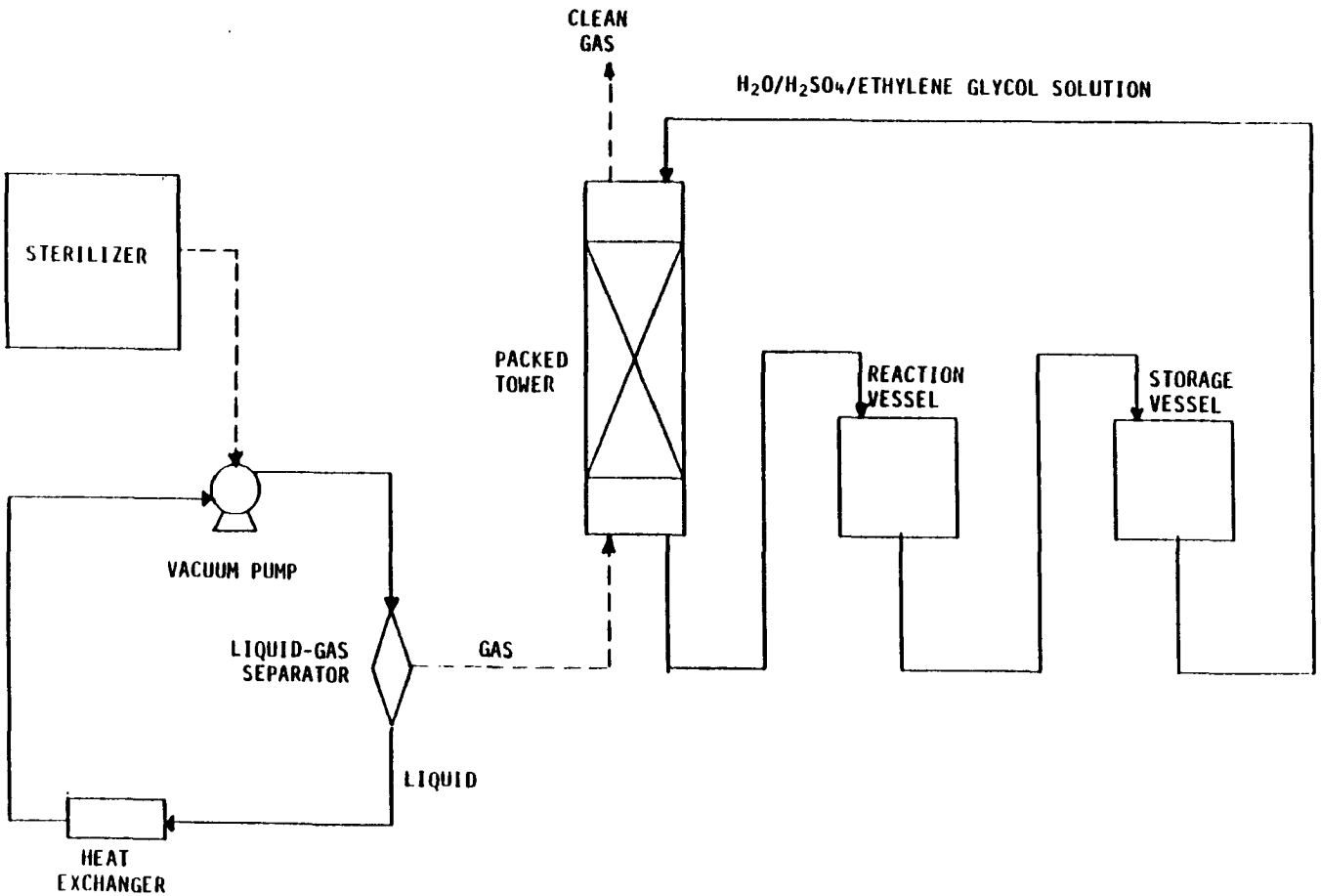

Figure 4-1. Countercurrent packed scrubbing system.

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

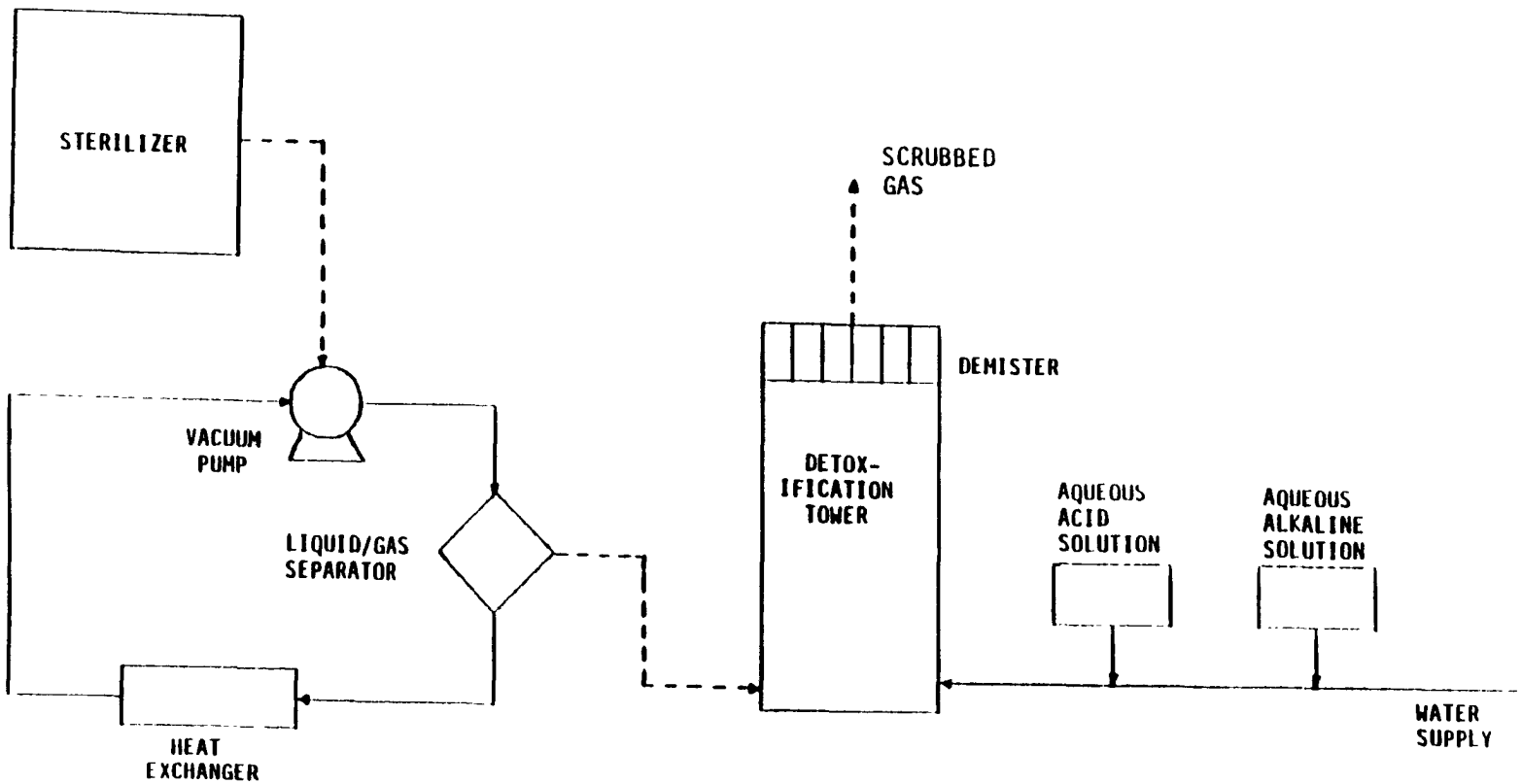

Figure 4-2. Detoxification tower control system.

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]

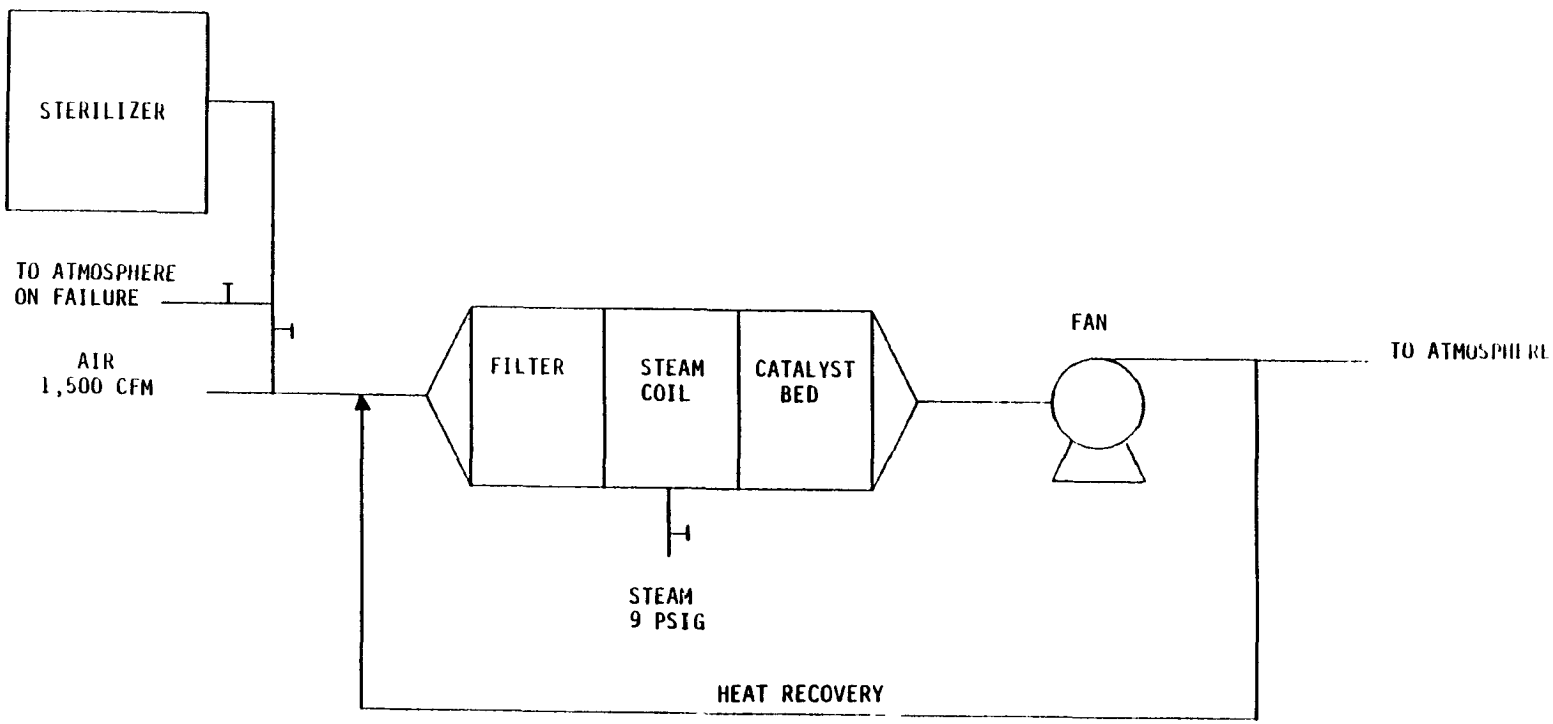

Figure 4-3. Catalytic oxidation system.

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

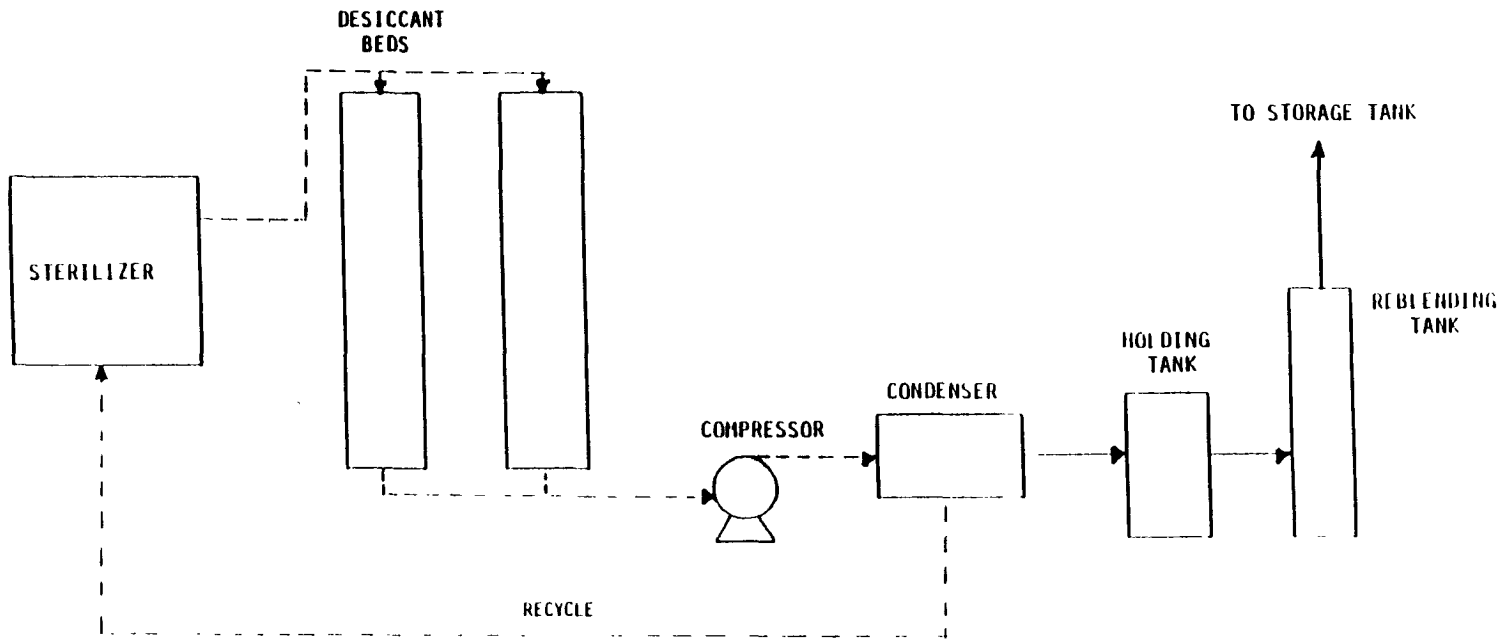

Figure 4-4. Condensation/reclamation system.

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

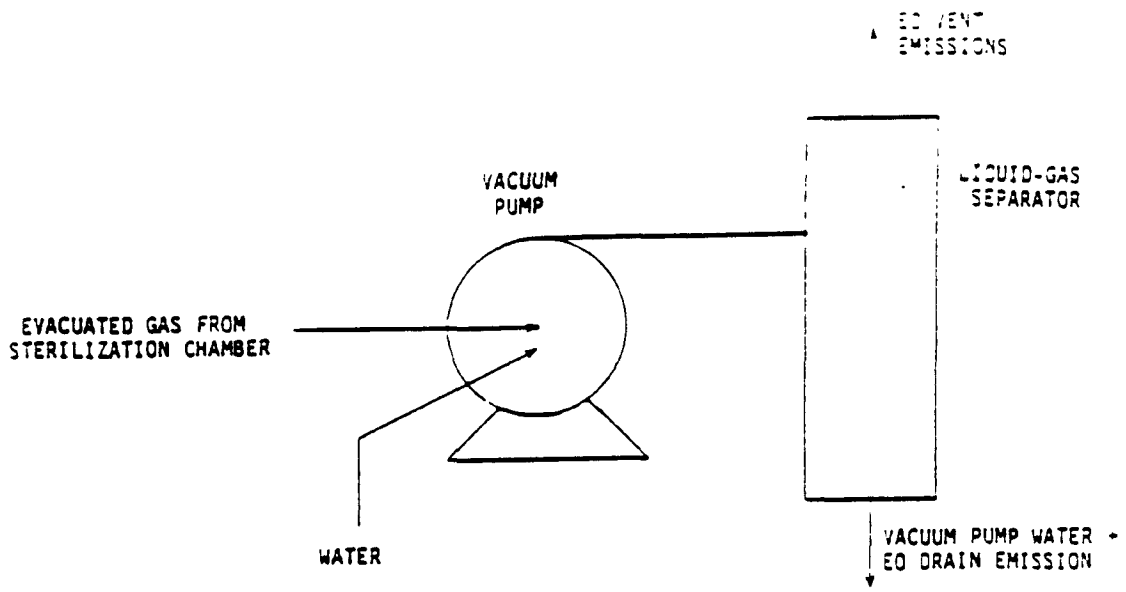

Figure 4-5a. Once-through liquid-ring vacuum pump.

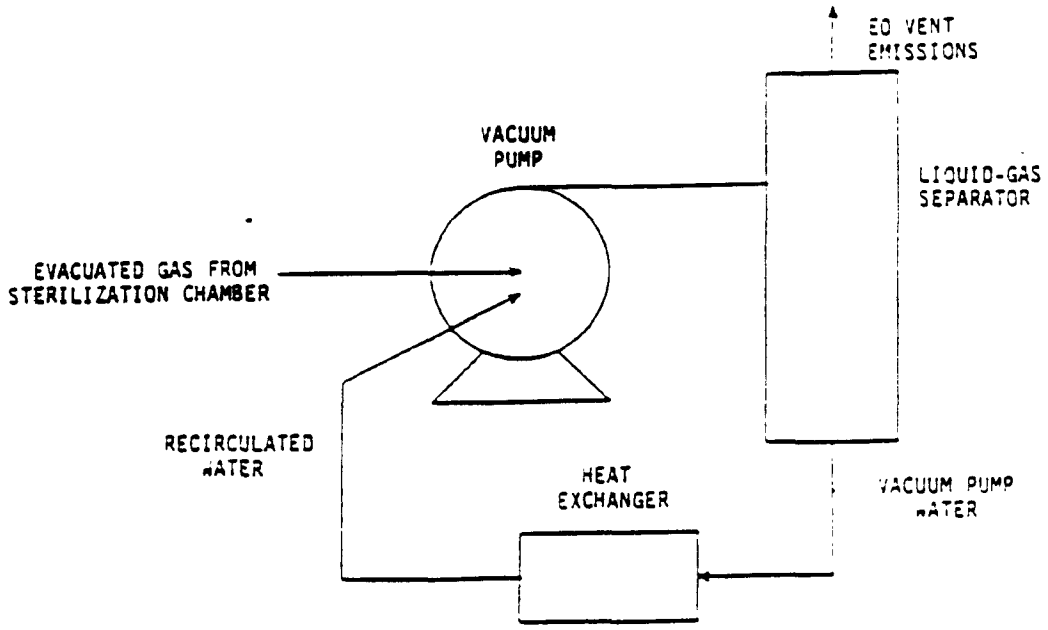

Figure 4-5b. Recirculating liquid-ring vacuum pump.

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[i]
(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)

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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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