UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Signed by Steve Luftig & Larry Weinstock on August 22, 1997

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER No. 9200.4-18

MEMORANDUM

SUBJECT: Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination

FROM: Stephen D. Luftig, Director *s/Stephen D. Luftig*
Office of Emergency and Remedial Response

Larry Weinstock, Acting Director *s/Larry Weinstock*
Office of Radiation and Indoor Air

TO: Addressees

PURPOSE

This memorandum presents clarifying guidance for establishing protective cleanup levels[1] for radioactive contamination at Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) sites. The policies stated in this memorandum are inclusive of all radioactive contaminants of concern at a site including radon.[2] The directive is limited to providing guidance regarding the

[1]This directive provides guidance on cleanup levels expressed as a risk, exposure, or dose level and not as a soil concentration level. The concentration level for various media, such as soil, that corresponds to a given risk level should be determined on a site-specific basis, based on factors such as the assumed land use and the physical characteristics (e.g., important surface features, soils, geology, hydro geology, meteorology, and ecology) at the site. This guidance does not alter the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) expectations regarding treatment of principal threat waste and the use of containment and institutional controls for low level threat waste.

[2]Since radon is not covered in some Federal radiation regulations it is important to note that the cleanup guidance clarifications in this memorandum include radon. Attachment A is a listing of standards for radionuclides (including radon) that may be applicable or relevant and appropriate requirements (ARARs) for Superfund sites.

protection of human health and does not address levels necessary to protect ecological receptors.

This document provides guidance to EPA staff. It also provides guidance to the public and to the regulated community on how EPA intends that the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) be implemented. The guidance is designed to describe EPA's national policy on these issues. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

BACKGROUND

All remedial actions at CERCLA sites must be protective of human health and the environment and comply with Applicable or Relevant and Appropriate Requirements (ARARs) unless a waiver is justified. Cleanup levels for response actions under CERCLA are developed based on site-specific risk assessments, ARARs, and/or to-be-considered material[3] (TBCs).

A listing is attached of radiation standards that are likely to be used as ARARs to establish cleanup levels or to conduct remedial actions. Cleanup standards have been under development by EPA under the Atomic Energy Act (AEA) and will be ARARs under certain circumstances if issued.

ARARs are often the determining factor in establishing cleanup levels at CERCLA sites. However, where ARARs are not available or are not sufficiently protective, EPA generally sets site-specific remediation levels for: 1) carcinogens at a level that represents an excess upper bound lifetime cancer risk to an individual of between 10^{-4} to 10^{-6}; and for 2) non-carcinogens such that the cumulative risks from exposure will not result in adverse effects to human populations (including sensitive sub-populations) that may be exposed during a lifetime or part of a lifetime, incorporating an adequate margin of safety. (See 40 CFR 300.430(e)(2)(i)(A)(2).) Since all radionuclides are carcinogens, this guidance addresses carcinogenic risk. If non-carcinogenic risks are posed by specific radionuclides, those risks should be taken into account in establishing cleanup levels or suitable remedial actions. The site-specific level of cleanup is determined using the nine criteria specified in Section 300.430(e)(9)(iii) of the NCP.

It is important to note that a new potential ARAR was recently promulgated :

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[3]To-be-considered material (TBCs) are non-promulgated advisories or guidance issued by Federal or State governments that are not legally binding and do not have the status of potential ARARs. However, TBCs will be considered along with ARARs as part of the site risk assessment and may be used in determining the necessary level of cleanup for protection of health and the environment.

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NRC's Radiological Criteria for License Termination (See 62 FR 39058, July 21, 1997). We expect that NRC's implementation of the rule for License Termination (decommissioning rule) will result in cleanups within the Superfund risk range at the vast majority of NRC sites. However, EPA has determined that the dose limits established in this rule as promulgated generally will not provide a protective basis for establishing preliminary remediation goals (PRGs) under CERCLA.[4] The NRC rule set an allowable cleanup level of 25 millirem per year (equivalent to approximately 5×10^{-4} increased lifetime risk) as the primary standard with exemptions allowing dose limits of up to 100 millirem per year (equivalent to approximately 2×10^{-3} increased lifetime risk). Accordingly, while the NRC rule standard must be met (or waived) at sites where it is applicable or relevant and appropriate, cleanups at these sites will typically have to be more stringent than required by the NRC dose limits in order to meet the CERCLA and NCP requirement to be protective.[5] Guidance that provides for cleanups outside the risk range (in general, cleanup levels exceeding 15 millirem per year which equates to approximately 3×10^{-4} increased lifetime risk) is similarly not protective under CERCLA and generally should not be used to establish cleanup levels.

The lack of a protective comprehensive set of regulatory cleanup levels for radiation, together with the possibility of confusion as to the status of other Federal Agency regulations and guidance as ARARs or TBCs, may cause uncertainty as to the cleanup levels deemed protective under CERCLA. Until a protective comprehensive radiation cleanup rule is available, this guidance clarifies the Agency's position on CERCLA cleanup levels for radiation.

OBJECTIVE

This guidance clarifies that cleanups of radionuclides are governed by the risk range for all carcinogens established in the NCP when ARARs are not available or are not sufficiently protective. This is to say, such cleanups should generally achieve risk levels in the 10^{-4} to 10^{-6} range. EPA has a consistent methodology for assessing cancer risks and determining PRGs at CERCLA sites no matter the type of contamination.[6] Cancer risks for radionuclides should generally be estimated using the slope factor approach identified in this methodology. Slope factors were developed by EPA for more than 300 radionuclides in the *Health Effects Assessment Summary Tables*

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[4]See letter, Carol Browner, Administrator, EPA, to Shirley Jackson, Chairman, Nuclear Regulatory Commission, February 7, 1997.

[5]See attachment B for a detailed discussion of the basis for the conclusion that the dose limits in the NRC rule are not adequately protective.

[6]U.S. EPA, "Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) Interim Final," EPA//540/1-89/002, December 1989. U.S. EPA, "Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals", EPA/540/R-92/003, December 1991.

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(HEAST).[7] Cleanup levels for radioactive contamination at CERCLA sites should be established as they would for any chemical that poses an unacceptable risk and the risks should be characterized in standard Agency risk language consistent with CERCLA guidance.

Historically, radiation exposure and cleanup levels have often been expressed in units unique to radiation (e.g., millirem or picoCuries). It is important for the purposes of clarity that a consistent set of existing risk-based units (i.e., # $x10^{-\#}$) for cleanups generally be used. This will also allow for ease and clarity of presenting cumulative risk for all contaminants, an objective consistent with EPA's policy on risk characterization.[8]

Cancer risk from both radiological and non-radiological contaminants should be summed to provide risk estimates for persons exposed to both types of carcinogenic contaminants. Although these risks initially may be tabulated separately, risk estimates contained in proposed and final site decision documents (e.g., proposed plans, Record of Decisions (RODs), Action Memos, ROD Amendments, Explanation of Significant Differences (ESDs)) should be summed to provide an estimate of the combined risk to individuals presented by **all** carcinogenic contaminants.

IMPLEMENTATION

The approach in this guidance should be considered at current and future CERCLA sites for which response decisions have not been made.

Overall Exposure Limit:

Cleanup should generally achieve a level of risk within the 10^{-4} to 10^{-6} carcinogenic risk range based on the reasonable maximum exposure for an individual. The cleanup levels to be specified include exposures from all potential pathways, and through all media (e.g., soil, ground water, surface water, sediment, air, structures, biota). As noted in previous policy, "the upper boundary of the risk range is not a discrete line at 1×10^{-4}, although EPA generally uses 1×10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable if justified based on site-specific conditions".[9]

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[7]U.S. EPA, "Health Effects Assessment Summary Tables FY-1995 Annual," EPA/540/R-95/036, May 1995; and U.S. EPA, "Health Effects Assessment Summary Tables FY-1995 Supplement," EPA/540/R-95/142, Nov. 1995.

[8]For further discussion of EPA's policy, see memorandum from EPA Administrator Carol Browner entitled: "EPA Risk Characterization Program," March 21, 1995.

[9]Memo from Assistant Administrator Don Clay to the Regions; "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions'" OSWER Directive 9355.0-30; April 22, 1991.

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If a dose assessment is conducted at the site[10] then 15 millirem per year (mrem/yr) effective dose equivalent (EDE) should generally be the maximum dose limit for humans. This level equates to approximately 3×10^{-4} increased lifetime risk and is consistent with levels generally considered protective in other governmental actions, particularly regulations and guidance developed by EPA in other radiation control programs.[11]

Background Contamination:

Background radiation levels will generally be determined as background levels are determined for other contaminants, on a site-specific basis. In some cases, the same constituents are found in on-site samples as well as in background samples. The levels of each constituent are compared to background to determine its impact, if any, on site-related activities. Background is generally measured only for those radionuclides that are contaminants of concern and is compared on a contaminant specific basis to cleanup level. For example, background levels for radium-226 and radon-222 would generally not be evaluated at a site if those radionuclides were not site-related contaminants.

In certain situations background levels of a site-related contaminant may equal or exceed PRGs established for a site. In these situations background and site-related levels of radiation will be addressed as they are for other contaminants at CERCLA sites.[12]

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[10]Cleanup levels not based on ARARs should be expressed as risk, although levels may at the same time be expressed in millirem.

[11]Further discussion and analysis of the basis for this recommendation is contained in the materials in the docket for the AEA standard under development by EPA, which is available at the following address: U.S. EPA, 401 M Street, S.W., Room M1500, Air Docket No. A-93-27, Washington D.C. 20460. The material is also available via computer modem through the Cleanup Regulation Electronic Bulletin Board (800-700-7837 outside the Washington area and 703-790-0825 locally), or on-line through the Radiation Site Cleanup Regulation HomePage (http://www.epa.gov/radiation/cleanup/). Cleanup levels based on some older ARARs that use a 25/75/25 mrem/yr standard (i.e., 25 mrem/yr to the whole body, 75 mrem/yr to the thyroid, and 25 mrem/yr to any other critical organ) may appear to permit greater risk than those based on 15 mrem EDE but on average correspond to approximately 10 mrem/yr EDE, using current risk methodologies. Similarly, ARARs based on a 25/75 mrem/yr standard used as an ARAR (i.e., 25 mrem/yr to whole body and 75 mrem/yr to any critical organ) would on average correspond to those cleanups based on 15 mrem/yr EDE. (See also "Comparison of Critical Organ and EDE Radiation Dose Rate Limits for Situations Involving Contaminated Land;" Office of Radiation and Indoor Air; April 1997.) See also Attachment B.

[12]For further information regarding EPA's approach for addressing background at CERCLA sites see: National Oil and Hazardous Substances Pollution Contingency Plan, 55 FR 8717-8718, March 8, 1990; U.S. EPA "Guidance on Remedial Actions for Contaminated Ground Water at Superfund Sites," EPA/540/G-88/003, December 1988, pg. 4-9; U.S. EPA "Soil Screening Guidance: User's Guide," EPA/540/R-96/018, April 1996, pg. 8; and U.S. EPA "Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A)," EPA/540/1-89/02, December 1989, pp. 4-5 to 4-10 and 5-18 to 5-19. It should be noted that certain ARARs specifically address how to factor background into cleanup levels. For example, some radiation ARAR levels are established as increments above background concentrations. (See attached chart for a listing of radiation standards that are likely to be used as ARARs.) In these circumstances, rather then follow the general guidance cited above, background should be addressed in the manner

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Land Use and Institutional Controls:

The concentration levels for various media that correspond to the acceptable risk level established for cleanup will depend in part on land use at the site. Land uses that will be available following completion of a response action are determined as part of the remedy selection process considering the reasonably anticipated land use or uses along with other factors.[13] Institutional controls (ICs) generally should be included as a component of cleanup alternatives that would require restricted land use in order to ensure the response will be protective over time. The institutional controls should prevent an unanticipated change in land use that could result in unacceptable exposures to residual contamination, or at a minimum, alert future users to the residual risks and monitor for any changes in use.

Future Changes in Land Use:

Where waste is left on-site at levels that would require limited use and restricted exposure to ensure protectiveness, EPA will conduct reviews at least once every five years to monitor the site for any changes including changes in land use. Such reviews should analyze the implementation and effectiveness of any ICs with the same degree of care as other parts of the remedy. Should land use change in spite of land use restrictions, it will be necessary to evaluate the implications of that change for the selected remedy, and whether the remedy remains protective (e.g., a greater volume of soil may need to be removed or managed to achieve an acceptable level of risk for a less restrictive land use).

Ground Water Levels:

Consistent with CERCLA and the NCP, response actions for contaminated ground water at radiation sites must attain (or waive as appropriate) the Maximum Contaminant Levels (MCLs) or non-zero Maximum Contaminant Level Goals (MCLGs) established under the Safe Drinking Water Act, where the MCLs or MCLGs are relevant and appropriate for the site. This will typically be the case where ground waters are a current or potential source of drinking water.[14] The ARARs should generally be attained throughout the plume (i.e., in the aquifer).

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prescribed by the ARAR ARARs, such as 40 CFR 192, are available to establish cleanup levels for those naturally occurring radionuclides that pose the most risk (such as radium-226 or Thorium in soil, and indoor radon) when those radionuclides are site related contaminants.

[13]In developing Land use assumptions, decision makers should consult the guidance provided in the memorandum from Elliott Laws A.A., OSWER entitled: "Land Use in the CERCLA Remedy Selection Process" (OSWER Directive No. 9355.7-04), May 25, 1995.

[14]In making decisions on ground water protection, decision makers should consult the guidance provided in "Presumptive Response Strategy and Ex-Situ Treatment Technologies for Contaminated Ground Water at CERCLA Sites" (OSWER Directive No. 9355.7-04) October 1996.

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Modeling Assessment of Future Exposures:

Risk levels, ground water cleanup, and dose limits should be predicted using appropriate models to examine the estimated future threats posed by residual radioactive material following the completion of the response action.[15] The modeling assessment should: (1) assume that the current physical characteristics (e.g., important surface features, soils, geology, hydrogeology, meteorology, and ecology) will continue to exist at the site; (2) take into account for each particular radionuclide that is a site-related contaminant, the following factors:

- radioactive decay and the ingrowth of radioactive decay products when assessing risk levels;
- the year of peak concentration in the ground water when assessing protection (e.g., remediating previous contamination and preventing future contamination) of ground water, and;
- the year of peak dose when assessing dose limits; and,

(3) model the expected movement of radioactive material at the site both within media (i.e., soil, ground water, surface water, sediment, structures, air, biota) and to other media.

FURTHER INFORMATION

The subject matter specialists for this directive are Jeffrey Phillips of OERR and John Karhnak of ORIA. General questions about this directive, should be directed to 1-800-424-9346.

Attachments

Addressees

National Superfund Policy Managers
Superfund Branch Chiefs (Regions I-X)
Superfund Branch Chiefs, Office of Regional Counsel (Regions I-X)
Radiation Program Managers (Regions I, IV, V, VI, VII, X)
Radiation Branch Chief (Region II)
Residential Domain Section Chief (Region III)
Radiation and Indoor Air Program Branch Chief (Region VIII)
Radiation and Indoor Office Director (Region IX)
Federal Facilities Leadership Council
OERR Center Directors

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[15]For further information regarding the basis for this recommendation, see U.S. EPA, "Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) Interim Final," EPA//540/1-89/002, December 1989, pp. 10-22 and 10-24.

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OSWER Directive 9200.4-18
Attachment A

Likely Federal Radiation Applicable or Relevant and Appropriate Requirements (ARARs)

The attached draft table of Federal standards is a listing of Federal radiation regulations that may be "Applicable or Relevant and Appropriate Requirements" (ARARs) for Superfund response actions. This list is not a comprehensive list of Federal radiation standards. It must also be cautioned that the selection of ARARs is site-specific and those site-specific determinations may differ from the attached analysis for some of the following ARARs.

Likely Federal Radiation (AEA, UMTRCA, CAA, CWA, SDWA) ARARs			
Standard	**Citation**	**When is standard Applicable (Conduct/Operation or Level of Cleanup[1])**	**When is standard potentially a Relevant and Appropriate Requirement**
Maximum contaminant levels (MCLs). Drinking water regulations designed to protect human health from the potential adverse effects of drinking water contaminants.	40 CFR 141	*Rarely:* At the tap where water will be provided directly to 25 or more people or will be supplied to 15 or more service connections.	Where ground or surface water is considered a potential or current source of drinking water
Concentration limits for liquid effluents from facilities that extract and process uranium, radium, and vanadium ores.	40 CFR 440 Subpart C	*Very Unlikely:* Applies to surface water discharges from certain kinds of mines and mills	Discharges to surface waters of some kinds of radioactive waste.

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Likely Federal Radiation (AEA, UMTRCA, CAA, CWA, SDWA) ARARs			
Standard	**Citation**	**When is standard Applicable (Conduct/Operation or Level of Cleanup[1])**	**When is standard potentially a Relevant and Appropriate Requirement**
Federal Water Quality Criteria (FWQC) and State Water Quality Standards (WQS). Criteria/standards for protection of aquatic life and/or human health depending upon the designated water use.	Water Quality Criteria; Report of the National Technical Advisory Committee to the Secretary of the Interior; April 1, 1968.	Discharge from a CERCLA site to surface water. (C/O)	Restoration of contaminated surface water. (LC)
Concentration limits for cleanup of radium-226, radium-228, and thorium in soil at inactive uranium processing sites designated for remedial action.[2]	40 CFR 192.12(a), 192.32(b)(2), and 192.41	*Never*: Standards are applicable only to UMTRCA sites that are exempt from CERCLA	Sites with soil contaminated with radium-226, radium-228, and/or thorium

[2]For further information, see OSWER directive entitled "Use of Soil Cleanup Criteria in Subpart B of 40 CFR Part 192 as Remediation Goals for CERCLA sites."

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Likely Federal Radiation (AEA, UMTRCA, CAA, CWA, SDWA) ARARs			
Standard	**Citation**	**When is standard Applicable (Conduct/Operation or Level of Cleanup[1])**	**When is standard potentially a Relevant and Appropriate Requirement**
Combined exposure limits for cleanup of radon decay products in buildings at inactive uranium processing sites designated for remedial action	40 CFR 192.12(b)(1) and 192.41(b)	*Never*: Standards are applicable only to UMTRCA sites that are exempt from CERCLA	Sites with radioactive contamination that is currently, or may potentially, result in radon that is caused by site related contamination migrating from the soil into buildings
Concentration limits for cleanup of gamma radiation in buildings at inactive uranium processing sites designated for remedial action	40 CFR 192.12(b)(2)	*Never*: Standards are applicable only to UMTRCA sites that are exempt from CERCLA	Sites with radioactive contamination that is currently, or may potentially, emit gamma radiation
Design requirements for remedial actions that involve disposal for controlling combined releases of radon-220 and radon-222 to the atmosphere at inactive uranium processing sites designated for remedial action	40 CFR 192.02	*Never*: Standards are applicable only to UMTRCA sites that are exempt from CERCLA	Sites with radon-220 or radon-222 as contaminants which will be disposed of on-site.

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Likely Federal Radiation (AEA, UMTRCA, CAA, CWA, SDWA) ARARs			
Standard	**Citation**	**When is standard Applicable (Conduct/Operation or Level of Cleanup[1])**	**When is standard potentially a Relevant and Appropriate Requirement**
Performance objectives for the land disposal of low level radioactive waste (LLW).	10 CFR 61.41	*Unlikely:* Existing licensed LLW disposal sites at the time of license renewal. (LC) *Unlikely that this would occur.*	Previously closed sites containing LLW if the waste will be permanently left on site.
National Emission Standards for Hazardous Air Pollutants (NESHAPs) under the Clean Air Act, that apply to radionuclides.	40 CFR 61 Subparts H and I	Airborne emissions during the cleanup of Federal Facilities and licensed NRC facilities. (CO)	Cleanup of other sites with radioactive contamination.
Radiological criteria for license termination.	10 CFR 20 Subpart E	Existing licensed sites at the time of license termination. (LC)	Previously closed sites.

1.Conduct/operation (C/O) refers to those standards which are typically ARARs for the conduct or operation of the remedial action. Level of Cleanup (L/C) refers to those standards which are typically ARARs for determining the final level of cleanup.

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OSWER Directive 9200.4-18
Attachment B

Analysis of what Radiation Dose Limit is Protective of Human Health at CERCLA Sites (Including Review of Dose Limits in NRC Decommissioning Rule)

Introduction

The Nuclear Regulatory Commission ("NRC") has finalized a rule titled "Radiological Criteria for License Termination" (see 62 FR 39058, July 21, 1997). EPA has determined that the dose limits established in this rule generally will not provide a protective basis for establishing preliminary remediation goals ("PRGs")under the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA").[1] The NRC rule sets an allowable cleanup level of 25 millirem per year effective dose equivalent (EDE) (equivalent to approximately 5 x 10^{-4} lifetime cancer risk) as the primary standard with exemptions allowing cleanup levels of up to 100 millirem per year (mrem/yr) EDE (equivalent to approximately 2 x 10^{-3} lifetime risk).[2] While the NRC standards must be met (or waived) at sites where it is applicable or relevant and appropriate, cleanups at these sites will typically have to be more protective than required by the NRC rule dose limits in order to meet the requirement to be protective established in CERCLA and the 1990 revisions to the National Oil and Hazardous Substances Pollution Contingency Plan ("NCP").[3]

Protectiveness for carcinogens under CERCLA is generally determined with reference to a cancer risk range of 10^{-4} to 10^{-6} deemed acceptable by EPA. Consistent with this risk range, EPA has considered cancer risk from radiation in a number of different contexts, and has consistently concluded that levels of 15 mrem/yr EDE (which

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[1] See letter, Carol Browner, Administrator, EPA, to Shirley Jackson, Chairman, Nuclear Regulatory Commission, February 7, 1997.

[2] Throughout this analysis risk estimates for dose levels were derived using a risk assessment methodology consistent with CERCLA guidance for assessing risks.

[3] Similarly, guidance that provides for radiation cleanups outside the risk range is generally not protective and should not be used to establish preliminary remediation goals .

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equate to approximately a 3 x 10^{-4} cancer risk) or less are protective and achievable.[4] EPA has explicitly rejected levels above 15 mrem/yr EDE as being not sufficiently protective.

The dose levels established in the NRC Decommissioning rule, however, are not based on this risk range or on an analysis of other achievable protective cleanup levels used for radiation and other carcinogenic standards. Rather, they are based on a different framework for risk management recommended by the International Commission on Radiation Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP). NRC's application of this framework starts with the premise that exposure to radiation from all man-made sources, excluding medical and natural background exposures, of up to 100 mrem/yr., which equates to a cancer risk of 2 x 10^{-3}, is acceptable. Based on that premise, it concludes that exposure from decommissioned facilities of 25 mrem/yr, which equates to a cancer risk of approximately 5 x 10^{-4}, is acceptable, and allows the granting of exceptions in certain instances permitting exposure up to the full dosage of 100 mrem/yr from these facilities. EPA has carefully reviewed the basis for the NRC dose levels and does not believe they are generally protective within the framework of CERCLA and the NCP. Simply put, NRC has provided, and EPA is aware of, no technical, policy, or legal rationale for treating radiation risks differently from other risks addressed under CERCLA and for allowing radiation risks so far beyond the bounds of the CERCLA risk range.

1. Rationale for 15 mrem/yr as Minimally Acceptable Dose Limit

To determine an acceptable residual level of risk from residual radioactive materials following a response action that would be protective of human health, EPA examined the precedents established by EPA for acceptable exposures to radiation in regulations and site-specific cleanup decisions in light of the CERCLA risk range for carcinogens. EPA's conclusion is that to be considered protective under CERCLA, remedial actions should generally attain dose levels of no more than 15 mrem/yr EDE for those sites at which a dose assessment is conducted. This dose level corresponds to an excess lifetime cancer risk of approximately 3 x 10^{-4}.

1.1 The CERCLA risk range

Under CERCLA, all remedies are required to attain cleanup levels that "at a minimum. . . assure protection of human health and the environment." CERCLA

[4]It should be noted that 15 mrem/yr is a dose level, not a media remediation level. Accordingly, this level could be achieved at CERCLA sites through appropriate site-specific combinations of active remediation and land-use restrictions to ensure no unacceptable exposures.

§121(d)(1). The NCP provides that, for carcinogens, preliminary remediation goals should generally be set at levels that represent an upper-bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6}. 40 CFR § 300.430(e)(2)(I)(A)(1). This regulatory level was set based on EPA's conclusion that the CERCLA protectiveness mandate is complied with "when the amount of exposure is reduced so that the risk posed by contaminants is very small, i.e., at an acceptable level. EPA's risk range of 10^{-4} to 10^{-6} represents EPA's opinion on what are generally acceptable levels." 55 Fed. Reg. at 8716 (March 8, 1990). EPA's adoption of this risk range was sustained in judicial review of the NCP. State of Ohio v. EPA, 997 F.2d 1520, 1533 (D.C. Cir. 1993).

Under appropriate circumstances, risks of greater than 1×10^{-4} may be acceptable. CERCLA guidance states that "the upper boundary of the risk range is not a discrete line at 1×10^{-4}, although EPA generally uses 1×10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable if justified based on site-specific conditions."[5] Other EPA regulatory programs have developed a similar approach to determining acceptable levels of cancer risk. For example, in a Clean Air Act rulemaking establishing NESHAPs for NRC licensees, Department of Energy facilities, and many other kinds of sites, EPA concluded that a risk level of "3×10^{-4} is essentially equivalent to the presumptively safe level of 1×10^{-4}." 54 Fed. Reg. at 51677 and 51682 (December 15, 1989). EPA explicitly rejected a risk level of 5.7×10^{-4} as not being equivalent to the presumptively safe level of 1×10^{-4} (in the case of elemental phosphorus plants) in this rulemaking. 54 Fed. Reg. at 51670.

1.2 Prior rulemaking decisions

EPA has examined the protectiveness of various radiation levels on a number of occasions. In each case, EPA's determination of what constitutes an adequate level of protection was reached in a manner consistent with EPA's regulation of other carcinogens. The conclusions from these efforts support the determination that 15 mrem/yr EDE should generally be the maximum dose level allowed at CERCLA sites. For example, EPA's Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes ("High-Level Waste Rule," 40 CFR Part 191) sets a dose limit of 15 mrem/yr EDE for all pathways.

In addition, EPA set an effective dose equivalent of 10 mrem/yr EDE (excluding radon-222) for air emissions of radionuclides from federal facilities, NRC licensees, and uranium fuel cycle facilities under the National Emissions Standards for Hazardous Air

[5] "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" from EPA Assistant Administrator Don R. Clay, April 22, 1991.

Pollutants (NESHAP, 40 CFR Part 61). This lower limit included all air pathways, but excluded releases to surface and ground waters.

Not all EPA rules apply the current dose methodology of effective dose equivalent (EDE). A dose limit of 15 mrem/yr EDE is also consistent with the dose levels allowed under older multi-media standards that were based on the critical organ approach to dose limitation. Critical organ standards developed by EPA and NRC consist of a combination of whole body and critical organ dose limits. Three of these critical organ standards (EPA's uranium fuel cycle rule, 40 CFR 190.10(a), developed for NRC licensees; NRC's low level waste rule, 10 CFR 61.41; and EPA's management and storage of high level waste by NRC and agreement states rule, 40 CFR 191.03(a)), referred to here as '25/75/25 mrem/yr' dose limits, are expressed as 25 mrem/yr to the whole body, 75 mrem/yr to the thyroid, and 25 mrem/yr to any critical organ other than the thyroid. One standard (EPA's management and storage of high level waste by DOE rule, 40 CFR 191.03(b)), referred to here as a "25/75 mrem/yr" dose limit, is expressed as 25 mrem/yr to the whole body and 75 mrem/yr to any critical organ (including the thyroid). To compare the dose level allowed under standards expressed in terms of EDE with the dose levels allowed under the critical organ approach to dose limitation, EPA has analyzed the estimated effective dose equivalent levels that would result if sites were cleaned up to the numerical dose limits used in these standards.[6] The analysis indicates that if sites were cleaned up under a 25/75/25 mrem/yr dose limit, the residual contamination would correspond to approximately 10 mrem/yr EDE. For sites cleaned up under a 25/75 mrem/yr dose limit, the residual contamination would correspond to approximately 15 mrem/yr EDE. These findings are similar to those mentioned in the preamble to the high-level waste rule (40 CFR Part 191; December 20, 1993; 58 FR 66402). In that rulemaking, EPA noted that the dose limit of 25 mrem/yr to the whole body or 75 mrem/yr to any critical organ, which was used in a previous high-level waste rule (September 19, 1985; 50 FR 38066) corresponds to the same level of risk as that associated with a 15 mrem/yr EDE. A cleanup level of 15 mrem/yr EDE is thus generally consistent with all of these other standards, although there are minor differences.

Finally, standards for the cleanup of certain radioactively contaminated sites have been issued under the Uranium Mill Tailings Radiation Control Act (UMTRCA), P.L. 95-604. Those standards are codified at 40 CFR Part 192. Among other provisions, the UMTRCA standards limit the concentration of radium-226, radium-228, thorium-230 and thorium-232, within 15 centimeters (cm) of the surface to no more than 5 picoCuries per gram (pCi/g) over background. They also limit the concentration of these radionuclides below the surface to no more than 15 pCi/g over background. Since these standards were

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[6] "Comparison of Critical Organ and EDE Radiation Dose Rate Limits for Situations Involving Contaminated Land" Office of Radiation and Indoor Air; April 1997.

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developed for the specific conditions found at the mill sites to which they apply (for example, all mill sites are required by law to remain in federal control), correlating these concentrations to dose requires a site-specific determination considering both the distribution and nature of contaminants at the site and the selected land use. Therefore, those standards are less relevant for determining if 15 mrem/yr EDE is consistent. However, analysis indicates that the cleanup of UMTRCA sites is consistent with the minimally acceptable dose limit of 15 mrem/yr EDE under a residential exposure scenario for radium-226, radium-228, and thorium-232, and is much more stringent for thorium-230.[7] For land uses other than residential (e.g., commercial/industrial, recreational) the UMTRCA cleanup standards are more stringent for all four radionuclides.[8]

1.3 Site-Specific Decisions

EPA has examined the cleanup decisions made under Superfund to address sites contaminated with radioactive wastes. Many of these cleanup actions used the UMTRCA cleanup standard (40 CFR Part 192) as an ARAR. Some of the sites used State regulations as ARARs. For a number of major DOE cleanup actions such as those at the Hanford reservation and Rocky Flats, a 15 mrem/yr EDE cleanup level has been decided upon or proposed. In other cases of CERCLA radiation cleanup actions that are not based on ARARs, cleanup levels between 1×10^{-5} and 1×10^{-6} have been selected (Bomark, NJ; Fernald, OH; Charleston Naval Shipyard, SC; and Mare Island Naval Shipyard, CA). Overall EPA finds that a 15 mrem/yr EDE level (with a risk of 3×10^{-4}) is at the upper end of remediation levels that have generally been selected at radioactively contaminated CERCLA sites.

2.0 Dose Limits in NRC's Rule are not Protective

EPA reviewed the dose limits that are contained in NRC's Radiological Criteria for License Termination (see 62 FR 39058, July 21, 1997). The NRC rule allows a cleanup level of 25 mrem/yr EDE (equivalent to approximately 5×10^{-4} lifetime risk) with exemptions allowing cleanup levels of up to 100 mrem/yr EDE (equivalent to approximately 2×10^{-3} lifetime risk). These limits are beyond the upper bound of the risk

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[7] *Reassessment of Radium and Thorium Soil Concentrations and Annual Dose Rates*. Office of Radiation and Indoor Air, July 22, 1996.

[8] A level of 15 mrem/yr is also supported by EPA's draft Federal Radiation Protection Guidance for Exposure of the General Public (59 FR 66414, December 23, 1994). The draft guidance recommends that the maximum dose to individuals from specific sources or categories of sources be established as small fractions of a 100 mrem/yr upper bound on doses from all current and potential future sources combined, and cites the regulations that are discussed in Section 1.2 of this paper as appropriate implementation of this recommendation. All of the regulatory examples cited support the selection of cleanup levels at 15 mrem/yr or less. However, because this guidance is in draft form and is subject to continued review within EPA prior to finalization, it should not be used as a basis for establishing acceptable cleanup levels.

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range generally considered protective under CERCLA. In addition, they present risks that are higher than levels EPA has found to be protective for carcinogens in general and for radiation, in particular, in other contexts. EPA has no technical or policy basis to conclude that these levels are protective under CERCLA.

The risk levels corresponding to the 25 to 100 mrem/yr EDE range allowed by the NRC rule (5×10^{-4} to 2×10^{-3}) are unacceptably high relative to 1×10^{-4}, which is the risk level generally used as the upper boundary of the CERCLA risk range for making risk management decisions at CERCLA sites. This determination is consistent with EPA's explicit rejection of a risk level of 5.7×10^{-4} for elemental phosphorus plants in the preamble for a NESHAP rulemaking (54 FR 51670). In the same preamble, EPA stated that a risk level of "3×10^{-4} is essentially equivalent to the presumptively safe level of 1×10^{-4}" (54 FR 51677). It was during this same NESHAP rulemaking that NCRP first recommended to EPA its regulatory scheme (a dose limit of 25 mrem/yr EDE for a single source that if met would not require analyzing other sources, otherwise a dose limit of 100 mrem/yr EDE from all sources combined) that NRC cites as a source for the regulatory approach taken in its decommissioning rule.[9] EPA rejected NCRP's recommended regulatory scheme, and promulgated dose limits of no more than 10 mrem/yr EDE in its NESHAP rulemaking for radionuclides, while concluding that "individual dose levels greater than 10 mrem/y ede are inconsistent with the requirements of section 112" of the Clean Air Act. 54 Fed. Reg. at 51686.

The documentation and analysis supporting the NRC rule dose levels provide no basis for such a significant departure from the CERCLA risk range. Indeed, as discussed above, EPA's past analyses and experience have demonstrated that exposures of 15 mrem/yr EDE or less are attainable and that such a departure is unwarranted. A dose limit of 25 mrem/yr EDE represents almost a doubling of the allowable risk from previous radiation rulemakings; the risk represented by a dose limit of 100 mrem/yr EDE is seven times as high as previously allowed. As note in Section 1.2, a dose limit of 25 mrem/yr effective dose equivalent is inconsistent with the dose levels allowed under older standards using a previous dose methodology (multi-media standards that were based on the critical organ approach to dose limitation). If these older dose standards were to be applied to the cleanup of contaminated sites, the average dose level would correspond to approximately 10 or 15 mrem/yr EDE on average.[10] Also, analysis indicates that the cleanup of UMTRCA sites using the 5 pCi/g and 15 pCi/g soil standards under 40 CFR 192 is consistent with an upper bound of 15 mrem/yr EDE under a rural residential exposure

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[9] "Control of Air Emissions of Radionuclides" NCRP Position Statement No. 6. The report cited by NRC, NCRP No. 116, merely references this previous NCRP position statement.

[10] "Comparison of Critical Organ and EDE Radiation Dose Rate Limits for Situations Involving Contaminated Land" Office of Radiation and Indoor Air; April 1997.

scenario for radium-226, radium-228, and thorium-232, and is much more stringent for thorium-230.[11] For land uses other than residential (e.g., commercial/industrial, recreational) the UMTRCA cleanup standards are more stringent for all four radionuclides.

[11] *Reassessment of Radium and Thorium Soil Concentrations and Annual Dose Rates*. Office of Radiation and Indoor Air, July 22, 1996.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Signed by Timothy Fields on August 22, 1997

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER No. 9200.4-23

MEMORANDUM

SUBJECT: Clarification of the Role of Applicable, or Relevant and Appropriate Requirements in Establishing Preliminary Remediation Goals under CERCLA

FROM: Timothy J. Fields, Jr., Acting *s/Timothy Fields, Jr.*
Assistant Administrator

TO: Addressees

PURPOSE

This memorandum clarifies the relationship between the two key remedy selection mandates of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA): 1) the requirement to protect human health and the environment; and 2) the requirement to attain, or waive if justified based on site-specific circumstances, applicable or relevant and appropriate requirements (ARARs). Specifically, this memorandum clarifies that, in rare instances, the Agency may establish preliminary remediation goals (PRGs) at levels more protective than required by ARARs, even at sites that do not involve multiple contaminants or pathways of exposure.

This document provides guidance to Regional staff, in dealing with the public and the regulated community, regarding how EPA intends to implement the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). It describes national policy. This document is not a substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances.

BACKGROUND

In administering the CERCLA program since the promulgation of the 1990 revisions to the NCP, questions have periodically arisen over the relationship between the statutory mandates to: 1) protect human health and the environment; and, 2) attain, or waive if justified based on site-specific circumstances, ARARs. Specifically, questions have arisen over the circumstances under which it is appropriate to establish PRGs that are more protective than ARARs. It has been EPA's policy that "compliance with a chemical-specific ARAR generally will be considered protective even if it is outside the [cancer] risk range (unless there are extenuating circumstances such as exposures to multiple contaminants or pathways of exposure)."[1]

FURTHER EXPLANATION OF POLICY

It remains EPA's policy that ARARs will generally be considered protective absent multiple contaminants or pathways of exposure. However, this Directive clarifies that, in rare situations, EPA Regional offices should establish PRGs at levels more protective than required by a given ARAR, even absent multiple pathways or contaminants, where application of the ARAR would not be protective of human health or the environment. This judgment should be made based on a review of the level of risk associated with application of the ARAR; the soundness of the technical basis for the ARAR; and other factors relating to the ARAR or to its application at an individual site.

This balanced approach most fully implements the requirements of the NCP and the CERCLA. On one hand, it was clearly EPA's intention in promulgating the NCP that PRGs would generally be based on ARARs in the absence of multiple contaminants or pathways. (See 40 CFR 300.430(e)(2)(I)(D); 55 Fed. Reg. at 8712.) This approach is sound; the protectiveness of health-based regulatory levels should not routinely be re-evaluated in individual CERCLA remedy selection decisions.

On the other hand, ARARs cannot be an absolute upper bound on cleanup levels in every case in the absence of multiple pathways or contaminants. CERCLA and the NCP establish separate requirements to be protective and meet ARARs. (CERCLA § 121(d)(1), (2); 40 CFR § 300.430(f)(1)(I)(A).) Indeed, protecting human health and the environment is the paramount objective of the Superfund program. (See 55 Fed. Reg.

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[1]OSWER Directive 9355.0-30, "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (April 22, 1991). This policy is consistent with the NCP. (See 40 CFR 300.430(e)(2)(I)(D) (authorizing consideration of the cancer risk range where attainment of ARARs will result in cumulative cancer risk of greater than 10^{-4} due to multiple pathways or contaminants). See also 1990 NCP Preamble, 55 Fed. Reg. at 8712 ("[w]hen health-based ARARs are not available or are not sufficiently protective due to multiple exposures or multiple contaminants, EPA sets remediation goals" based on site-specific risk-based factors, such as the cancer risk range).)

8700 (the NCP remedy selection process "is founded on CERCLA's overarching mandate to protect human health and the environment").) Furthermore, CERCLA requires that remedial actions attain ARARs "at a minimum," clearly contemplating that remedial actions may be more protective than required by ARARs when circumstances so require. (CERCLA § 121(d)(2)(A).)

EPA's policy of generally establishing PRGs based on ARARs, in the absence of multiple pathways or contaminants, is based on the assumption that individual ARARs will be protective. For example, the NCP expressly authorizes consideration of the cancer risk range in setting PRGs where attainment of ARARs would result in a cumulative risk in excess of 10^{-4} due to multiple contaminants or pathways. (40 CFR 300.430(e)(2)(I)(D).) The assumption underlying this provision is plainly that individual ARARs would achieve a risk of 10^{-4} or less. Similarly, the NCP preamble explains that EPA will modify PRGs to be protective where cumulative risks "make ARARs nonprotective" (55 Fed. Reg. at 8713); again, the assumption is that individual ARARs would be protective absent these cumulative risks. In cases where, based on available information, this assumption is not accurate, PRGs should be set at levels more protective than required by the ARAR in order to ensure protection of human health and the environment.

IMPLEMENTATION

In the rare circumstances where, based on available information, application of an ARAR would not be protective of human health or the environment, EPA should establish PRGs at levels that are more protective than required by the ARAR even absent multiple pathways or contaminants. As noted above, in deciding whether a PRG should be established at a level more protective than required by an ARAR, consideration should be given to the level of risk associated with application of the ARAR; the soundness of the technical basis for the ARAR; and other factors relating to the ARAR or to its application at an individual site.

Before making a site-specific determination that an ARAR at a given site is not protective of human health and the environment and should not be used as the basis for establishing PRGs, the site decision maker should consult with Headquarters, unless a prior determination has been made by Headquarters that a particular ARAR should not generally be used to establish PRGs at CERCLA sites.[2] The subject matter specialist for this guidance is Robin Anderson of OERR and Brian Grant of OGC. General questions about this guidance should be directed to 1-800-424-9346.

Addressees
National Superfund Policy Managers

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[2]For an example of a Headquarters determination that the numerical limits established by a particular ARAR should not generally be used as the basis to establish PRGs at CERCLA sites, see the memorandum from Stephen D. Luftig titled: "Establishment of cleanup levels for CERCLA sites with radioactive contamination" (OSWER Directive 9200.4-18), August 1997, p. 3.

Superfund Branch Chiefs (Regions I-X)
Superfund Branch Chiefs, Office of Regional Counsel (Regions I-X)
Radiation Program Managers (Regions I, IV, V, VI, VII, X)
Radiation Branch Chief (Region II)
Residential Domain Section Chief (Region III)
Radiation and Indoor Air Program Branch Chief (Region VIII)
Radiation and Indoor Office Director (Region IX)
Federal Facilities Leadership Council
OERR Center Directors