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

DEC 17 1999

MEMORANDUM

SUBJECT: Distribution of OSWER Radiation Risk Assessment Q & A's Final Guidance

FROM: Stephen D. Luftig, Director
Office of Emergency and Remedial Response (OERR)
Office of Solid Waste and Emergency Response

Stephen D. Page, Director
Office of Radiation and Indoor Air (ORIA)
Office of Air and Radiation

TO: Addressees

PURPOSE

The purpose of this memorandum is to transmit to you a final guidance document entitled: "Radiation Risk Assessment At CERCLA Sites: Q & A." The guidance provides answers to several common questions about radiation risk assessments at CERCLA sites. It should be especially useful to Remedial Project Managers (RPMs), On-Scene Coordinators (OSCs), and risk assessors.[1]

BACKGROUND

The U.S. Environmental Protection Agency (EPA) issued guidance entitled "Establishment of Cleanup Levels for CERCLA Levels for CERCLA Sites with Radioactive Contamination" (OSWER No. 9200.4-18, August 22, 1997). This 1997 guidance provided clarification for establishing protective cleanup levels for radioactive contamination at Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) sites. The 1997 guidance reiterated 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. Cleanup should generally achieve a cumulative risk within the 10^{-4} to 10^{-6} carcinogenic risk range based on the reasonable maximum exposure. The cleanup levels should consider exposures from all potential

[1]The attached document provides guidance on risk assessment issues involved at CERCLA sites and is consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). It does not alter the NCP expectations regarding treatment of principal threat waste and the use of containment and institutional controls for low level threat waste. Consistent with CERCLA and the NCP, response actions must attain or waive Applicable or relevant and appropriate requirements (ARARs). CERCLA 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.

9794

pathways, and through all relevant media (e.g., soil, ground water, surface water, sediment, air, structures, etc.) The 1997 guidance also provides a listing of radiation standards that are likely to be used as ARARs to establish cleanup levels or to conduct remedial actions.

Since issuance of the 1997 guidance, regional staff have requested additional guidance on specific Superfund process and requirements related to radiation cleanups. Today's guidance responds to these requests.

The attached final Risk Q & A fact sheet is part of a continuing effort between the Office of Emergency and Remedial Response (OERR) and the Office of Radiation and Indoor Air (ORIA) to provide updated guidance for addressing radioactively contaminated sites that is consistent with our guidance for addressing chemically contaminated sites, except to account for the technical differences between radionuclides and chemicals. This effort is intended to facilitate compliance with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) at radioactively contaminated sites while incorporating the improvements to the Superfund program that have been implemented through Administrative Reforms.

Two issues addressed in this Risk Q & A should be noted here. First, the answer to question 32 in the Risk Q & A is intended to further clarify that 15 millirem per year is not a presumptive cleanup level under CERCLA, but rather site decision-makers should continue to use the risk range when ARARs are not used to set cleanup levels. There has been some confusion among stakeholders regarding this point because of language in the 1997 guidance. EPA is issuing further guidance today to site decision makers on this topic. This Risk Q&A clarifies that, in general, dose assessments should only be conducted under CERCLA where necessary to demonstrate ARAR compliance. Further, dose recommendations (e.g., guidance such as DOE Orders and NRC Regulatory Guides) should generally not be used as to-be-considered material (TBCs). Although in other statutes EPA has used dose as a surrogate for risk, the selection of cleanup levels for carcinogens for a CERCLA remedy is based on the risk range when ARARs are not available or are not sufficiently protective. Thus, in general, site decision-makers should not use dose-based guidance rather than the CERCLA risk range in developing cleanup levels. This is because for several reasons, using dose-based guidance would result in unnecessary inconsistency regarding how radiological and non-radiological (chemical) contaminants are addressed at CERCLA sites. These reasons include: (1) estimates of risk from a given dose estimate may vary by an order of magnitude or more for a particular radionuclide, and; (2) dose based guidance generally begins an analysis for determining a site-specific cleanup level at a minimally acceptable risk level rather than the 10^{-6} point of departure set out in the NCP.

Second, it is important that data that support remedial decisions be of known and acceptable quality. There are a number of EPA guidances available that may aid the decision maker in gathering data of acceptable quality. One such guidance is the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM). The determination of what data are needed is a site-specific decision and it is the responsibility of the site decision-maker (e.g., RPM, OSC) to use the tools that are most appropriate for that situation.

IMPLEMENTATION

For questions regarding radiation site policy and guidance for CERCLA cleanup actions, readers are referred to the RCRA/Superfund Hotline at 1-800-424-9346. The subject matter specialists for this fact sheet are Stuart Walker of OERR and Dr. Kung-Wei Yeh of ORIA.

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

cc:

Jim Woolford, FFRRO
Elizabeth Cotsworth, OSW
Craig Hooks, FFEO
Barry Breen, OSRE
Joanna Gibson, HOSC/OERR
Earl Salo, OGC
Bob Cianciarulo, Region I

United States
Environmental Protection Agency

Office of
Emergency and
Remedial Response

Office of
Radiation and
Indoor Air

Directive 9200.4-31P
EPA 540/R/99/006
December 1999

Radiation Risk Assessment At CERCLA Sites: Q & A

NOTICE: The policies set out in this document are intended solely as guidance to U.S. Environmental Protection Agency (EPA) personnel; they are not final EPA actions and do not constitute rulemaking. These policies are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on analysis of specific-site circumstances. EPA also reserves the right to change the guidance at any time without public notice.

INTRODUCTION

Some sites on the U.S. Environmental Protection Agency's National Priorities List (NPL) are radioactively contaminated. To assist in the evaluation and cleanup of these sites and surrounding areas under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), EPA's Office of Emergency and Remedial Response (OERR) and the Office of Radiation and Indoor Air (ORIA) have developed guidance for conducting radiation risk assessments during the remedial investigation/feasibility study (RI/FS) process. This guidance is provided primarily in the multi-part document, *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual* (*RAGS*). Guidance specific to radiation risk includes:

- Chapter 10, "Radiation Risk Assessment Guidance," of *RAGS* Part A (U.S. EPA, 1989a) which covers data collection and evaluation, exposure and dose assessment, toxicity assessment, and risk characterization for sites contaminated with radioactive substances;

- Chapter4, "Risk-based PRGs for Radioactive Contaminants," of *RAGS* Part B (U.S. EPA, 1991a) which presents standardized exposure parameters and equations that should generally be used for calculating preliminary remediation goals (PRGs) for radionuclides under residential and commercial/industrial land use exposure scenarios [the equations for residential land use will be updated shortly with a new soil screening guidance for radionuclides (U.S. EPA, 1998d)];

- Appendix D, "Radiation Remediation Technologies," of *RAGS* Part C (U.S. EPA, 1991b) which provides guidance on using risk information to evaluate and select remediation technologies for sites with radioactive substances; and

- *RAGS* Part D, *Standardized Planning, Reporting, and Review of Superfund Risk Assessments* (U.S. EPA, 1998a), which provides guidance on standardized risk assessment planning, reporting, and review throughout the CERCLA process (Radionuclides Worksheet to be developed).

In addition to *RAGS*, EPA has published several other guidance documents and OSWER Directives concerning risk assessment methods for radioactive and nonradioactive contaminants. Attachment 1 presents a bibliography of selected Agency guidance documents on risk assessment. OSWER Directives specific to radioactive contaminants include:

- OSWER No. 9200.4-18, *Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination* (U.S. EPA 1997a), which provides guidance for establishing protective cleanup levels for radioactive contamination at CERCLA sites; and

- OSWER No. 9200.4-25, *Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA Sites* (U.S. EPA 1998c), which provides guidance regarding the circumstances under which the subsurface soil cleanup criteria in 40 CFR Part 192 should be considered an applicable or relevant and appropriate requirement (ARAR) for radium or thorium in developing a response action under CERCLA.

Overall, the process for assessing radionuclide exposures and radiation risks presented in *RAGS* and in supplemental guidance documents parallels the process for assessing risks from chemical exposures. Both types of assessments follow the same four-step evaluation process (exposure assessment, toxicity assessment, risk characterization, ecological assessments), consider similar exposure scenarios and pathways (except the external "direct exposure" pathway which is unique to radiation), determine exposure point concentrations, and provide estimates of cancer risks to humans.

However, several aspects of risk assessment for radioactive contaminants do differ substantially from those considered for chemical contaminants. Occasionally these differences—in measurement units, exposure terms and concepts, field and laboratory procedures and detection limits, and toxicity criteria, among others—have led to questions concerning the Agency's recommended approach for addressing radionuclide contamination and risk and the cleanup of CERCLA radiation sites.

PURPOSE

OERR and ORIA have prepared this document to provide answers to several commonly asked questions regarding risk assessments at radioactively contaminated CERCLA sites raised by Remedial Project Managers (RPMs), On-Scene Coordinators (OSCs), risk assessors, Federal, State and local agencies, potentially responsible parties (PRPs), and contractors. Its purpose is to provide an overview of current EPA guidance for risk assessment and related topics for radioactively contaminated CERCLA sites. Guidance issued by other organizations (e.g., NRC, DOE, ICRP, NCRP) may provide technical assistance, however the reader should exercise caution since some of these documents utilize a framework for risk management (e.g., allowable dose limits of 25, 100, or 500 mrem/yr) that EPA has determined is not suitable for use at CERCLA sites.

The questions and answers (Q & A) that follow are presented in sections corresponding to the four basic steps in the CERCLA risk assessment process:

1. Data Collection and Evaluation
2. Exposure Assessment
3. Toxicity Assessment
4. Risk Characterization

In addition, a bibliography of selected reference materials related to radiation risk assessment is provided in Attachment 1.

Readers are strongly encouraged to direct all questions concerning site-specific evaluations involving radioactive contaminants to the EPA Regional Radiation Program Office or Regional Superfund Office in the EPA Region in which their site is located. EPA has found that early involvement of the Regional Radiation Program and Superfund staff in all phases of site characterization and cleanup improves and expedites the entire process.

For general questions on, or assistance with, radiation surveys or radioanalytical procedures, readers are directed to EPA's National Air and Radiation Environmental Laboratory (NAREL) in Montgomery, AL, or Radiation and Indoor Environments National Laboratory (RIENL) in Las Vegas, NV. For questions regarding radiation site policy and guidance, readers are also referred to the RCRA/Superfund Hotline at 1-800-424-9346. The subject matter specialists for this fact sheet are Dr. Kung-Wei Yeh of ORIA and Stuart Walker of OERR.

I. DATA COLLECTION AND EVALUATION

Q1. What strategy and key information should be considered during the initial planning stage for radiological data collection?

A. The Data Quality Objectives (DQO) process is an important tool for project managers and planners to determine the types, quantity, and quality of data needed to support decisions. Detailed guidance on the DQO Process can be found in *Guidance for the Data Quality Objectives Process* (U.S. EPA, 1994a) and *Data Quality Objectives for Superfund* (U.S. EPA, 1993a). Additional guidance on the application of this process at radiation sites can be found in the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) (U.S. EPA et al. 1997). The DQO process outlined in these documents should be completed during the initial planning stage for data collection.

At a minimum, site characterization should include the following key information and considerations:

✔ Review of the site history and records collected during the preliminary assessment and site inspection (PA/SI), considering:

- past site operations
- types and quantities of radioactive material used or produced
- radioactive waste stream characteristics
- disposal practices and records
- previous radiological characterization data and/or environmental monitoring data
- physical site characteristics (hydrology, geology, meteorology, etc.)
- demography
- current and potential future land use

✔ Formulation of a conceptual site model to:

- identify radionuclides of concern
- identify the time period for assessment
- identify potentially contaminated environmental media
- identify likely release mechanisms and exposure pathways
- identify potential human and ecological receptors
- focus initial surveys and sampling and analysis plans

✔ Development of comprehensive sampling plans based on the conceptual site model and available historical information to

- confirm the identities of radionuclide contaminants
- confirm release mechanisms and exposure pathways
- measure or model exposure point concentrations and point exposure rate (as appropriate for the type of radioactive decay)
- confirm human and ecological receptors
- specify cleanup levels or develop preliminary remediation goals
- establish DQOs

The MARSSIM (U.S. EPA et al. 1997) provides guidance on planning, implementing, and evaluating radiological site surveys. This multi-agency consensus document was developed collaboratively by the four Federal Agencies having authority and control over radioactive materials: the Department of Defense (DoD), Department of Energy (DOE), EPA, and the Nuclear Regulatory

Commission (NRC). While the primary focus of MARSSIM is on final status surveys to demonstrate compliance with dose- or risk-based criteria, guidance is also provided for designing and conducting scoping and characterizing surveys, based on the DQO process.

Q2. How should a list of radionuclides of concern be constructed?

A. An initial list of radionuclides of potential concern should be based on a review of previous site operations that contributed to the current levels of contamination and the conceptual site model. As a first consideration, all radionuclides used or produced at the site should be included on the list. If appropriate, the list should also include all radioactive decay products that may have formed since disposal or termination of operations. Radionuclides with short half-lives and no parent radionuclide to support ingrowth may be considered for exclusion from the list. However, before a short-lived radionuclide is excluded from the list, careful consideration should be given to its initial and current activity inventories, its radioactive half-life, and the time elapsed since the contamination occurred to the present.

Site characterization efforts should be directed to confirming or refuting the presence of the radionuclides of concern in on-site sources and in environmental media contaminated by releases migrating off-site. The activity concentrations of radionuclides (and decay products, if appropriate) in each medium should then be compared with site-specific background concentrations of those radionuclides (i.e., radionuclide concentrations in environmental media not related to site operations or releases), PRGs, screening levels, or potential remediation criteria (see Q3). Caution should be exercised in making such comparisons, since radionuclide concentrations in environmental media may change over time due to radioactive decay and ingrowth; therefore, consideration should be given to the radioactive half-life of the radionuclides of concern and any decay products, and the time period over which risks will be evaluated.

Q3. What criteria should be used to determine areas of radioactive contamination or radioactivity releases?

A. Section 7 of EPA's revised Hazard Ranking System (HRS) (see Appendix A to 40 CFR Part 300) provides general criteria for comparing concentrations of radionuclides in sources and various environmental media against background levels for use in screening sites for inclusion on the NPL. Table 1 presents a summary of the HRS criteria for establishing observed radiological contamination or observed releases of radioactive materials; key considerations include the measurement of radionuclide concentrations significantly above site-specific background levels. General guidance is provided in the following Agency documents:

- *Methods for Evaluating the Attainment of Cleanup Standards—Volume 1: Soil and Soil Media* (U.S. EPA, 1989b)
- *Statistical Methods for Evaluating the Attainment of Cleanup Standards—Volume 2: Ground Water* (U.S. EPA, 1992a)
- *Statistical Methods for Evaluating the Attainment of Cleanup Standards—Volume 3: Reference-Based Standards for Soils and Solid Media* (U.S. EPA, 1992b)

Although these documents do not specifically address radionuclides, most of the evaluation methods and tests provided in these documents should be applicable to both radioactive and nonradioactive contaminants. More specific guidance for the measurement and evaluation of radiological contaminants is provided in the MARSSIM (U.S. EPA et al. 1997); MARSSIM also provides guidance on the determination of site-specific background levels for comparison to site measurements. Additional guidance regarding soil screening levels (SSLs) for radionuclides is currently under development (U.S. EPA 1998d). The SSLs are not cleanup standards, but may be used to identify areas that may require further investigation at NPL sites. The SSL equations should also be used to establish PRGs for residential land use where ARARs are not available or sufficiently protective. For additional guidance on this issue, readers should contact the appropriate EPA Regional Radiation Program Office or Regional Superfund Office, as appropriate, or ORIA-HQ.