

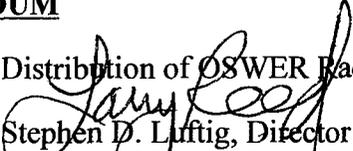


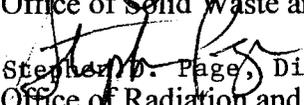
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 17 1999

MEMORANDUM

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

FROM: 
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Office of Emergency and Remedial Response (OERR)
Office of Solid Waste and Emergency Response


Stephen W. 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

¹The 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.

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
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- Craig Hooks, FFEO
- Barry Breen, OSRE
- Joanna Gibson, HOSC/OERR
- Earl Salo, OGC
- Bob Cianciarulo, Region I



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;
- Chapter 4, "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.

Table 1. EPA's Hazard Ranking System Criteria for Establishing Radionuclide Contamination/Releases*

Based on:	Criteria for Establishing Observed Contamination or Observed Releases of Radionuclides
Direct Observation	Applies to All Radionuclides
	<ul style="list-style-type: none"> (i) For each migration pathway, a material that contains one or more radionuclides has been seen entering the atmosphere, surface water, or ground water, as appropriate, or is known to have entered ground water or surface water through direct deposition, or (ii) For the surface water migration pathway, a source area containing radioactive substances has been flooded at a time that radioactive substances were present and one or more radioactive substances were in contact with the flood waters.
Analysis of Radionuclide Concentrations in Samples (ground water, soil, air, surface water, benthic, or sediment samples)	Applies to Naturally Occurring Radionuclides and Man-made Radionuclides With Ubiquitous Background Concentrations in the Environment
	<ul style="list-style-type: none"> (i) Measured concentrations (in units of activity, for example pCi per kilogram [pCi/kg], pCi per liter [pCi/L], pCi per cubic meter [pCi/m³]) of a given radionuclide in the sample are at a level that: <ul style="list-style-type: none"> (a) Equals or exceeds a value 2 standard deviations above the mean site-specific background concentration for that radionuclide in that type of sample, or (b) Exceeds the upper-limit value of the range of regional background concentration values for that specific radionuclide in that type of sample. (ii) Some portion of the increase must be attributed to the site to establish the observed release (or observed contamination). (iii) For the soil exposure pathway only, the radionuclide must also be present at the surface or covered by 2 feet or less of cover material (for example, soil) to establish observed contamination. **
	Applies to Man-made Radionuclides Without Ubiquitous Background Concentrations in the Environment:
<ul style="list-style-type: none"> (i) Measured concentrations (in units of activity) of a given radionuclide in the sample equals or exceeds the sample quantitation limit for that specific radionuclide in that type of media and is attributable to the site. <ul style="list-style-type: none"> (a) However, if the radionuclide concentration equals or exceeds its sample quantitation limit, but its release can also be attributed to one or more neighboring sites, then the measured concentration of that radionuclide must also equal or exceed a value either 2 standard deviations above the mean concentration of that radionuclide contributed by the neighboring sites or 3 times its background concentration, whichever is lower. (ii) If the sample quantitation limit cannot be established: <ul style="list-style-type: none"> (a) use the EPA contract-required quantitation limit (CRQL) in place of the sample quantitation limit in establishing an observed release (or observed contamination) if the sample analysis was performed under the EPA Contract Laboratory Program, or (b) use the detection limit in place of the sample quantitation limit if the sample analysis is not performed under the EPA Contract Laboratory Program. (iii) For the soil exposure pathway only, the radionuclide must also be present at the surface or covered by 2 feet or less of cover material (for example, soil) to establish observed contamination.** 	
Gamma Radiation Exposure Rate Measurements	Applies to Gamma-Emitting Radionuclides
	<ul style="list-style-type: none"> (i) The gamma radiation exposure rate in microroentgens per hour (μR/hr) using a survey instrument held 1 meter away from the ground surface (or 1 meter away from an aboveground source), equals or exceeds 2 times the site-specific background gamma radiation exposure rate. (ii) Some portion of the increase must be attributable to the site to establish observed contamination. (iii) The gamma-emitting radionuclides do not have to be within 2 feet of the surface of the source.

* Source: *Hazard Ranking System; Final Rule*, Environmental Protection Agency, 55 FR 51532, December 14, 1990.

** Note: This criterion should not be interpreted to mean that radionuclides present in soils at depths greater than 2 feet below the surface would not warrant investigation and potential response action, but only that such materials may not be readily detected by surface measurements.

Q4. How should the areal extent and depth of radioactivity contamination be determined?

- A. As noted in Q1, a conceptual site model should be developed to identify reasonable boundaries for investigating the nature and extent of contamination. General guidance for site characterization activities is provided in *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (U.S. EPA 1988a).

The choice of a specific method or methods to characterize sites contaminated with radioactive substances depends on several factors, including the decay characteristics of the radionuclides potentially present at the site, suspected contamination patterns, and activity concentrations. For gamma-emitting radionuclides in near-surface sources, walk-over radiation surveys are typically conducted to characterize the areal extent of contamination. For subsurface contamination, borehole logging for gamma emitters, core sampling programs for radionuclides that emit only alpha or beta particles, or a combination of both types of methods, may be advisable. In addition to measurements to determine volumetric contamination in environmental media, measurements of surface contamination on building and equipment surfaces may also be required. Additional discussion of measurement techniques and their limitations is provided in MARSSIM (U.S. EPA et al. 1997). For site-specific assessments, readers should consult the appropriate EPA Regional Radiation Program Office or Regional Superfund Office.

Q5. What field radiation survey instruments should be used and what are their lower limits of detection?

- A. Selection of appropriate radiation detection instruments for site characterization depends on the decay characteristics of the radionuclides potentially present at the site, suspected contamination patterns, and activity concentrations, among other factors. Numerous documents have been written on this topic. For a general discussion on radiation survey instruments, readers are directed to MARSSIM (U.S. EPA 402-R-96-018) and Chapter 10 of RAGs Part A (U.S. EPA, 1989a). For supplemental information regarding the usability of analytical data for performing a baseline risk assessment at sites contaminated with radioactivity, readers should refer to "Guidance for Data Usability in Risk Assessment, Part B" (U.S. EPA, 1992d). For site-specific applications of field radiation survey instruments, readers should contact their appropriate Regional Radiation Program Office or Regional Superfund Office.

Q6. What sample measurement units for radiation risk assessment are typically used?

- A. Concentrations of radionuclides in environmental media are typically expressed in terms of "activity" of the radionuclide per unit mass (for soil, sediment, and food-

stuffs) or volume (for water and air) of the environmental medium. Two different systems of units for radioactivity are currently in common usage: the International System (SI) units and the "conventional" or "traditional" units which were used before the advent of the SI system. The principal unit of radioactivity in the SI system is the becquerel (1 Bq = 1 disintegration/second), while the basic conventional unit of activity is the Curie (1 Ci = 3.7×10^{10} Bq). Since most radiation standards in the U.S. are expressed in conventional units, this system is used for the purpose of this document. Concentrations of radionuclides in environmental media at contaminated sites are typically far below Curie quantities, and are commonly expressed in units of picocuries (1 pCi = 10^{-12} Ci = 3.7×10^{-2} Bq). Typical conventional units for reporting environmental measurements are pCi/g for soil (dry-weight), pCi/L for groundwater or surface water, and pCi/m³ for air.

A special unit, the working level (WL), is used as a measure of the concentration of short-lived radon decay products in air. WL is any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of 1.3×10^5 million electron volts (MeV) of alpha energy. The Working Level Month (WLM) is the exposure to 1 WL for 170 hours (1 working month).

In addition to radionuclide concentrations in environmental media, the radiation "exposure" rate is often reported. Radiation exposure, in this context, refers to the transfer of energy from a gamma radiation field to a unit mass of air. The unit for radiation exposure is the roentgen (1 R = 2.58×10^{-4} coulombs of charge per kg of air). Exposure rates at contaminated sites are typically expressed in units of microroentgens/hour (μ R/hr).

Radionuclide concentrations on building or equipment surfaces are specified in units of the activity concentrations of the radionuclide of concern in a specified surface area, typically dpm (disintegration per minute) per 100 cm² or pCi per 100 cm².

Q7. What sample measurement units for remedial action evaluation may be used?

For remedial action evaluations it is often useful to express radionuclide concentrations in terms of mass (mass concentration). The carcinogenic effects of a radionuclide are due to its disintegration rate that occurs during its decay process, concentrations of radionuclides are generally measured in terms of activity for health evaluation purposes. Mass units, however, provide insight and information into treatment selection, treatment compatibility, and treatment efficiency, particularly for remedial actions involving mixed waste. The practice of using activity concentration should continue for response actions at CERCLA sites. Mass concentration estimates contained in proposed and final site decision documents [e.g., proposed plans, Record of Decisions (RODs)] may

include, in addition to activity measurements, estimates of concentrations in terms of mass consistent with those used for non-radiological contaminants. Typically units for expressing mass in environmental media for soil and water are mg/kg for soil and mg/l for water. These mass units also can be expressed as parts per million (ppm) for soil and water, which is equivalent to mg/kg and mg/l. To estimate the radionuclide concentrations in ppm, the following equations are given below:

$$\text{mg/kg}_{\text{soil}} = (2.8 \times 10^{-12}) \times A \times T_{1/2} \times \text{pCi/g}$$

$$\text{mg/l}_{\text{water}} = (2.8 \times 10^{-15}) \times A \times T_{1/2} \times \text{pCi/l}$$

$$\text{ppm}_{\text{soil}} = (2.8 \times 10^{-12}) \times A \times T_{1/2} \times \text{pCi/g}$$

$$\text{ppm}_{\text{water}} = (2.8 \times 10^{-15}) \times A \times T_{1/2} \times \text{pCi/l}$$

where A is the radionuclide atomic weight and $T_{1/2}$ is the radionuclide half-life in years. Most radionuclides have half-lives ranging from a few years to 10,000 years, which means that for most radionuclides, an activity of 1 pCi/g would mean the concentration value of the radionuclide would be well under 1×10^{-6} ppm.

Q8. Are radionuclides included in EPA's Contract Laboratory Program (CLP)? If not, where should comparable radioanalytical services be obtained?

A. Radionuclides are not standard analytes in EPA's CLP program. However, EPA has published guidance for radionuclide methods in Chapter 10 of *RAGS Part A* (U.S. EPA, 1989a). In addition, EPA's *Radiochemistry Procedures Manual* (U.S. EPA, 1984) provides information for radionuclide-specific analytical techniques. For additional guidance on selection of radiological laboratories and analytical methods, readers should contact the appropriate Regional Radiation Program Office or Regional Superfund Office, NAREL, or RIENL.

Q9. How can I decide if the data collected are complete and of good quality?

A. EPA's *Guidance for Data Quality Assessment* (U.S. EPA, 1995), *Guidance for Data Useability in Risk Assessment, Part A* (U.S. EPA, 1992c) and *Part B* (U.S. EPA, 1992d), provide procedures and statistical tests that may be used to determine whether or not collected data are of the correct type, quality, and quantity to support their intended use. In addition, the MARSSIM (U.S. EPA et al. 1997) addresses quality assurance and quality control requirements for radiological data.

II. EXPOSURE ASSESSMENT

Q10. How does the exposure assessment for radionuclides differ from that for chemicals?

A. Exposure assessment for radionuclides is very similar to that for chemicals. Both nonradioactive chemical assessments and radionuclide assessments follow the same basic steps—i.e., characterizing the exposure setting, identifying exposure pathways and potential receptors, estimating exposure point concentrations, and estimating exposures/intakes. In addition to the exposure pathways considered for chemicals (e.g., ingestion of contaminated water, soil, or foodstuffs, and inhalation of contaminated air), external exposure to penetrating radiation (i.e., gamma radiation and x-rays) may be an important exposure pathway for certain radionuclides in near-surface soils. On the other hand, with the primary exception of tritium (H-3) as tritiated water or water vapor, dermal absorption is typically not a significant exposure pathway for radionuclides and generally need not be considered. (Other possible exceptions could include organic compounds containing radionuclides.) Figure 1 depicts typical exposure pathways for radionuclides; additional pathways that may be considered on a site-specific basis, where appropriate, are discussed in Q11. Additional discussion of radiation exposure pathways is provided in the Radiation Exposure and Risk Assessment Manual (RERAM), June 1996 (EPA 402-R-96-016).

Q11. Can exposure pathways be added or deleted based on site-specific conditions?

A. Yes. Inclusion or deletion of exposure pathways should be based upon site-specific conditions, including local hydrology, geology, potential receptors, and current and potential future land use, among other factors. Accordingly, some exposure pathways may not be appropriate for a given site and may be deleted, if justification is provided. In other cases, exposure pathways that are typically not significant may be important for the site-specific conditions (e.g., ingestion of contaminated fish for recreational scenarios, ingestion of contaminated meat or milk from livestock for agricultural scenarios) and should be included in the assessment.

Q12. How should radioactive decay products be addressed?

A. All radionuclides, by definition, undergo radioactive decay. In this process, one unstable nucleus of an element transforms (decays) spontaneously to a nucleus of another element. As the unstable nucleus decays, energy is released as particulate or photon radiation, or both, and the radionuclide is transformed in atomic number and/or atomic mass. The resulting decay products, or progeny, may also be radioactive and undergo further decay. Various decay products may have different physical and chemical characteristics that affect their fate and transport in the environment as well as their radiotoxicity. In cases where decay products have greater radiotoxicity than the original radionuclide, the potential radiation dose and health risk may increase over time; in such cases, the exposure assessment should consider the change in concentrations of

all decay products over time, to determine the time of maximum potential impact.

Consideration of all potential radioactive decay products is a key element of the exposure assessment for radionuclides. Many of the computerized mathematical models available for simulating the behavior of radionuclides in the environment (see Q15) incorporate the ingrowth and decay of radioactive decay products as a function of time; these models are very useful in pinpointing the time of maximum dose or risk. Similarly, slope factors (see Q20) and dose conversion factors (see Q21) for some radionuclides may include consideration of radioactive decay products, where appropriate, to facilitate these considerations in estimating potential radiation dose and risk. However, such values typically assume that all decay products are present at the same concentration as the primary radionuclide (i.e., secular equilibrium), which may not be appropriate for all situations. Readers should consult their Regional Radiation Program Office or Regional Superfund Office for additional information regarding such limitations. See also section "Modeling Assessment of Future Exposures" in OSWER Directive 9200.4-18 (U.S. EPA 1997a) for information modeling decay products.

Q13. To what extent should generic and site-specific factors and parameter values be used in exposure assessments?

- A. For both radionuclide and chemical assessments, EPA recommends the use of empirically-derived, site-specific factors and parameter values, where such values can be justified and documented. For generic assessments, EPA recommends the use of the default parameter values provided in OSWER Directive 9285.6-03 *Standard Default Exposure Factors* (U.S. EPA, 1991c) and the *Exposure Factors Handbook* (U.S. EPA, 1990, 1997b).

Q14. How should exposure point concentrations be determined?

- A. As for chemical contaminants, exposure point concentrations of radionuclides in environmental media and radiation exposure rates (e.g., alpha, beta, gamma) should be either measured, modeled, or both. To the extent possible, measurement data should be used to evaluate current exposures. When measurements at the exposure locations cannot be made, or when predicting potential concentrations and exposures at future times, modeling is required (see Q15).

Q15. What calculation methods or multimedia radionuclide transport and exposure models are recommended by EPA for Superfund risk assessments?

- A. Currently, only the equations in RAGS Part B (U.S. EPA, 1991a) - which are used to develop risk-based preliminary remediation goals for hazardous chemicals and radio-

nuclides - are recommended by EPA for Superfund radiation risk assessments. (Note: The *Soil Screening Guidance for Radionuclides* (U.S. EPA 1998d) is expected to supersede the RAGS Part B algorithms when finalized.) Numerous computerized mathematical models have been developed by EPA and other organizations to predict the fate and transport of radionuclides in the environment; these include single-media models (e.g., ground water transport) as well as multi-media models. These models have been designed for a variety of goals, objectives and applications, but no single model may be appropriate for all site-specific conditions. While the Agency has approved individual models for specific applications (e.g., CAP88 or COMPLY for atmospheric transport calculations to demonstrate compliance with 40 CFR Part 61 requirements), no model has yet been formally endorsed for evaluating potential impacts from radionuclides in soil. For further information on selection of models appropriate to meet a specific-site characteristics and requirements, readers can refer to *Ground-Water Modeling Compendium* (U.S. EPA 1994c), and *A Technical Guide to Ground-Water Model Selection at Sites Contaminated with Radioactive Substances* (U.S. EPA 1994d). While these documents specifically address groundwater models, the model selection criteria and logic may be useful for other types of models as well.

Attachment 1 provides a bibliography of reference documents for numerous models currently available. Readers are strongly encouraged to consult with the appropriate EPA Regional Radiation Program Office or Regional Superfund Office in which the site is located for guidance on selection and use of radionuclide fate and transport models for site-specific applications.

Q16. How should Radon-222 (radon) and Radon-220 (thoron) exposures and risks be evaluated?

- A. Radon-222 (Rn-222) and Radon-220 (Rn-220) are radioactive gases that are isotopes of the element radon (Rn). Each is produced by the radioactive decay of an isotope of radium (Ra). For Rn-222 (also called radon), the parent radium isotope is Ra-226 and for Rn-220 (also called thoron), the parent radium isotope is Ra-224. (Although thoron is produced from the radioactive decay of Ra-224, it is often referred to as a decay product of Ra-228, which is a longer-lived precursor typically measured in environmental samples.) Each radon isotope gives rise to a series or chain of short-lived radioactive decay products that emit alpha particles which can damage lung tissues if inhaled. Of the two decay chains, the radon series is longer lived and more hazardous than the thoron series. Consequently, most (but not all) radon exposure and risk assessments deal with radon (Rn-222) arising from radium (Ra-226) contamination.

Structures built on radium-contaminated soil or constructed with radium-bearing materials can accumulate elevated concentrations of radon in indoor air. Some radiation protection standards which may be potential ARARs at a site, explicitly exclude dose or risk from radon and its decay products from consideration. Other potential ARARs and to-be-considered (TBC) information directly address radon and its decay products (e.g., allowable concentrations of radon decay products in indoor air under 40 CFR 192(b)(1) of a standard of 0.003 working level (WL) and a goal of 0.002 WL, as well as the U.S. EPA Guideline of 4 pCi radon-222 per liter of indoor air).

Several EPA-approved methods are available for measuring radon and progeny concentrations in indoor air (EPA et al, 1997). Computer codes have been developed to predict radon concentrations in indoor air and potential human exposure, based on simplified equations and assumptions; these models may yield results that are meaningful on average (e.g., for a geographical region) but highly imprecise for an individual house or structure. Despite their widespread use, these codes should be used with caution and their estimates interpreted carefully.

Readers are encouraged to consult with the EPA Regional Radiation Program Office or Regional Superfund Office for specific guidance and recommendations concerning measurement of radon concentrations in indoor air, evaluation of potential exposures, and applicable

mitigation measures. Also, some states have their own radon testing and mitigation requirement or recommendations. Readers should also determine if any of the standards for radon are potential ARARs at their site (see Q 34).

Q17. How long a time period should be considered for possible future exposures?

A. Section "Modeling Assessment of Future Exposures" in OSWER Directive 9200.4-18 (U.S. EPA 1997a) provides guidance for estimating future threats. Also, in some cases, Federal or State ARARs may include specific time-frame requirements for a given purpose, such as disposal of radioactive materials in an approved waste repository.

Q18. How should the results of the exposure assessment for radionuclides be presented?

A. Results of the exposure assessment for radionuclides should be presented in two stages: (1) intake and external exposure estimates for use in risk characterization; and (2) estimates of radiation dose (see Q22 for discussion of specific dosimetric quantities that may be appropriate) for comparison with dose-based standards. Note that intake estimates for radionuclides should not be divided by body weight or averaging time as is done for chemical contaminants. Intake estimates for inhalation or ingestion pathways should include the total activity of each

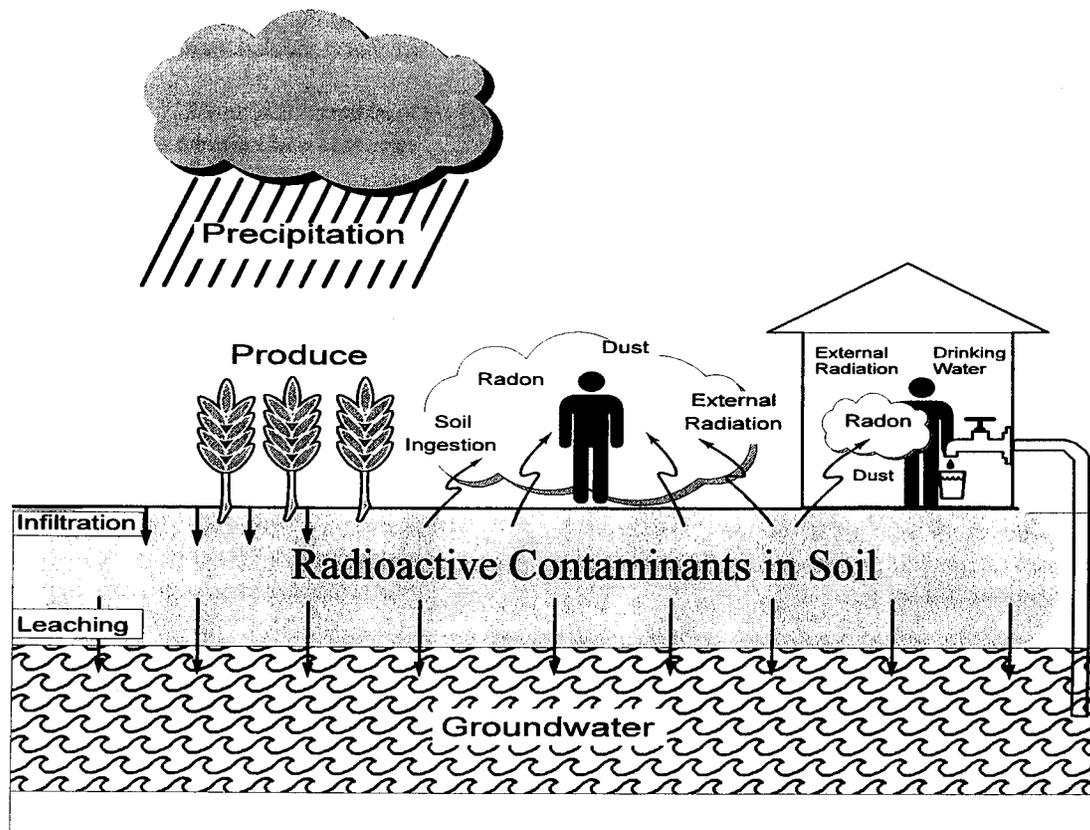


Figure 1. Typical Radionuclide Exposure Pathways

radionuclide inhaled or ingested via each pertinent route of exposure (e.g., ingestion of contaminated drinking water, direct ingestion of contaminated soil, ingestion of contaminated produce/milk/meat). Measured or predicted external exposure rates should be presented, along with the exposure time, frequency, and duration. In the absence of measured exposure rates, the concentration of each radionuclide in soil is needed to estimate the risk from the external pathway using slope factors. When present, estimates of radiation surface contamination also should be presented by radiation type (alpha, beta, gamma).

III. TOXICITY ASSESSMENT

Q19. What is the mechanism of radiation damage?

- A. Radiation emitted by radioactive substances can transfer sufficient localized energy to atoms to remove electrons from the electric field of their nucleus (ionization). In living tissue, this energy transfer can produce chemically reactive ions or free radicals, destroy cellular constituents, and damage DNA. Irreparable DNA damage is thought to be a major factor in carcinogenesis. [While ionizing radiation may also cause other detrimental health impacts, only radiogenic cancer risk is normally considered in CERCLA risk assessments (see Q24).]

The type of ionizing radiation emitted by a particular radionuclide depends upon the exact nature of the nuclear transformation, and may include emission of alpha particles, beta particles (electrons or positrons), and neutrons; each of these transformations may be accompanied by emission of photons (gamma radiation or x-rays). Each type of radiation differs in its physical characteristics and in its ability to inflict damage to biological tissue. For purposes of radiation risk estimates, the various types of radiation are often categorized as low linear energy transfer (LET) radiation (photons and electrons) and high-LET radiations (alpha particles and neutrons).

Ionizing radiation can cause deleterious effects on biological tissues only when the energy released during radioactive decay is absorbed in tissue. The average energy imparted by ionizing radiation per unit mass of tissue is called the "absorbed dose". The SI unit of absorbed dose is the joule per kilogram, also assigned the special name the Gray (1 Gy = 1 joule/kg); the conventional unit of absorbed dose is the rad (1 rad = 100 ergs/g = 0.01 Gy).

Q20. What are radionuclide slope factors?

- A. EPA has developed slope factors for estimating incremental cancer risks resulting from exposure to radionuclides via inhalation, ingestion, and external exposure pathways. Slope factors for radionuclides represent the probability of cancer incidence as a result of

a unit exposure to a given radionuclide averaged over a lifetime. It is the age-averaged lifetime excess cancer incident rate per unit intake (or unit exposure for external exposure pathway) of a radionuclide (U.S. EPA 1989a).

Current radionuclide slope factors incorporate the age- and gender-specific radiogenic cancer risk models from *Estimating Radiogenic Cancer Risks* (U.S. EPA, 1994b). Age-specific estimates of absorbed dose rate are used, where available, for internal exposure pathways, whereas dose estimates for external exposure are taken directly from *Federal Guidance Report No. 12* (U.S. EPA 1993b). Population mortality statistics and baseline cancer rates reflect the U.S. population of 1989-1991 (1979-1981 for slope factors derived prior to 1998). Detailed information on the derivation and application of risk coefficients and radionuclide slope factors is presented in *Radiation Exposure and Risk Assessment Manual (RERAM)* (U.S. EPA, 1996, 1998h). Agency-recommended slope factors for radionuclides (as well as nonradioactive carcinogens) are published in EPA's *Health Effects Assessment Summary Tables (HEAST)* (U.S. EPA, 1998e). EPA plans to revise the HEAST tables based on information in *Federal Guidance Report No. 13: Health Risks from Low-Level Environmental Exposure to Radionuclides* (U.S. EPA 1998g).

Q21. What are radionuclide dose conversion factors?

- A. Dose conversion factors (DCFs), or "dose coefficients", for a given radionuclide represent the dose equivalent per unit intake (i.e., ingestion or inhalation) or external exposure of that radionuclide. These DCFs are used to convert a radionuclide concentration in soil, air, water, or foodstuffs to a radiation dose. DCFs may be specified for specific body organs or tissues of interest, or as a weighted sum of individual organ dose, termed the effective dose equivalent (these quantities are discussed further in Q21). These DCFs may be multiplied by the total activity of each radionuclide inhaled or ingested per year, or the external exposure concentration to which a receptor may be exposed, to estimate the dose equivalent to the receptor.

EPA-approved DCFs for inhalation and ingestion exposure are published in *Federal Guidance Report No. 11* (U.S. EPA, 1988b). EPA-approved DCFs for external exposure are published in *Federal Guidance Report No. 12* (U.S. EPA, 1993b). Both compilations provide DCF values for a reference adult only, but it is anticipated that future revisions will include values for other age groups.

Q22. What is dose equivalent, effective dose equivalent, and related quantities?

As discussed in Q18, different types of radiation have differing effectiveness in transferring their energy to living tissue. Since it is often desirable to compare doses from different types of radiation, the quantity "dose equivalent"

has been defined as a measure of the energy absorbed by living tissues, adjusted for the relative biological effectiveness of the type of radiation present. The SI unit for dose equivalent is the sievert (Sv) and the conventional unit is the rem (1 rem = 0.01 Sv). For computation of dose equivalent, the absorbed dose is multiplied by Quality Factor (Q) or radiation weighting factor (w_R); these values range from 1 for photons and electrons to 10 for neutrons to 20 for alpha particles (i.e., for an equal amount of energy absorbed, an alpha particle will inflict approximately 20 times more damage to biological tissue than that inflicted by a beta particle or gamma ray). Internally deposited (i.e., inhaled or ingested) radionuclides may be deposited in various organs and tissues long after initial deposition. The "committed dose equivalent" is defined as the integrated dose equivalent that will be received by an individual during a 50-year period (based on occupational exposure) following the intake. By contrast, external radiation exposure contribute to dose only as long as the receptor is present within the external radiation field.

When exposed to equal doses of radiation, different organs and tissues in the human body will exhibit different cancer induction rates. The quantity "effective dose equivalent" was developed by the International Commission on Radiological Protection (ICRP) to account for these differences and to normalize radiation doses and effects on a whole body basis for regulation of occupational exposure. The effective dose equivalent is computed as a weighted sum of organ-specific dose equivalent values, with weighting factors specified by the ICRP (ICRP 1977, 1979). The effective dose equivalent is equal to that dose equivalent, delivered at a uniform whole-body rate, that corresponds to the same number (but possibly dissimilar distribution) of fatal stochastic health effects as the particular combination of organ dose equivalents.

Q23. What is the critical organ approach to dose limitation?

- A. Critical organ standards developed by EPA and NRC usually consist of a combination of whole body and critical organ dose limits, such 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. When these standards were adopted, dose was calculated and controlled for each organ in the body and uniform radiation of the "whole body." The "critical organ" was the organ that received the most dose for the radionuclide concerned. With the adoption of the dose equivalent concept, the dose to each organ is weighted according to the effect of the radiation on the overall system (person). The new system allows for one value of dose equivalent to be assigned as a limit, which is protective of the entire system. The critical organ approach required individual limits for each organ based on the effect of radiation on that organ.

It should be noted that although most critical organ

standards include 25 mrem/yr or higher (75 mrem/yr) dose limits, these critical organ standards are not comparable to 25 mrem/yr effective dose equivalent standards or guidance. EPA's determination that the 25 mrem/yr dose level found in NRC's decommissioning standard and various guidance should not be used to establish cleanup levels at CERCLA sites does not apply to critical organ standards.

Q24. How should radionuclide slope factors and dose conversion factors be used?

- A. EPA recommends that radionuclide slope factors be used to estimate the excess cancer risk resulting from exposure to radionuclides at radiologically contaminated sites for comparison with EPA's target risk range (i.e., 10^{-4} to 10^{-6} lifetime excess cancer risk). The incremental risk is calculated by multiplying estimates of the lifetime intake via inhalation and ingestion of each radionuclide of concern, and the duration and concentration in environmental media to which the receptor is exposed via the external exposure pathway, by the appropriate slope factor values for that exposure pathway and radionuclide. Additional information on the use of radionuclide slope factors and their underlying assumptions, which introduce significant uncertainties, is provided in the Radiation Exposure and Risk Assessment Manual (RERAM) (U.S. EPA 1996a, 1999b).

Estimates of cancer risk from radionuclide exposures may also be computed by multiplying the effective dose equivalent computed using the DCFs by a risk-per-dose factor. EPA recommends that this method **not** be used at CERCLA sites to estimate risks for PRGs or cleanup levels, and estimates computed using this method may tend to inaccurately estimate potential risks, with the magnitude of discrepancy dependent on the dominant radionuclides and exposure pathways for the site-specific conditions. These differences can be attributed to factors such as the consideration of competing mortality risks and age-dependent radiation risk models in the development of the slope factors, different distributions of relative weights assigned to individual organ risks in the two methods, and differences in dosimetric and toxicological assumptions. Some key differences in the two methods are summarized in Table 2.

Due to these factors, no simple and direct conversion between radiation dose and radiogenic cancer risk is available. Given the differing dosimetric and radiotoxicological characteristics of different radionuclides, as reflected in the DCFs and slope factors, respectively, a given dose from one radionuclide via a given exposure pathway may present a much greater cancer risk than the same dose from another radionuclide and/or exposure pathway. Therefore, any conversion between dose and risk now must be performed on a radionuclide- and pathway-specific basis.

The primary use of DCFs should generally be to compute doses resulting from site-related exposures for comparison with radiation protection standards and dose limits (see Q31-32) that are determined to be ARARs or TBCs. This is accomplished by multiplying the exposure estimates produced through the exposure assessment (i.e., the intake of each radionuclide of concern via inhalation and ingestion, and the duration of exposure and concentration of each radionuclide of concern in environmental media for external exposure) by the appropriate DCF values for that exposure pathway and radionuclide. Unlike excess cancer risk, which represents cumulative lifetime exposure, dose estimates are typically expressed in terms of annual exposure (e.g., the effective dose equivalent resulting from exposure during a one-year period, mrem/year).

Unless otherwise stated in the standard, DCFs from *Federal Guidance Report No. 11* (U.S. EPA, 1988b) and *Federal Guidance Report No. 12* (U.S. EPA, 1993b) should be used for complying with ARARs based on effective dose equivalent, while DCFs from ICRP 2 should be used when complying with ARARs based on the critical organ approach.

Q25. In addition to cancer, should the potential teratogenic and genetic effects of radiation exposures be considered?

- A. Biological effects associated with exposure to ionizing radiation in the environment may include carcinogenicity (i.e., induction of cancer), mutagenicity (i.e., induction of mutations in somatic or reproductive cells, including genetic effects), and teratogenicity (i.e., effects on the growth and development of an embryo or fetus). Agency guidance (U.S. EPA, 1989a, 1994b) indicates that the radiogenic cancer risk is normally assumed to be limiting for risk assessments at Superfund sites, and evaluation of teratogenic and genetic effects is not required. Similarly, consideration of acute effects normally is not required, since these effects occur only at doses much higher than normally associated with environmental exposures.

Q26. Should chemical toxicity of radionuclides be considered?

- A. At Superfund radiation sites, EPA generally evaluates potential human health risks based on the radiotoxicity (i.e., the adverse health effects caused by ionizing radiation), rather than on the chemical toxicity, of each radionuclide present. Uranium, in soluble form, is a kidney toxin at mass concentrations slightly above background levels, and is the only radionuclide for which the chemical toxicity has been identified to be comparable to or greater than the radiotoxicity, and for which a reference dose (RfD) has been established to evaluate chemical toxicity. For radioisotopes of uranium, both effects (radiogenic cancer risk and chemical toxicity) should be considered.

IV. RISK CHARACTERIZATION

Q27. How should radionuclide risks be estimated?

- A. Risks from radionuclide exposures should be estimated in a manner analogous to that used for chemical contaminants. That is the estimates of intakes by inhalation and ingestion and the external exposure over the period of exposure estimated for the land use (e.g., 30 years residential, 25 years commercial/industrial) from the exposure assessment should be coupled with the appropriate slope factors for each radionuclide and exposure pathway. Only excess cancer risk should be considered for most radionuclides (except for uranium as discussed in Q25). The total incremental lifetime cancer risk attributed to radiation exposure is estimated as the sum of the risks from all radionuclides in all exposure pathways.

Q28. Should radionuclide and chemical risks be combined?

- A. **Yes. Excess cancer risk from both radionuclides and chemical carcinogens should be summed to provide an estimate of the combined risk presented by all carcinogenic contaminants as specified in OSWER directive 9200.4-18 (U.S. EPA 1997a).** An exception would be cases in which a person reasonably can not be exposed to both chemical and radiological carcinogens. Similarly, the chemical toxicity from uranium should be combined with that of other site-related contaminants. As recommended in RAGS Part A (U.S. EPA 1989a), risk estimates for radionuclides and chemical contaminants also should be tabulated and presented separately in the risk characterization report.

There are generally several differences between slope factors for radionuclides and chemicals. However, similar differences also occur between different chemical slope factors. In the absence of additional information, it is reasonable to assume that excess cancer risks are additive for purposes of evaluating the total incremental cancer risk associated with a contaminated site.

Q29. How should risk characterization results for radionuclides be presented?

- A. Results should be presented according to the standardized reporting format presented in *RAGS Part D* (U.S. EPA, 1998a). However, specific guidance for radionuclides (i.e., the Radionuclides Worksheet) is not yet available.

EPA guidance for risk characterization (U.S. EPA, 1992e) indicates that four descriptors of risk are generally needed for a full characterization of risk: (1) central tendency (e.g., median, mean) estimate of individual risk; (2) high-end estimate (e.g., 95th percentile) of individual risk; (3) risk to important subgroups (e.g., children) of the population, such as highly exposed or highly susceptible groups or individuals, if known; and (4) population risk. The reasonable maximum exposure (RME) estimate of individ-

ual risk typically presented in Superfund risk assessments represents a measure of the high-end individual exposure and risk. While the RME estimate remains the primary scenario for risk management decisions, additional risk descriptors may be included to describe site risks more fully.

Q30. Should the collective risk to populations be estimated along with that to individual receptors?

A. Risk to potential individual receptors is the primary measure of protectiveness under the CERCLA process (i.e., the target range of 10^{-6} to 10^{-4} lifetime excess cancer risk to the RME receptor). As noted in Q28, however, Agency guidance (U.S. EPA, 1992e) also indicates that the collective risk to the potentially exposed population and to important subgroups of the population also should be evaluated where possible. Consideration of population risk provides additional input to risk management decisions; such considerations may be either qualitative or quantitative depending on the availability of data and the magnitude of projected population risk.

Q31. How should uncertainty in estimates of radiation risk be addressed in the risk characterization report?

A. Consideration of uncertainty in estimates of risks from potential exposure to radioactive materials at CERCLA sites is essential for informed risk management decisions. RAGS and subsequent guidance (U.S. EPA, 1992e, 1995b) stress the importance of a thorough presentation of the uncertainties, limitations, and assumptions that underlay estimates of risk. Either qualitative or quantitative evaluation may be appropriate, depending on the availability of data and the magnitude of predicted risk. In either case, the evaluation should address both uncertainty (i.e., “the lack of knowledge about specific factors, parameters, or models”) and variability (i.e., “observed differences attributable to true heterogeneity or diversity in a population or exposure parameter”). Estimates of potential risk should include both central tendency estimates (median, mean) and high-end estimates (e.g., RME or 95th percentile).

Table 2. Comparison of Radiation Risk Estimation Methodologies: Slope Factors vs Effective Dose Equivalent

Parameter	Slope Factor Approach	Effective Dose Equivalent x Risk Factor Approach
Competing Risks	<ul style="list-style-type: none"> Persons dying from competing causes of death (e.g., disease, accidents) are not considered susceptible to radiogenic cancer. Probability of dying at a particular age from competing risks is considered based on the mortality rate from all causes at that age in the 1989-1991 (previously 1979-1981) U.S. population. 	<ul style="list-style-type: none"> Competing risks not considered.
Risk Models	<ul style="list-style-type: none"> Age-dependent and gender-dependent risk models for 14 cancer sites are considered individually and integrated into the slope factor estimate. 	<ul style="list-style-type: none"> Risk estimate averaged over all ages, sexes, and cancer sites.
Genetic Risk	<ul style="list-style-type: none"> Genetic risk is not considered in the slope factor estimates; however, ovary is considered as a potential cancer site. 	<ul style="list-style-type: none"> Effective dose equivalent (EDE) value includes genetic risk component.
Dose Estimates	<ul style="list-style-type: none"> Low-LET and high-LET dose estimates considered separately for each target organ. 	<ul style="list-style-type: none"> Dose-equivalent includes both low-LET and high-LET radiation, multiplied by appropriate Quality Factors.
RBE for high-LET (alpha) radiation	<ul style="list-style-type: none"> 20 for most sites (8 prior to 1994) 10 for breast (8 prior to 1994) 1 for leukemia (1.117 prior to 1994) 	<ul style="list-style-type: none"> 20 (all sites)
Organs Considered	<ul style="list-style-type: none"> Estimates of absorbed dose to 16 target organs/tissues considered for 13 specific cancer sites plus residual cancers. 	<ul style="list-style-type: none"> EDE (ICRP, 1979) considers dose estimates to 6 specific target organs plus remainder (weighted average of 5 other organs).
Lung Dose Definition	<ul style="list-style-type: none"> Absorbed dose used to estimate lung cancer risk computed as weighted sum of dose to tracheobronchial region (80%) and pulmonary lung (20%). 	<ul style="list-style-type: none"> Average dose to total lung (mass weighted sum of doses to the tracheobronchial region, pulmonary region, and pulmonary lymph nodes).
Integration Period	<ul style="list-style-type: none"> Variable length (depending on organ-specific risk models and consideration of competing risks) not to exceed 110 years. 	<ul style="list-style-type: none"> Fixed integration period of 50 years typically considered.
Dosimetric / Metabolic Models	<ul style="list-style-type: none"> Metabolic models and parameters for dose estimates follow recent recommendations of the ICRP series of documents on age-specific dosimetry (ICRP, 1989, 1993, 1995a, 1995b), where available; previous estimates based primarily on ICRP 30 (ICRP, 1979). 	<ul style="list-style-type: none"> Typically employ ICRP Publication 30 (ICRP, 1979) models and parameter for radionuclide uptake, distribution, and retention.

For both chemical carcinogens and radionuclides, extrapolation from high dose and dose rate exposure is generally required to estimate risks of low-level exposures. This extrapolation typically constitutes the greatest source of uncertainty. For chemical carcinogens, additional uncertainty may be introduced due to extrapolation of animal data to humans. Slope factors for both radionuclides and chemicals are used to estimate incremental cancer risk, which typically represents a small increment over a relatively high baseline incidence. Other sources of uncertainty may include that associated with instrumentation and measurements used to characterize the nature and extent of radionuclides of concern, and the parameters used to characterize potential exposures of current and future receptors (e.g., intake rates, frequency of exposure).

Probabilistic Risk Assessment (PRA) may be used to provide quantitative estimates of the uncertainties in the risk assessment. However, probabilistic estimates of risk should always be presented as a supplement to - not instead of - the deterministic (i.e., point estimate) methods outlined in *RAGS Part A*. A tiered approach is often useful, with the rigor of the analysis dependent on the magnitude of predicted risk. Factors to be considered in conducting a probabilistic analysis typically should include the sensitivity of parameters, the correlation or dependencies between parameters, and the distributions of parameter values and model estimates. Detailed guidance on this topic is provided in *Use of Probabilistic Techniques (Including Monte Carlo Analysis) in Risk Assessment* (U.S. EPA 1997c) and *Guiding Principles for Monte Carlo Analysis* (U.S. EPA 1997d).

Q32. When should a dose assessment be performed?

OSWER Directive 9200.4-18 (U.S. EPA 1997a) specifies that 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. **Cleanup levels not based on an ARAR should be based on the carcinogenic risk range (generally 10^{-4} to 10^{-6} , with 10^{-6} as the point of departure and 1×10^{-6} used for PRGs) and expressed in terms of risk ($\# \times 10^{-6}$).** While the upper end of the risk range is not a discrete line at 1×10^{-4} , EPA generally uses 1×10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable if based on site-specific circumstances. For further discussion of how EPA uses the risk range, see OSWER Directive 9355.0-30, Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions (U.S. EPA 1991d). In general, dose assessment used as a method to assess risk is not recommended at CERCLA sites.

Please note that the references to 15 mrem/yr in OSWER Directive 9200.4-18 are intended as guidance for the

evaluation of potential ARARs and TBCs, and should not be used as a TBC for establishing 15 mrem/yr cleanup levels at CERCLA sites. **At CERCLA sites dose assessments should generally not be performed to assess risks or to establish cleanup levels except to show compliance with an ARAR that requires a dose assessment (e.g., 40 CFR 61 Subparts H and I, and 10 CFR 61.41).**

Q33 How and when should exposure rate be used to estimate radionuclide risks?

As discussed previously (see Q24 and Q27), EPA recommends that estimates of radiation risk should be derived using slope factors, in a manner analogous to that used for chemical contaminants. However, there may be circumstances where it is desirable to also consider estimates of risk based on direct exposure rate measurements of penetrating radiation. Instances where it may be beneficial to also use direct measurements for assessing risk from external exposure to penetrating radiation include:

- During early site assessment efforts when the site manager is attempting to communicate the relative risk posed by areas containing elevated levels of radiation,
- As a real-time method for indicating that remedial objectives are being met during the conduct of the response action. The use of exposure rate measurements during the conduct of the response actions may not decrease the need for a final status survey.
- When risk estimates developed during a risk assessment may underestimate the level of risk posed by radionuclides. An example of this situation would be where the source of the radiation is highly irregular (inside a contaminated structure) instead of being an infinite plane, which is the standard assumption used during risk assessments.

When developing risk estimates under any of these situations, risk factors from "Estimating Radiogenic Cancer Risks, EPA 402-R-93-076" or HEAST plus shape & area factor, should be used in conjunction with the measured dose rate to develop a risk estimate for external exposure to penetrating radiation.

Direct radiation exposure rate measurements may provide important indications of radiation risks at a site, particularly during early investigations, when these may be the first data available. However, such data may only reflect a subset of the radionuclides and exposure pathways of potential concern (e.g., only external exposure from gamma-emitting radionuclides in near-surface soil), and may present an incomplete picture of site risks (e.g., risk from internal exposures, or potential increased future risks from radionuclides in subsurface soils). In most cases, more accurate estimation of radiation risks will require additional

site characterization data, including concentrations of all radionuclides of concern in all pertinent environmental media. The principal benefits of exposure rate measurements is the speed and convenience of analysis, and the elimination of potential modeling uncertainties. However, these data should be used in conjunction with, rather than instead of, characterization data of radionuclides concentrations in environmental media to obtain a complete picture of potential site-related risks.

Q34. What radiation standards may be applicable or relevant and appropriate requirements (ARARs)?

- A. In some cases, cleanup levels may be derived based on compliance with ARARs. Attachment A "Likely Federal Radiation Applicable or Relevant and Appropriate Requirements (ARARs)" of OSWER Directive 9200.4-18 (U.S. EPA 1997a) provides information regarding the circumstances in which federal standards that have often been selected as ARARs may be either applicable or relevant and appropriate for particular site-specific conditions. **It should be noted that the Agency has determined that the NRC decommissioning requirements (e.g., 25, 100 mrem/yr dose limits) under 10 CFR 20 Subpart E should generally not be used to establish cleanup levels under CERCLA, even when these regulations are ARARs.** OSWER Directive 9200.4-25, *Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation Goals for CERCLA Sites* (U.S. EPA 1998c), provides more detailed discussion on the use of the concentration limits for radium and/or thorium in subsurface soils.

V. ECOLOGICAL ASSESSMENTS

Q35. What guidance is available for conducting ecological risk assessments.

- A. OSWER Directive 9285.7-25, *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (U.S. EPA June 1997) is intended to facilitate defensible and appropriately-scaled site-specific ecological risk assessments at CERCLA sites. This guidance is not intended to dictate the scale, complexity, protocols, data needs, or investigation methods for such assessments. Professional judgement is required to apply the process outlined in this guidance to ecological risk assessments at specific sites.

VI. BACKGROUND CONTAMINATION

Q36. How should background levels of radiation be addressed?

- A. Background radiation levels on a specific site will generally be determined as background levels are determined for other contaminants, on a radionuclide-specific basis when the same constituents are found in on-

site samples as well as in background samples. The levels of each constituent in background are compared to that on site-related contaminant to determine its impact, if any. Background is generally measured only for those radionuclides that are contaminants of concern and is compared on a radionuclide specific basis to determine cleanup levels. 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. For further information regarding background, see section "Background Contamination" in OSWER Directive 9200.4-18 (U.S. EPA 1997a).

WHERE TO GO FOR FURTHER INFORMATION

Attachment 1 provides a bibliography of selected EPA documents related to radiation risk assessment. Readers should periodically consult the EPA Headquarters and Regional Superfund and Radiation Program Offices for updates on current guidances and for copies of new documents. Copies of many of the documents listed in Attachment 1 are available to the public for a fee from the National Technical Information Service (NTIS) at (703) 605-6000 or (800) 553-6847. Many documents are also available from EPA on the Internet.

Radiation and radioactive materials pose special hazards and require specialized detection instrumentation, techniques and safety precautions. EPA strongly encourages RPMs and risk assessors to consult with individuals trained and experienced in radiation measurements and protection. Such individuals include health physicists and radiochemists who can provide additional assistance in designing and executing radionuclide sampling and analysis plans and interpreting radioanalytical results.

The subject matter specialists for this fact sheet are Dr. Kung-Wei Yeh of ORIA and Stuart Walker of OERR. General questions about this fact sheet should be directed to 1-800-424-9346.

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