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Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals)

Interim

Office of Emergency and Remedial Response
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This guidance is based on policies in the Final Rule of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which was published on March 8, 1990 (55 *Federal Register* 8666). The NCP should be considered the authoritative source.

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DEFINITIONS

Term	Definition
Applicable or Relevant and Appropriate Requirements (ARARs)	"Applicable" requirements are those clean-up standards, standards of control, and other substantive environmental protection requirements, criteria, or limitations promulgated under federal or state law that specifically address a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance at a Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) site. "Relevant and appropriate" requirements are those clean-up standards which, while not "applicable" at a CERCLA site, address problems or situations sufficiently similar to those encountered at the CERCLA site that their use is well-suited to the particular site. ARARs can be action-specific, location-specific, or chemical-specific.
Cancer Risk	Incremental probability of an individual's developing cancer over a lifetime as a result of exposure to a potential carcinogen.
Conceptual Site Model	A "model" of a site developed at scoping using readily available information. Used to identify all potential or suspected sources of contamination, types and concentrations of contaminants detected at the site, potentially contaminated media, and potential exposure pathways, including receptors. This model is also known as "conceptual evaluation model".
Exposure Parameters	Variables used in the calculation of intake (e.g., exposure duration, inhalation rate, average body weight).
Exposure Pathway	The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also would be indicated.
Exposure Point	A location of potential contact between an organism and a chemical or physical agent.
Exposure Route	The way a chemical or physical agent comes in contact with an organism (i.e., by ingestion, inhalation, dermal contact).
Final Remediation Levels	Chemical-specific clean-up levels that are documented in the Record of Decision (ROD). They may differ from preliminary remediation goals (PRGs) because of modifications resulting from consideration of various uncertainties, technical and exposure factors, as well as all nine selection-of-remedy criteria outlined in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP).

DEFINITIONS (Continued)

Term	Definition
Hazard Index (HI)	The sum of two or more hazard quotients for multiple substances and/or multiple exposure pathways.
Hazard Quotient (HQ)	The ratio of a single substance exposure level over a specified time period to a reference dose for that substance derived from a similar exposure period.
"Limiting" Chemical(s)	Chemical(s) that are the last to be removed (or treated) from a medium by a given technology. In theory, the cumulative residual risk for a medium may approximately equal the risk associated with the limiting chemical(s).
Preliminary Remediation Goals (PRGs)	Initial clean-up goals that (1) are protective of human health and the environment and (2) comply with ARARs. They are developed early in the process based on readily available information and are modified to reflect results of the baseline risk assessment. They also are used during analysis of remedial alternatives in the remedial investigation/feasibility study (RI/FS).
Quantitation Limit (QL)	The lowest level at which a chemical can be accurately and reproducibly quantitated. Usually equal to the method detection limit multiplied by a factor of three to five, but varies for different chemicals and different samples.
Reference Dose (RfD)	The Agency's preferred toxicity value for evaluating potential noncarcinogenic effects in humans resulting from contaminant exposures at CERCLA sites. (See RAGS/HHEM Part A for a discussion of different kinds of reference doses and reference concentrations.)
Risk-based PRGs	Concentration levels set at scoping for individual chemicals that correspond to a specific cancer risk level of 10^{-6} or an HQ/HI of 1. They are generally selected when ARARs are not available.
Slope Factor (SF)	A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual's developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.
Target Risk	A value that is combined with exposure and toxicity information to calculate a risk-based concentration (e.g., PRG). For carcinogenic effects, the target risk is a cancer risk of 10^{-6}. For noncarcinogenic effects, the target risk is a hazard quotient of 1.

ACRONYMS/ABBREVIATIONS

Acronym/ Abbreviation	Definition
ARARs	Applicable or Relevant and Appropriate Requirements
CAA	Clean Air Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CWA	Clean Water Act
EAG	Exposure Assessment Group
ECAO	Environmental Criteria and Assessment Office Superfund Health Risk Technical Support Center
EF	Exposure Frequency
EPA	U.S. Environmental Protection Agency
FWQC	Federal Water Quality Criteria
HEAST	Health Effects Assessment Summary Tables
HHEM	Human Health Evaluation Manual
HI	Hazard Index
HQ	Hazard Quotient
HRS	Hazard Ranking System
IRIS	Integrated Risk Information System
LLW	Low-level Radioactive Waste
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NPL	National Priorities List
OSWER	Office of Solid Waste and Emergency Response
OERR	Office of Emergency and Remedial Response

ACRONYMS/ABBREVIATIONS (Continued)

Acronyms/ Abbreviation	Definition
PA/SI	Preliminary Assessment/Site Inspection
PEF	Particulate Emission Factor
PRG	Preliminary Remediation Goal
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
RfC	Reference Concentration
RfD	Reference Dose
RI/FS	Remedial Investigation/Feasibility Study
RME	Reasonable Maximum Exposure
ROD	Record of Decision
RPM	Remedial Project Manager
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act
SF	Slope Factor
TR	Target Risk
VF	Volatilization Factor
WQS	State Water Quality Standards

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- Policy and Analysis Staff, Office of Emergency and Remedial Response;
- Environmental Response Branch, Office of Emergency and Remedial Response;
- Office of General Counsel; and
- Exposure Assessment Group, Office of Research and Development.

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PREFACE

Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (RAGS/HHEM) Part B is one of a three-part series. Part A addresses the baseline risk assessment; Part C addresses human health risk evaluations of remedial alternatives. Part B provides guidance on using U.S. Environmental Protection Agency (EPA) toxicity values and exposure information to derive risk-based preliminary remedial goals (PRGs) for a Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) site. Initially developed at the scoping phase using readily available information, risk-based PRGs generally are modified based on site-specific data gathered during the remedial investigation/feasibility study (RI/FS). This guidance does not discuss the risk management decisions that are necessary at a CERCLA site (e.g., selection of final remediation goals). The potential users of Part B are those involved in the remedy selection and implementation process, including risk assessors, risk assessment reviewers, remedial project managers, and other decision-makers.

This manual is being distributed as an interim document to allow for a period of field testing and review. RAGS/HHEM will be revised in the future, and Parts A, B, and C will be incorporated into a single final guidance document. Additional information for specific subject areas is being developed for inclusion in a later revision. These areas include:

- development of goals for additional land uses and exposure pathways;
- development of short-term goals;
- additional worker health and safety issues; and
- determination of final remediation goals (and attainment).

Comments addressing usefulness, changes, and additional areas where guidance is needed should be sent to:

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CHAPTER 1

INTRODUCTION

The purpose of this guidance is to assist risk assessors, remedial project managers (RPMs), and others involved with risk assessment and decision-making at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites in developing preliminary remediation goals (PRGs). This guidance is the second part (Part B) in the series *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual* (RAGS/HHEM).

Part A of this series (EPA 1989d) assists in defining and completing a site-specific baseline risk assessment; much of the information in Part A is necessary background for Part B. Part B provides guidance on using U.S. Environmental Protection Agency (EPA) toxicity values and exposure information to derive risk-based PRGs. Initially developed at the scoping phase using readily available information, risk-based PRGs generally are modified based on site-specific data gathered during the remedial investigation/feasibility study (RI/FS). Part C of this series (EPA 1991d) assists RPMs, site engineers, risk assessors, and others in using risk information both to evaluate remedial alternatives during the FS and to evaluate the selected remedial alternative during and after its implementation. Exhibit 1-1 illustrates how the three parts of RAGS/HHEM are all used during the RI/FS and other stages of the site remediation process.

The remainder of this introduction addresses the definition of PRGs, the scope of Part B, the statutes, regulations, and guidance relevant to PRGs, steps in identifying and modifying PRGs, the communication and documentation of PRGs, and the organization of the remainder of this document.

1.1 DEFINITION OF PRELIMINARY REMEDIATION GOALS

In general, PRGs provide remedial design staff with long-term targets to use during analysis and selection of remedial alternatives. Ideally, such goals, if achieved, should both comply with applicable or relevant and appropriate requirements (ARARs) and result in residual risks that fully satisfy the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) requirements for the protection of human health and the environment. By developing PRGs early in the decision-making process (before the RI/FS and the baseline risk assessment are completed), design staff may be able to streamline the consideration of remedial alternatives.

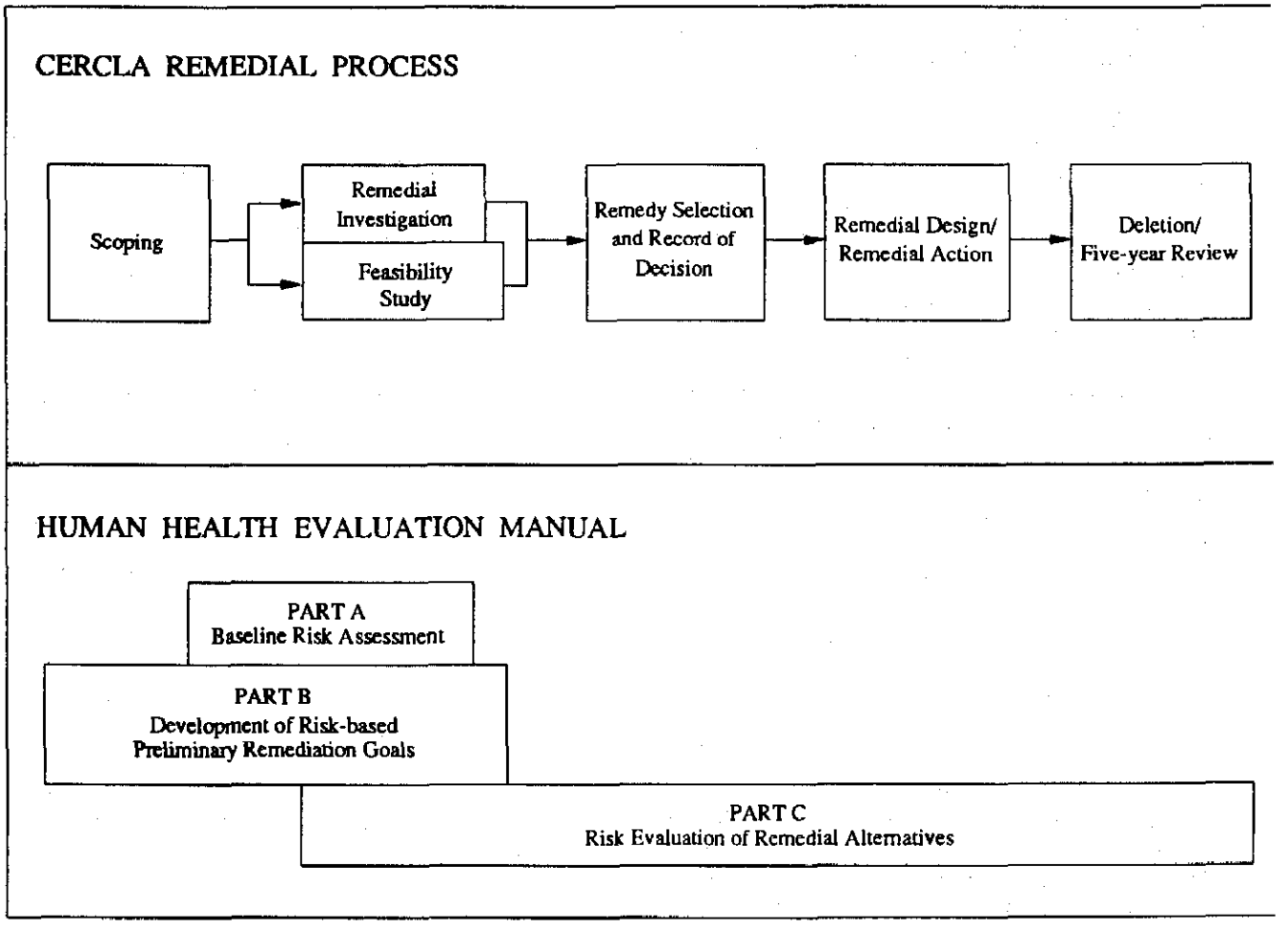
Chemical-specific PRGs are concentration goals for individual chemicals for specific medium and land use combinations at CERCLA sites. There are two general sources of chemical-specific PRGs: (1) concentrations based on ARARs and (2) concentrations based on risk assessment. ARARs include concentration limits set by other environmental regulations (e.g., non-zero maximum contaminant level goals [MCLGs] set under the Safe Drinking Water Act [SDWA]). The second source for PRGs, and the focus of this document, is risk assessment or risk-based calculations that set concentration limits using carcinogenic and/or noncarcinogenic toxicity values under specific exposure conditions.

1.2 SCOPE OF PART B

The recommended approach for developing remediation goals is to identify PRGs at scoping, modify them as needed at the end of the RI or during the FS based on site-specific information from the baseline risk assessment, and ultimately select remediation levels in the Record of Decision (ROD). In order to set chemical-specific PRGs in a site-specific context, however, assessors must answer fundamental questions about the site. Information on the chemicals that are present onsite, the specific contaminated media, land-use assumptions, and the exposure assumptions behind pathways of individual exposure is necessary in order to develop chemical-specific PRGs. Part B provides guidance for considering this information in developing chemical-specific PRGs.

EXHIBIT 1-1

RELATIONSHIP OF THE HUMAN HEALTH EVALUATION TO THE CERCLA PROCESS



Because Part B focuses on developing chemical-specific PRGs based on protection of human health, there are important types of information that are not considered and that may significantly influence the concentration goals needed to satisfy the CERCLA criteria for selection of a remedy. For example, no consideration is given to ecological effects in this guidance. Other types of remedial action "goals" not addressed in detail include action-specific ARARs (e.g., technology- or performance-based standards) and location-specific ARARs.

Throughout Part B, the term "chemical-specific" should be understood to refer to both nonradioactive and radioactive chemical hazardous substances, pollutants, or contaminants. Therefore, the process described in this guidance of selecting and modifying PRGs at a site should be applied to each radionuclide of potential concern. Chapter 10 of RAGS/HHEM Part A provides background information concerning radionuclides, and Chapter 4 of RAGS/HHEM Part B includes radionuclide risk-based equations and a case study of a hypothetical radiation site.

This guidance only addresses in detail the initial selection of risk-based PRGs. Detailed guidance regarding other factors that can be used to further modify PRGs during the remedy selection process is presented in other documents (see Section 1.3).

1.3 RELEVANT STATUTES, REGULATIONS, AND GUIDANCE

This section provides relevant background on the CERCLA statute and the regulations created to implement the statute (i.e., the NCP). In addition, other CERCLA guidance documents are listed and their relationship to the site remediation process is discussed.

1.3.1 CERCLA/SARA

CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), is the authority for EPA to take response actions. (Throughout this guidance, reference to CERCLA should be understood to mean "CERCLA as amended by SARA.")

Several sections of CERCLA, especially section 121 (Clean-up Standards), set out the requirements and goals of CERCLA. Two fundamental requirements are that selected remedies be protective of human health and the environment, and comply with ARARs. CERCLA indicates a strong preference for the selection of remedial alternatives that permanently and significantly reduce the volume, toxicity, or mobility of wastes. To the maximum extent practicable, the selected remedial alternatives should effect permanent solutions by using treatment technologies. Both the law and the regulation (see below) call for cost-effective remedial alternatives.

1.3.2 NATIONAL CONTINGENCY PLAN

Regulations implementing CERCLA are found in Volume 40 of the Code of Federal Regulations (CFR), Part 300, and are referred to collectively as the NCP. Section 300.430 of the NCP, and several portions of the preambles in the *Federal Register* (55 *Federal Register* 8666, March 8, 1990 and 53 *Federal Register* 51394, December 21, 1988), address how the Superfund and other CERCLA programs are to implement the Act's requirements and goals concerning clean-up levels.

Nine criteria have been developed in the NCP to use in selecting a remedy. These criteria are listed in the next box. The first criterion — overall protection of human health and the environment — is the focus of this document. This criterion coupled with compliance with ARARs are referred to as "threshold criteria" and must be met by the selected remedial alternative. PRGs are developed to quantify the standards that remedial alternatives must meet in order to achieve these threshold criteria. See the second box on the next page for highlights from the NCP on remediation goals.

1.3.3 GUIDANCE DOCUMENTS

There are several existing documents that provide gudiance on related steps of the site remediation process. These documents are described in the box on page five. When documents are referenced throughout this guidance, the abbreviated titles, indicated in parentheses after the full titles and bibliographic information, are used.

NINE EVALUATION CRITERIA FOR ANALYSIS OF REMEDIAL ALTERNATIVES
(40 CFR 300.430(e)(9)(iii))

Threshold Criteria:
- Overall Protection of Human Health and the Environment
- Compliance with ARARs

Balancing Criteria:
- Long-term Effectiveness and Permanence
- Reduction of Toxicity, Mobility, or Volume Through Treatment
- Short-term Effectiveness
- Implementability
- Cost

Modifying Criteria:
- State Acceptance
- Community Acceptance

1.4 INITIAL DEVELOPMENT OF PRELIMINARY REMEDIATION GOALS

The NCP preamble indicates that, typically, PRGs are developed at scoping or concurrent with initial RI/FS activities (i.e., prior to completion of the baseline risk assessment). This early determination of PRGs facilitates development of a range of appropriate remedial alternatives and can focus selection on the most effective remedy.

Development of PRGs early in the RI/FS requires the following site-specific data:

- media of potential concern;
- chemicals of potential concern; and
- probable future land use.

This information may be found in the preliminary assessment/site inspection (PA/SI) reports or in the conceptual site model that is developed prior to or during scoping. (When a site is listed on the National Priorities List [NPL], much of this information is compiled during the PA/SI as part of the Hazard Ranking System [HRS] documentation record.) Once these factors are known, all potential ARARs must be identified. When ARARs do not exist, risk-based PRGs are calculated using EPA health criteria (i.e., reference doses or cancer slope factors) and default or site-specific exposure assumptions.

NCP RULE HIGHLIGHTS
RISK AND REMEDIATION GOALS
(40 CFR 300.430(e)(2))

"In developing and, as appropriate, screening ... alternatives, the lead agency shall: (i) Establish remedial action objectives specifying contaminants and media of concern, potential exposure pathways, and remediation goals. Initially, preliminary remediation goals are developed based on readily available information, such as chemical-specific ARARs or other reliable information. Preliminary remediation goals should be modified, as necessary, as more information becomes available during the RI/FS. Final remediation goals will be determined when the remedy is selected. Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following:

(A) Applicable or relevant and appropriate requirements ..., and the following factors:

(1) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;

(2) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper-bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of multiple contaminants at a site or multiple pathways of exposure ..."

It is important to remember that risk-based PRGs (either at scoping or later on) are initial guidelines. They do not establish that cleanup to meet these goals is warranted. A risk-based concentration, as calculated in this guidance, will be considered a final remediation level only after appropriate analysis in the RI/FS and ROD.

GUIDANCE DOCUMENTS

- *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual Part A* (EPA 1989a) (RAGS/HHEM Part A) contains background information and is particularly relevant for developing exposure and toxicity assessments that are required when refining chemical-specific risk-based concentrations, and accounting for site-specific factors such as multiple exposure pathways.

- *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988c) (RI/FS Guidance) presents detailed information about implementing the RI/FS and general information on the use of risk-based factors and ARARs in the context of the RI/FS.

- *Guidance on Remedial Action for Contaminated Ground Water at Superfund Sites* (EPA 1988d) (Ground-water Guidance) details some of the key issues in development, evaluation, and selection of ground-water remedial actions at CERCLA sites.

- *CERCLA Compliance with Other Laws Manuals* (Part I, EPA 1988a; and Part II, EPA 1989a) (CERCLA Compliance Manuals) provide guidance for complying with ARARs. Part I addresses the Resource Conservation and Recovery Act (RCRA), the Clean Water Act (CWA), and the SDWA; Part II addresses the Clean Air Act (CAA), other federal statutes, and state requirements.

- *Methods for Evaluating the Attainment of Cleanup Standards (Volume 1: Soils and Solid Waste)* (EPA 1989e) and *Methods for Evaluating the Attainment of Cleanup Standards (Volume 2: Water)* (Draft, 1988, EPA, Statistical Policy Branch) (Attainment Guidance) provide guidance on evaluating the attainment of remediation levels, including appropriate sampling and statistical procedures to test whether the chemical concentrations are significantly below the remediation levels.

- *Interim Final Guidance on Preparing Superfund Decision Documents* (EPA 1989b) (ROD Guidance) provides guidance that: (1) presents standard formats for documenting CERCLA remedial action decisions; (2) clarifies the roles and responsibilities of EPA, states, and other federal agencies in developing and issuing decision documents; and (3) explains how to address changes made to proposed and selected remedies.

- *Catalog of Superfund Program Publications*, Chapter 5 (EPA 1990a) lists all ARARs guidance documents that have been issued by EPA, shown in order of date of issuance.

- *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (EPA 1991c) provides clarification on the role of the baseline risk assessment in developing and selecting CERCLA remedial alternatives.

- *Guidance for Data Useability in Risk Assessment* (EPA 1990b) (Data Useability Guidance) provides guidance on how to obtain a minimum level of quality for all environmental analytical data required for CERCLA risk assessments. It can assist with determining sample quantitation limits (SQLs) for chemical-specific analyses.

- *Guidance on Remedial Actions for Superfund Sites with PCB Contamination* (EPA 1990c) describes the recommended approach for evaluating and remediating CERCLA sites having PCB contamination.

- *Conducting Remedial Investigations/Feasibility Studies for CERCLA Municipal Landfill Sites* (EPA 1991a) (Municipal Landfill Guidance) offers guidance on how to streamline both the RI/FS and the selection of a remedy for municipal landfills.

1.5 MODIFICATION OF PRELIMINARY REMEDIATION GOALS

The initial list of PRGs may need to be revised as new data become available during the RI/FS. Therefore, upon completion of the baseline risk assessment, it is important to review the media and chemicals of potential concern, future land use, and exposure assumptions originally identified at scoping. Chemicals may be added or dropped from the list, and risk-based PRGs may need to be recalculated using site-specific exposure factors. PRGs that are modified based on the results of the baseline risk assessment must still meet the

"threshold criteria" of: (1) protection of human health and the environment and (2) compliance with ARARs. However, the NCP also allows for modification of PRGs during final remedy selection based on the "balancing" and "modifying" criteria and factors relating to uncertainty, exposure, and technical feasibility.

Final remediation levels are not determined until the site remedy is ready to be selected; final remediation levels are then set out in the ROD. PRGs are refined into final remediation goals throughout the process leading up to remedy selection. The ROD itself, however, should include a statement of final clean-up levels based on these goals, as noted in NCP section 300.430(e)(2)(i)(A). In the ROD, it is preferable to use the term "remediation level" rather than "remediation goal" in order to make clear that the selected remedy establishes binding requirements.

1.6 DOCUMENTATION AND COMMUNICATION OF PRELIMINARY REMEDIATION GOALS

Clear and concise communication of risk-based PRGs among the risk assessor, the RPM, the ARARs coordinator, site engineers, analytical chemists, hydrogeologists, and others is important in the development of PRGs. The involvement of the RPM in the direction and development of risk-based PRGs is important to ensure that communication is facilitated and that the PRGs are used effectively in streamlining the RI/FS process.

Because PRGs are most useful during the RI/FS (e.g., for streamlining the consideration of remedial alternatives), it is important to communicate them to site engineers as soon as possible. A memorandum from either the site risk assessor or the RPM to the site engineers and others concerned with PRGs would be appropriate for transmitting the initial PRGs. A brief cover page could highlight key assumptions, as well as changes, if any, to the standard equations (i.e., those presented in this guidance). Following this brief discussion, the PRGs could be presented using a table similar to that in Section 3.4 of this guidance.

The RI/FS Guidance recommends that "chemical- and/or risk-based remedial objectives associated with the alternative should be documented in the final RI/FS report to the extent possible." Therefore, the RI/FS report is a logical place to present PRGs that have been modified after the baseline risk assessment. A summary table such as the one developed in Section 3.4 of Part B could be incorporated into the RI/FS following the presentation of the baseline risk assessment. Along with the table, a discussion of issues of particular interest, such as assumptions used and the relationship between ARARs and risk-based PRGs at the site, could be included. Also, it is always appropriate to discuss how findings of the baseline risk assessment were incorporated into the calculation of PRGs.

1.7 ORGANIZATION OF DOCUMENT

The remainder of this guidance is organized into three additional chapters and two appendices. Chapter 2 discusses the initial identification of PRGs and provides guidance for modifying appropriate values during the RI/FS. Chapter 3 outlines equations that can be used to calculate risk-based PRGs for residential and commercial/industrial land uses. These equations are presented in both "reduced" format (i.e., incorporating certain default assumptions discussed in Chapter 2) and expanded format (i.e., with all variables included so that the user of this guidance can incorporate site-specific values). Particular considerations regarding radionuclides are provided in Chapter 4.

Appendix A supports several points made in Chapter 2 by providing illustrations of remedial alternatives where one or more chemicals "limit" remediation and, thus, represent a major portion of the residual risk. Appendix B lists equations for media-specific exposure pathways, enabling the risk assessor to derive site-specific equations that differ from those presented in Chapter 3.

Throughout Chapters 2, 3, and 4, case studies are presented that illustrate the process of determining PRGs. These case studies are contained in boxes with a shadow box appearance. Other types of boxed information (e.g., NCP quotes) is contained in boxes such as those in Chapter 1, which have thicker lines on the top and bottom than on the sides.

CHAPTER 2

IDENTIFICATION OF PRELIMINARY REMEDIATION GOALS

This chapter provides guidance on the initial identification of PRGs during the scoping phase of the RI/FS. As discussed in Chapter 1, medium-specific PRGs (ARAR-based and/or risk-based) should be identified during scoping for all chemicals of potential concern using readily available information. Sections are provided in this chapter on how to use this information to identify media and chemicals of potential concern, the most appropriate future land use, potential exposure pathways, toxicity information, potential ARARs, and risk-based PRGs. Finally, a section is provided on the modification of PRGs.

When using PRGs developed during scoping, the design engineers should understand that these may be modified significantly depending on information gathered about the site. The subsequent process of identifying key site contaminants, media, and other factors (i.e., during the baseline risk assessment) may require that the focus of the RI/FS be shifted (e.g., chemicals without ARARs may become more or less important). Thus, the design of remedial alternatives should remain flexible until the modified (i.e., more final) PRGs are available.

Prior to identifying PRGs during scoping, a conceptual site model should be developed (see the next box). Originally developed to aid in planning site activities (e.g., the RI/FS), the conceptual site model also contains information that is valuable for identifying PRGs. For example, it can be relied upon to identify which media and chemicals need PRGs. More information on developing and using a conceptual site model during the RI/FS process can be found in Chapter 2 of the RI/FS Guidance and Chapter 4 of RAGS/HHEM Part A.

To illustrate the process of calculating risk-based PRGs at the scoping stage of remediation, hypothetical CERCLA sites will be examined in boxes in appropriate sections throughout Chapters 2, 3, and 4. See the box on the next page for an introduction to the first site. (The radiation case study is addressed in Chapter 4.) The information (e.g., toxicity values) contained in these case studies is for illustration only, and should not be used for any other purpose. These case studies have been simplified (e.g., only ground water will be examined) so that the steps involved in developing risk-based PRGs can be readily discerned.

CONCEPTUAL SITE MODEL

During project planning, the RPM gathers and analyzes available information and develops the conceptual site model (also called the conceptual evaluation model). This model is used to assess the nature and the extent of contamination. It also identifies potential contaminant sources, potential exposure pathways, and potential human and/or environmental receptors. Further, this model helps to identify data gaps and assists staff in developing strategies for data collection. Site history and PA/SI data generally are extremely useful sources of information for developing this model. The conceptual site model should include known and suspected sources of contamination, types of contaminants and affected media, known and potential routes of migration, and known or potential human and environmental receptors.

2.1 MEDIA OF CONCERN

During scoping, the first step in developing PRGs is to identify the media of potential concern. The conceptual site model should be very useful for this step. These media can be either:

- currently contaminated media to which individuals may be exposed or through which chemicals may be transported to potential receptors; or

CASE STUDY: INTRODUCTION

The XYZ Co. site contains an abandoned industrial facility that is adjacent to a high-density residential neighborhood. Remnants of ~~drums, lagoons, and waste piles were found at~~ the site. Ground water in the area of the site is used by residents as a domestic water supply. There is also a small lake downgradient from the site that is used by some of the local residents for fishing and swimming.

- currently uncontaminated media that may become contaminated in the future due to contaminant transport.

Several important media often requiring direct remediation are ground water, surface water, soil, and sediment. Currently, only the first three of these media are discussed in this chapter and addressed by the equations provided in Chapters 3 and 4. If other media that may require the development of risk-based concentrations (e.g., sediments) are identified at scoping, appropriate equations for those media should be developed. Regional risk assessors should be consulted as early as possible to assist with this process.

CASE STUDY:

The PA/SI for the example site indicates that ground water beneath the site is contaminated. The source of this contamination appears to have been approximately 100 leaking drums of various chemicals that were buried in the soil but have since been removed. Lagoons and waste piles also may have contributed to the contamination. Thus, ground water and soil are media of concern.

Although evidence of lake water contamination was not found during the PA/SI, there is a reasonable possibility that it may become contaminated in the future due to contaminant transport either via ground-water discharge or surface water run-off. Thus, surface water (the lake) and sediments also may be media of concern.

2.2 CHEMICALS OF CONCERN

~~This step involves developing an initial~~ list of chemicals for which PRGs need to be developed. Chapters 4 and 5 of RAGS/HHEM Part A provide important additional information on identifying chemicals of potential concern for a site and should be consulted prior to development of the conceptual site model and PRGs at scoping.

~~Initially, the list of chemicals of potential concern should include any chemical reasonably expected to be of concern at the site based on what~~ is known during scoping. For example, important chemicals previously detected at the site, based on the PA/SI, the conceptual site model, or other prior investigations, generally should be included. In addition, the list may include chemicals that the site history indicates are likely to be present in significant quantities, even though they may not yet be detected. Sources of this latter type of information include records of chemicals used or disposed at the facility, and interviews with current or former employees. The list also may include chemicals that are probable degradation products of site contaminants where these are determined to be potential contributors of significant risk. An environmental chemist should be consulted for assistance in determining

2.3 FUTURE LAND USE

This step involves identifying the most appropriate future land use for the site so that the appropriate exposure pathways, parameters, and equations (discussed in the next section) can be used to calculate risk-based PRGs. RAGS/HHEM Part A (Chapter 6) and an EPA Office of Solid Waste and Emergency Response (OSWER) directive on the role of the baseline risk assessment in remedy selection decisions (EPA 1991b) provide additional guidance on identifying future land use. The standard default equations provided in Chapter 3 of Part B only address residential and commercial/industrial land uses. If land uses other than these are to be assumed (e.g., recreational), then exposure pathways, parameters,

CASE STUDY: IDENTIFY CHEMICALS OF CONCERN

The PA/SI for the XYZ Co. site identified the following seven chemicals in ground-water samples: benzene, ethylbenzene, hexane, isophorone, triallate, 1,1,2-trichloroethane, and vinyl chloride. Therefore, these chemicals are obvious choices for chemicals of potential concern.

Although not detected in any of the PA/SI samples, site history indicates that one other solvent — carbon tetrachloride — also was used in significant quantities by the facility that operated at the site. This chemical, therefore, is added to the list of chemicals of potential concern.

and equations will need to be developed for the others as well.

In general, residential areas should be assumed to remain residential. Sites that are surrounded by operating industrial facilities can be assumed to remain industrial areas unless there is an indication that this is not appropriate. Lacking site-specific information (e.g., at scoping), it may be appropriate to assume residential land use. This assumption will generally lead to conservative (i.e., lower concentration) risk-based PRGs. If not enough site-specific information is readily available at scoping to select one future land use over another, it may be appropriate to develop a separate set of risk-based PRGs for each possible land use.

When waste will be managed onsite, land-use assumptions and risk-based PRG development become more complicated because the assumptions for the site itself may be different from the land use in the surrounding area. For example, if waste is managed onsite in a residential area, the risk-based PRGs for the ground water beneath the site (or at the edge of the waste management unit) may be based on residential exposures, but the risk-based PRGs for the site soils may be based on an industrial land use with some management or institutional controls.

If a land-use assumption is used that is less conservative (i.e., leads to higher risk-based concentrations) than another, it generally will be necessary to monitor the future uses of that site. For example, if residential land use is not deemed to be appropriate for a particular site because local zoning laws prohibit residential development, any changes in local zoning would need to be monitored. Such considerations should be clearly documented in the site's ROD.

CASE STUDY: IDENTIFY FUTURE LAND USE

Based on established land-use trends, local renovation projects, and population growth projections in the area of the XYZ Co. site, the most reasonable future use of the land is determined to be residential use. Thus, site-specific information is sufficient to show that the generally more conservative assumption of residential land use should serve as the basis for development of risk-based PRGs.

2.4 APPLICABLE OR RELEVANT AND APPROPRIATE REQUIREMENTS

Chemical-specific ARARs are evaluated as PRGs because they are often readily available and provide a preliminary indication about the goals that a remedial action may have to attain. This step involves identifying all readily available chemical-specific potential ARARs for the chemicals of potential concern (for each medium and probable land use). Because at scoping it often is uncertain which potential ARAR is the most likely one to become the ARAR-based PRG, all potential ARARs should be included in a tabular summary (i.e., no potential ARAR should be discarded). If there is doubt about whether a value is a potential ARAR, and therefore whether it could be used as a PRG, it should be included at this stage.

This section summarizes the concept of ARARs and identifies the major types of ARARs, but provides only limited guidance on identifying the most appropriate (likely) ARAR of all possible ARARs to use as the chemical-specific PRG. More detailed information about the identification and evaluation of ARARs is available from two important sources:

- the NCP (see specifically 55 *Federal Register* 8741-8766 for a description of ARARs, and

8712-8715 for using ARARs as PRGs; see also 53 *Federal Register* 51394); and

- CERCLA Compliance Manuals (EPA 1988a and 1989a).

2.4.1 CHEMICAL-, LOCATION-, AND ACTION-SPECIFIC ARARs

The Agency has identified three general types of federal and state ARARs:

- chemical-specific, are usually health- or risk management-based numbers or methodologies that, when applied to site-specific conditions, result in the establishment of numerical values (e.g., chemical-specific concentrations in a given medium);

- location-specific, are restrictions placed upon the concentration of hazardous substances or the conduct of activities solely because they are in special locations (e.g., wetlands); and

- action-specific, are usually technology- or activity-based requirements or limitations on actions taken with respect to hazardous wastes.

This guidance primarily addresses only chemical-specific ARARs since it focuses on the identification of chemical-specific concentrations that represent target goals (e.g., PRGs) for a given medium.

2.4.2 SELECTION OF THE MOST LIKELY ARAR-BASED PRG FOR EACH CHEMICAL

This section briefly describes which, if any, of several potential ARAR values for a given chemical is generally selected as the most likely ARAR-based PRG (and therefore the most likely PRG at this point). Although the process for identifying the most likely ARAR-based PRG is specific to the medium, in general the process depends on two considerations: (1) the applicability of the ARAR to the site; and (2) the comparative stringency of the standards being evaluated. The previously cited documents should be carefully considered for specific recommendations on identifying ARARs.

Ground Water. SDWA maximum contaminant levels (MCLs), non-zero MCLGs, state drinking water standards, and federal water quality criteria (FWQC) are common ARARs (and, therefore, potential PRGs) for ground water. Other types of laws, such as state anti-degradation laws, may be PRGs if they are accompanied by allowable concentrations of a chemical. (Although state anti-degradation laws that are expressed as qualitative standards may also be potential ARARs, they generally would not be considered PRGs.)

As detailed in the NCP (see next box), the first step in identifying ground-water PRGs is to determine whether the ground water is a current or potential source of drinking water. If the aquifer is a potential source of drinking water, then potential ARARs generally will include the federal non-zero MCLG, MCL, or state drinking water standard, and the most stringent (i.e., the lowest concentration) is identified as the most likely ARAR-based PRG.

NCP ON GROUND-WATER GOALS
(NCP Preamble;
55 *Federal Register* 8717, March 8, 1990)

"Ground water that is not currently a drinking water source but is potentially a drinking water source in the future would be protected to levels appropriate to its use as a drinking water source. Ground water that is not an actual or potential source of drinking water may not require remediation to a 10^{-4} to 10^{-6} level (except when necessary to address environmental concerns or allow for other beneficial uses; . . .)."

If the aquifer is not a potential source of drinking water, then MCLs, MCLGs, state drinking water requirements, or other health-based levels generally are not appropriate as PRGs. Instead, environmental considerations (i.e., effects on biological receptors) and prevention of plume expansion generally determine clean-up levels. If an aquifer that is not a potential source of drinking water is connected to an aquifer that is a drinking water source, it may be appropriate to use PRGs to set clean-up goals for the point of interconnection.

For chemicals without MCLs, state standards, or non-zero MCLGs, the FWQC may be potentially relevant and appropriate for ground water when that ground water discharges to surface water that is used for fishing or shellfishing.

Surface Water. FWQC and state water quality standards (WQS) are common ARARs for surface water. An important determination for identifying ARARs and other criteria as potential PRGs for surface water is the current designated and future expected use of the water body. Because surface water potentially could serve many uses (e.g., drinking and fishing), several ARARs may be identified as potential PRGs for a chemical, with each ARAR corresponding to an identified use. A state WQS is generally the most likely ARAR for surface water unless a federal standard is more stringent.

If surface water is a current or potential source of drinking water, MCLs, state drinking water standards, non-zero MCLGs, and FWQC are potential ARARs. The analysis to determine which of these drinking water standards is the most likely ARAR-based PRG is the same as that conducted for ground water. An FWQC based on ingestion of water and fish might be an ARAR for surface water used for drinking.

If the designated or future expected use of surface water is fishing or shellfishing, and the state has not promulgated a WQS, an FWQC should be considered as a potential ARAR. The particular FWQC (i.e., for water and fish ingestion or fish ingestion alone) selected as the potential ARAR depends on whether exposure from one or both of the routes is likely to occur and, therefore, on the designated use of the water body. If other uses of the water are designated (e.g., swimming), a state WQS may be available.

Soil. In general, chemical-specific ARARs may not be available for soil. Certain states, however, have promulgated or are about to promulgate soil standards that may be ARARs and thus may be appropriate to use as PRGs. In addition, several EPA policies may be appropriate to use in developing PRGs (e.g., see EPA 1990c for guidance on PCB clean-up levels).

2.5 EXPOSURE PATHWAYS, PARAMETERS, AND EQUATIONS

This step is generally conducted for each medium and land-use combination and involves identifying the most appropriate (1) exposure pathways and routes (e.g., residential ingestion of drinking water), (2) exposure parameters (e.g., 2 liters/day of water ingested), and (3) equations (e.g., to incorporate intake). The equations include calculations of total intake from a given medium and are based on the identified exposure pathways and associated parameters. Information gathered in this step should be used to calculate risk-based PRGs using the default equations identified in Chapters 3 and 4. Site-specific equations can be derived if a different set of exposure pathways is identified for a particular medium; this option also is discussed in Chapters 3 and 4.

When risk-based concentrations are developed during scoping, readily available site-specific information may be adequate to identify and develop the exposure pathways, parameters, and equations (e.g., readily available information may indicate that the exposure duration should be 40 years instead of the standard default of 30 years). In the absence of readily available site-specific information, the standard default information in Chapters 3 and 4 generally should be used for the development of risk-based PRGs.

Exhibit 2-1 lists a number of the potential exposure pathways that might be present at a CERCLA site. The exposure pathways included in the medium-specific standard default equations (see Chapters 3 and 4) are italicized in this exhibit. Note that Chapters 3 and 4 may not address all of the exposure pathways of possible importance at a given CERCLA site. For example, the consumption of ground water that continues to be contaminated by soil leachate is not addressed. Guidance on goal-setting to address this exposure pathway is currently under development by EPA. In addition, the standard default equations do not address pathways such as plant and animal uptake of contaminants from soil with subsequent human ingestion. Under certain circumstances, these or other exposure pathways may present significant risks to human health. The standard default information, however, does address the quantifiable exposure pathways that are often significant contributors of risk for a particular medium and land use.

Chapters 3 and 4 show how exposures from several pathways are addressed in a single equation for a medium. For example, in the equation for ground water and surface water under the residential land-use assumption, the coefficients incorporate default parameter values for ingestion of drinking water and inhalation of volatiles during

EXHIBIT 2-1

TYPICAL EXPOSURE PATHWAYS BY MEDIUM FOR RESIDENTIAL AND COMMERCIAL/INDUSTRIAL LAND USES[a,b]

	Exposure Pathways, Assuming:	
Medium	Residential Land Use	Commercial/Industrial Land Use
Ground Water	***Ingestion from drinking***	Ingestion from drinking[d]
	Inhalation of volatiles	Inhalation of volatiles
	Dermal absorption from bathing	Dermal absorption
	Immersion - external[c]	
Surface Water	***Ingestion from drinking***	Ingestion from drinking[d]
	Inhalation of volatiles	Inhalation of volatiles
	Dermal absorption from bathing	Dermal absorption
	Ingestion during swimming	
	Ingestion of contaminated fish	
	Immersion - external[c]	
Soil	***Ingestion***	***Ingestion***
	Inhalation of particulates	***Inhalation of particulates***
	Inhalation of volatiles	***Inhalation of volatiles***
	Direct external exposure[c]	***Direct external exposure[c]***
	Exposure to ground water contaminated by soil leachate	Exposure to ground water contaminated by soil leachate
	Ingestion via plant uptake	Inhalation of particulates from trucks and heavy equipment
	Dermal absorption from gardening	

[a] Lists of land uses, media, and exposure pathways are not comprehensive.

[b] Exposure pathways included in RAGS/HHEM Part B standard default equations (Chapters 3 and 4) are italicized.

[c] Applies to radionuclides only.

[d] Because the NCP encourages protection of ground water to maximize its beneficial use, risk-based PRGs generally should be based on residential exposures once ground water is determined to be suitable for drinking. Similarly, when surface water will be used for drinking, general standards (e.g., ARARs) are to be achieved that define levels protective for the population at large, not simply worker populations. Residential exposure scenarios should guide risk-based PRG development for ingestion and other uses of potable water.

household water use. Full details of parameters used to develop each equation and a summary of the "reduced" standard default equations are provided in the text of these chapters.

Certain modifications of the default equations may be desirable or necessary. For example, if an exposure pathway addressed by an equation in Chapter 3 seems inappropriate for the site (e.g., because the water contains no volatiles and, therefore, inhalation of volatiles is irrelevant), or if information needed for a pathway (e.g., a chemical-specific inhalation slope factor [see Section 2.6]) is not readily available or derivable, then that pathway can be disregarded at this stage.

The decision about whether the risk assessor should collect site-specific human exposure pathway information (e.g., exposure frequency, duration, or intake rate data) is very important. There will frequently be methods available to gather such information, some of which are more expensive and elaborate than others. Determining whether the resulting data are reasonably representative of populations in the surrounding area, however, is often difficult. Collecting data by surveying those individuals most convenient or accessible to RPMs or risk assessors may not present a complete population exposure picture. In fact, poorly planned data gathering efforts may complicate the assessment process. For example, those surveyed may come to believe that their contributions will play a more meaningful role in the risk assessment than that planned by the risk assessors; this can result in significant demands on the risk assessor's time.

Before such data collection has begun, the risk assessor should determine, with the aid of screening analyses, what benefits are likely to result. Collection of the exposure data discussed in this section generally should not be attempted unless significant differences are likely to result in final reasonable maximum exposure (RME) risk estimates. If data collection is warranted, systematic and well-considered efforts that minimize biases in results should be undertaken. Estimates of future exposures are likely to rely heavily on conservative exposure assumptions. By definition, these assumptions will be unaffected by even the most extensive efforts to characterize current population activity.

At this stage, the risk assessor, site engineer, and RPM should discuss information concerning the absence or presence of important exposure pathways, because remediation goals should be designed for specific areas of the site that a particular remedy must address, and exposures expected for one area of the site may differ significantly from those expected in another area.

2.5.1 GROUND WATER/SURFACE WATER

The residential land-use default equations presented in Chapters 3 and 4 for ground water or surface water are based on ingestion of drinking water and inhalation of volatile (vapor phase) chemicals originating from the household water supply (e.g., during dish washing, clothes laundering, and showering).

Ingestion of drinking water is an appropriate pathway for all chemicals with an oral cancer slope factor or an oral chronic reference dose. For the purposes of this guidance, however, inhalation of volatile chemicals from water is considered routinely only for chemicals with a Henry's Law constant of 1×10^{-5} atm-m^3/mole or greater and with a molecular weight of less than 200 g/mole. Before determining inhalation toxicity values for a specific chemical (Section 2.6), it should be confirmed that the Henry's Law constant and molecular weight are in the appropriate range for inclusion in the inhalation pathway for water.

Default equations addressing industrial use of ground water are not presented. Because the NCP encourages protection of ground water to its maximum beneficial use, once ground water is determined to be suitable for drinking, risk-based PRGs generally should be based on residential exposures. Even if a site is located in an industrial area, the ground water underlying a site in an industrial area may be used as a drinking water source for residents several miles away due to complex geological interconnections.

2.5.2 SOIL

The residential land-use standard default equations for the soil pathway are based on exposure pathways of ingestion of chemicals in soil or dust. The industrial land-use equations are based on three exposure pathways: ingestion of soil and dust, inhalation of particulates, and inhalation of volatiles. Again, for the purposes of this guidance, inhalation of volatile chemicals is relevant only for chemicals with a Henry's Law constant of 1×10^{-5} atm-m^3/mole or greater and

with a molecular weight of less than 200 g/mole. For the inhalation pathways, in addition to toxicity information, several chemical- and site-specific values are needed. These values include molecular diffusivity, Henry's Law constant, organic carbon partition coefficient, and soil moisture content (see Chapter 3 for details).

CASE STUDY: IDENTIFY EXPOSURE PATHWAYS, PARAMETERS, AND EQUATIONS

For the potential residential land use identified at the XYZ Co. site, the contaminated ground water (one of several media of potential concern) appears to be an important source of future domestic water. Because site-specific information is not initially available to develop specific exposure pathways, parameters, and equations, the standard default assumptions and equations provided in Chapter 3 will be used to calculate risk-based PRGs. Exposure pathways of concern for ground water, therefore, are assumed to be ingestion of ground water as drinking water and inhalation of volatiles in ground water during household use.

2.6 TOXICITY INFORMATION

This step involves identifying readily available toxicity values for all of the chemicals of potential concern for given exposure pathways so that the appropriate slope factors (SFs; for carcinogenic effects) and reference doses (RfDs; for noncarcinogenic effects) are identified or derived for use in the site-specific equations or the standard default equations. Therefore, Chapter 7 of RAGS/HHEM Part A should be reviewed carefully before proceeding with this step.

The hierarchy for obtaining toxicity values for risk-based PRGs is essentially the same as that used in the baseline risk assessment. Briefly, Integrated Risk Information System (IRIS) is the primary source for toxicity information; if no verified toxicity value is available through IRIS, then Health Effects Assessment Summary Tables (HEAST) is the next preferred source. When the development of a toxicity value is required (and appropriate data are available), consultation with the Superfund Health Risk Assessment Technical Support Center is warranted. EPA staff can contact the Center by calling FTS-684-7300 (513-569-7300) or by FAX at FTS-684-7159 (513-569-7159). Others must fax to the above number or write to:

Superfund Health Risk Technical Support Center
Environmental Criteria and Assessment Office
U.S. Environmental Protection Agency
Mail Stop 114
26 West Martin Luther King Drive
Cincinnati, Ohio 45268

Other toxicity information that should be obtained includes EPA's weight-of-evidence classification for carcinogens (e.g., A, B1) and the source of the information (e.g., IRIS, HEAST).

Note that throughout this document, the term hazard index (HI) is used to refer to the risk level associated with noncarcinogenic effects. An HI is the sum of two or more hazard quotients (HQs). An HQ is the ratio of an exposure level of a single substance to the RfD for that substance. Because RfDs are generally exposure pathway-specific (e.g., inhalation RfD), the HQ is a single substance/ single exposure pathway ratio. An HI, on the other hand, is usually either a single substance/ multiple exposure pathway ratio, a multiple substance/single exposure pathway ratio, or a multiple substance/multiple exposure pathway ratio. In this document, however, only one exposure pathway is included in the default equation for some land-use and medium combinations (e.g., residential soil). In order to remain consistent, the term HI has been used throughout RAGS/HHEM Part B, even though for such a pathway, the term HQ could apply.

2.7 TARGET RISK LEVELS

This step involves identifying target risk concentrations for chemicals of potential concern. The standard default equations presented in Chapters 3 and 4 are based on the following target risk levels for carcinogenic and noncarcinogenic effects.

- For carcinogenic effects, a concentration is calculated that corresponds to a 10^{-6} incremental risk of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen from all significant exposure pathways for a given medium.

CASE STUDY: IDENTIFY TOXICITY INFORMATION[a]

Reference toxicity values for cancer and noncancer effects (i.e., SFs and RfDs, respectively) are required for chemicals without ARAR-based PRGs (only the case study chemicals without ARARs are listed here). Considering the ground-water medium only, ingestion and inhalation are exposure pathways of concern. Toxicity information is obtained from IRIS and HEAST, and is shown in the table below.

Chemical	RfD (mg/kg-day)	Source	SF $(mg/kg\text{-}day)^{-1}$	Weight of Evidence	Source
EXPOSURE ROUTE: INGESTION					
Hexane	0.06	HEAST	—	—	—
Isophorone	0.2	IRIS	0.0039	C	HEAST
Triallate	0.013	IRIS	—	—	—
EXPOSURE ROUTE: INHALATION					
Hexane	0.04	HEAST	—	—	—
Isophorone	—	—	—	C	HEAST
Triallate	—	—	—	—	—

[a] All information in this example is for illustration purposes only.

- For noncarcinogenic effects, a concentration is calculated that corresponds to an HI of 1, which is the level of exposure to a chemical from all significant exposure pathways in a given medium below which it is unlikely for even sensitive populations to experience adverse health effects.

At scoping, it generally is appropriate to use the standard default target risk levels described above and discussed in the NCP. That is, an appropriate point of departure for remediation of carcinogenic risk is a concentration that corresponds to a risk of 10^{-6} for one chemical in a particular medium. For noncarcinogenic effects, the NCP does not specify a range, but it generally is appropriate to assume an HI equal to 1.

2.8 MODIFICATION OF PRELIMINARY REMEDIATION GOALS

Upon completion of the baseline risk assessment (or as soon as data are available), it is important to review the future land use, exposure assumptions, and the media and chemicals of potential concern originally identified at scoping, and determine whether PRGs need to be modified. Modification may involve adding or subtracting chemicals of concern, media, and pathways or revising individual chemical-specific goals.

2.8.1 REVIEW OF ASSUMPTIONS

Media of Concern. As a guide to determining the media and chemicals of potential concern, the OSWER directive *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (EPA 1991c) indicates that action is generally warranted at a site when the cumulative carcinogenic risk is greater than 10^{-4} or the cumulative noncarcinogenic HI exceeds 1 based on RME assumptions. Thus, where the baseline risk assessment indicates that either the cumulative current or future risk associated with a medium is greater than 10^{-4} or that the HI is greater than 1, that medium presents a concern, and it generally is appropriate to maintain risk-based PRGs for contaminants in that medium or develop risk-based PRGs for additional media where PRGs are not clearly defined by ARARs.

When the cumulative current or future baseline cancer risk for a medium is within the range of 10^{-6} to 10^{-4}, a decision about whether or not to take action is a site-specific determination. Generally, risk-based PRGs are not needed for any chemicals in a medium with a cumulative cancer risk of less than 10^{-6}, where an HI is less than or

equal to 1, or where the PRGs are clearly defined by ARARs. However, there may be cases where a medium appears to meet the protectiveness criterion but contributes to the contamination of another medium (e.g., soil contributing to groundwater contamination). In these cases, it may be appropriate to modify existing or develop new risk-based PRGs for chemicals of concern in the first medium, assuming that fate and transport models can adequately predict the impacts of concern on other media. EPA is presently developing guidance on quantifying the impact of soil contamination on underlying aquifers.

Chemicals of Concern. As with the initial media of potential concern, the initial list of specific chemicals of potential concern in a given medium may need to be modified to reflect increased information from the RI/FS concerning the importance of the chemicals to the overall site risk. Chemicals detected during the RI/FS that were not anticipated during scoping should be considered for addition to the list of chemicals of potential concern; chemicals anticipated during scoping that were not detected during the RI/FS should be deleted from the list. Ultimately, the identity and number of contaminants that may require risk-based PRGs depends both on the results of the baseline risk assessment and the extent of action required, given site-specific circumstances.

Following the baseline risk assessment, any chemical that has an associated cancer risk (current or future) within a medium of greater than 10^{-6} or an HI of greater than 1 should remain on the list of chemicals of potential concern for that medium. Likewise, chemicals that present cancer risks of less than 10^{-6} generally should not be retained on the list unless there are significant concerns about multiple contaminants and pathways.

Land Use. After the RI/FS, one future land use can usually be selected based on the results of the baseline risk assessment and discussions with the RPM. In many cases, this land use will be the same as the land use identified at scoping. In other cases, however, additional information from the baseline risk assessment that was not available at scoping may suggest modifying the initial land-use and exposure assumptions. A qualitative assessment should be made — and should be available from the baseline risk assessment — of the likelihood that the assumed future land use will occur.

Exposure Pathways, Parameters, and Equations. For exposure pathways, this process of modifying PRGs consists of adding or deleting exposure pathways from the medium-specific equations in Chapters 3 and 4 to ensure that the equation accounts for all significant exposure pathways associated with that medium at the site. For example, the baseline risk assessment may indicate that dermal exposure to contaminants in soil is a significant contributor to site risk. In this case, the risk-based PRGs may be modified by adding equations for dermal exposure. EPA policy on assessing this pathway is currently under development; the risk assessor should consult the Superfund Health Risk Technical Support Center (FTS-684-7300 or 513-569-7300) to determine the current status of guidance. Likewise, when appropriate data (e.g., on exposure frequency and duration) have been collected during the RI/FS, site-specific values can be substituted for the default values in the medium-specific equations.

2.8.2 IDENTIFICATION OF UNCERTAINTIES

The uncertainty assessment for PRGs can serve as an important basis for recommending further modifications to the PRGs prior to setting final remediation goals. It also can be used during the post-remedy assessment (see Section 2.8.4) to identify areas needing particular attention.

Risk-based PRGs are associated with varied levels of uncertainty, depending on many factors (e.g., confidence that anticipated future land use is correct). To place risk-based PRGs that have been developed for a site in proper perspective, an assessment of the uncertainties associated with the concentrations should be conducted. This assessment is similar to the uncertainty assessment conducted during the baseline risk assessment (see RAGS/HHEM Part A, especially Chapters 6, 7, and 8). In fact, much of the uncertainty assessment conducted for a site's baseline risk assessment will be directly applicable to the uncertainty assessment of the risk-based PRGs.

In general, each component of risk-based PRGs discussed in this chapter — from media of potential concern to target risk level — should be examined, and the major areas of uncertainty highlighted. For example, the uncertainty

associated with the selected future land use should be discussed. Furthermore, the accuracy of the technical models used (e.g., for volatilization of contaminants from soil) to reflect site-specific conditions (present and future) should be discussed. If site-specific exposure assumptions have been made, it is particularly important to document the data supporting those assumptions and to assess their relevance for potentially exposed populations.

As the chemical- and medium-specific PRGs are developed, many assumptions regarding the RME individual(s) are incorporated. Although PRGs are believed to be fully protective for the RME individual(s), the proximity of other nearby sources of exposure (e.g., other CERCLA sites, RCRA facilities, naturally occurring background contamination) and/or the existence of the same contaminants in multiple media or of multiple chemicals affecting the same population(s), may lead to a situation where, even after attainment of all PRGs, protectiveness is not clearly achieved (e.g., cumulative risks may fall outside the risk range). The more likely it is that multiple contaminants, pathways, operable units, or other sources of toxicants will affect the RME individual(s), the more likely it will be that protectiveness is not achieved. This likelihood should be addressed when identifying uncertainties.

2.8.3 OTHER CONSIDERATIONS IN MODIFYING PRGs

The NCP preamble and rule state that factors related to exposure, technical limitations, and uncertainty should be considered when modifying PRGs (see next two boxes) and setting final remediation levels.

While the final remedial action objectives must satisfy the original "threshold criteria" of protection of human health and the environment and compliance with ARARs, the factors in the "balancing and modifying criteria" (listed in Section 1.3.2) also are considered in the detailed analysis for choosing among remedial alternatives. In cases where the alternative that represents the best balance of factors is not able to attain cancer risks within the risk range or an HI of 1, institutional controls may be used to supplement treatment and/or containment-based remedial action to ensure protection of human health and the environment.

NCP PREAMBLE: EXPOSURE, TECHNICAL, AND UNCERTAINTY FACTORS
(55 *Federal Register* 8717, March 8, 1990)

"Preliminary remediation goals ... may be revised ... based on the consideration of appropriate factors including, but not limited to: exposure factors, uncertainty factors, and technical factors. Included under exposure factors are: cumulative effect of multiple contaminants, the potential for human exposure from other pathways at the site, population sensitivities, potential impacts on environmental receptors, and cross-media impacts of alternatives. Factors related to uncertainty may include: the reliability of alternatives, the weight of scientific evidence concerning exposures and individual and cumulative health effects, and the reliability of exposure data. Technical factors may include: detection/quantification limits for contaminants, technical limitations to remediation, the ability to monitor and control movement of contaminants, and background levels of contaminants. The final selection of the appropriate risk level is made when the remedy is selected based on the balancing of criteria...."

NCP RULE: EXPOSURE, TECHNICAL, AND UNCERTAINTY FACTORS
(40 CFR 300.430(e)(2)(i))

"(i)...Remediation goals...shall be developed by considering the following:

"(A) Applicable or relevant and appropriate requirements...and the following factors:

"(*1*) For systemic toxicants, acceptable exposure levels...;

"(*2*) For known or suspected carcinogens, acceptable exposure levels...;

"(*3*) Factors related to technical limitations such as detection/quantification limits for contaminants;

"(*4*) Factors related to uncertainty; and

"(*5*) Other pertinent information."

Note that in the absence of ARARs, the 10^{-6} cancer risk "point of departure" is used as a starting point for analysis of remedial alternatives, which reflects EPA's preference for managing risks at the more protective end of the risk range, other things being equal. Use of "point of departure" target risks in this guidance does not reflect a presumption that the final remedial action should attain such goals. (See NCP preamble, 55 *Federal Register* 8718-9.)

2.8.4 POST-REMEDY ASSESSMENT

To ensure that protective conditions exist after the remedy achieves all individual remediation levels set out in the ROD, there generally will be a site-wide evaluation conducted following completion of a site's final operable unit (e.g., during the five-year review). This site-wide evaluation should adequately characterize the residual contaminant levels and ensure that the post-remedy cumulative site risk is protective. More detailed guidance on the post-remedy assessment of site "protectiveness" is currently under development by EPA.

CHAPTER 3

CALCULATION OF RISK-BASED PRELIMINARY REMEDIATION GOALS

This chapter presents standardized exposure parameters, the derivation of risk equations, and the corresponding "reduced" equations, for calculating risk-based PRGs at scoping for the media and land-use assumptions discussed in Chapter 2 (i.e., ground water, surface water, and soil for residential land use, and soil for commercial/industrial land use). Both carcinogenic and noncarcinogenic effects are addressed. Standardized default exposure parameters consistent with OSWER Directive 9285.6-03 (EPA 1991b) are used in this chapter; where default parameters are not available in that guidance, the references used are cited. If other media requiring risk-based PRGs are identified during the RI/FS, or other exposure parameters or land uses are assumed, then appropriate equations will need to be modified or new ones developed.

Risk-based equations have been derived in order to reflect the potential risk from exposure to a chemical, given a specific pathway, medium, and land-use combination. By setting the total risk for carcinogenic effects at a target risk level of 10^{-6} (the NCP's point of departure for analysis of remedial alternatives), it is possible to solve for the concentration term (i.e., the risk-based PRG). The total risk for noncarcinogenic effects is set at an HI of 1 for each chemical in a particular medium. Full equations with pathway-specific default exposure factors are presented in boxes with uniformly thin borders. Reduced equations are presented in the standard boxes (i.e., thicker top and bottom borders). At the end of this chapter, the case study that began in Chapter 2 is concluded (by showing how to calculate and present risk-based PRGs).

In general, the equations described in this chapter are sufficient for calculating the risk-based PRGs at the scoping stage of the RI/FS. Note, however, that <u>these equations are based on standard default assumptions that may or may not reflect site-specific conditions</u>. When risk-based PRGs are to be calculated based on site-specific conditions, the risk assessor should modify the full equations, and/or develop additional ones. Risk equations for individual exposure pathways for a given medium are presented in Appendix B of this document, and may be used to develop and/or modify the full equations. (See the introduction to Appendix B for more detailed instructions.)

Before examining the calculation of risk-based PRGs, several important points should be noted:

- Use of toxicity values in the equations as written currently assumes 100 percent absorption effeciency. That is, for the sake of simplicity at scoping, it is assumed that the dose administered to test animals in toxicity studies on which toxicity values are based was fully absorbed. This assumption may need to be revised in cases where toxicity values based on route-to-route extrapolation are used, or there are significant differences in absorption likely between contaminants in site media and the contaminants in the vehicle used in the toxicity study. Chapter 7 and Appendix A in RAGS/HHEM Part A (EPA 1989d) provide additional details on this point.

- The risk-based PRGs should contain at most two significant figures even though some of the parameters used in the reduced equations carry additional significant figures.

- The equations presented in this chapter calculate risk-based concentrations using inhalation reference doses (RfD_is) and inhalation slope factors (SF_is). If only the reference concentration (RfC) and/or inhalation unit risk are available for a particular compound in IRIS, conversion to an RfD_i and/or SF_i will be necessary. Many converted toxicity values are available in HEAST.

- <u>All</u> standard equations presented here incorporate pathway-specific default exposure

factors that generally reflect RME conditions. As detailed in Chapter 8 of RAGS/HHEM Part A (in the discussion on combining pathway risks [Section 8.3]), RME risks from one pathway should be combined with RME risks from another pathway only where there is good reason. Typically, RME from one pathway is not likely to occur with RME from another (unless there is a strong logical dependent relationship between exposures from the two pathways). If risk-based concentrations are developed for both the water and the soil pathways, the risk assessor ultimately may need to adjust exposure assumptions from one pathway (i.e., the one with the lower RME) to less conservative (more typical) values.

3.1 RESIDENTIAL LAND USE

3.1.1 GROUND WATER OR SURFACE WATER

Under residential land use, risk from surface water or ground-water contaminants is assumed to be due primarily to direct ingestion and to inhalation of volatiles from household water use. Therefore, only these exposure pathways are considered in this section. Additional exposure pathways (e.g., dermal absorption) are possible and may be significant at some sites for some contaminants, while perhaps only one exposure pathway (e.g., direct ingestion of water only) may be relevant at others. In any case, the risk-based PRG for each chemical should be calculated by considering all of the relevant exposure pathways.

In the case illustrated here, risks from two exposure pathways from ground water or surface water are combined, and the risk-based concentration is derived to be protective for exposures from both pathways. Default risk from ground water or surface water would be calculated as follows ("total" risk, as used below, refers to the combined risk for a single chemical from all exposure pathways for a given medium):

Total risk from water	=	Risk from ingestion of water (adult)	+	Risk from inhalation of volatiles from household water (adult)

At scoping, risk from indoor inhalation of volatiles is assumed to be relevant only for chemicals that easily volatilize. Thus, the risk equation incorporates a water-air concentration relationship that is applicable only to chemicals with a Henry's Law constant of greater than 1 x 10^{-5} atm-m^3/mole <u>and</u> a molecular weight of less than 200 g/mole. These criteria are <u>not</u> used to screen out chemicals that are not of potential concern for this exposure pathway but only to identify those that generally <u>should</u> be considered for the inhalation pathway when developing risk-based PRGs early in the process. Chemicals that do not meet these criteria may pose significant site risks (and require risk-based goals) through volatiles inhalation. The ultimate decision regarding which contaminants should be considered in the FS must be made on a site-specific basis following completion of the baseline risk assessment.

Based primarily on experimental data on the volatilization of radon from household uses of water, Andelman (1990) derived an equation that defines the relationship between the concentration of a contaminant in household water and the average concentration of the volatilized contaminant in air. In the derivation, all uses of household water were considered (e.g., showering, laundering, dish washing). The equation uses a default "volatilization" constant (K) upper-bound value of 0.0005 x 1000 L/m^3. (The 1000 L/m^3 conversion factor is incorporated into the equation so that the resulting air concentration is expressed in mg/m^3.) Certain assumptions were made in deriving the default constant K (Andelman 1990). For example, it is assumed that the volume of water used in a residence for a family of four is 720 L/day, the volume of the dwelling is 150,000 L and the air exchange rate is 0.25 m^3/hr. Furthermore, it is assumed that the average transfer efficiency weighted by water use is 50 percent (i.e., half of the concentration of each chemical in water will be transfered into air by all water uses [the range extends from 30% for toilets to 90% for dishwashers]). See the Andelman paper for further details.

Concentrations Based on Carcinogenic Effects. Total risk for carcinogenic effects of certain volatile chemicals would be calculated by combining the appropriate inhalation and oral SFs with the two intakes from water:

Total risk	=	SF_o x	Intake from ingestion of water	+	SF_i x	Intake from inhalation of volatiles from water

Adding appropriate parameters, and then rearranging the equation to solve for concentration, results in Equation (1).

Equation (1′) on the next page is the reduced version of Equation (1) using the standard default parameters, and is used to calculate the risk-based PRG at a prespecified cancer risk level of 10^{-6}. It combines the toxicity information of a chemical with standard default exposure parameters for residential land use to generate the concentration of that chemical that corresponds to a 10^{-6} carcinogenic risk level due to that chemical. If either the SF_o or SF_i in Equation (1′) is not available for a particular chemical, the term containing that variable in the equation can be ignored or equated to zero (e.g., for a chemical that does not have SF_i, the term $7.5(SF_i)$ in Equation (1′) is ignored). <u>If any of the default parameter values are changed to reflect site-specific conditions, the reduced equation cannot be used</u>.

RESIDENTIAL WATER — CARCINOGENIC EFFECTS

$$TR = \frac{SF_o \times C \times IR_w \times EF \times ED}{BW \times AT \times 365\ \text{days/yr}} + \frac{SF_i \times C \times K \times IR_a \times EF \times ED}{BW \times AT \times 365\ \text{days/yr}}$$

$$= \frac{EF \times ED \times C \times [(SF_o \times IR_w) + (SF_i \times K \times IR_a)]}{BW \times AT \times 365\ \text{days/yr}}$$

$$C\ (\text{mg/L; risk-based}) = \frac{TR \times BW \times AT \times 365\ \text{days/yr}}{EF \times ED \times [(SF_i \times K \times IR_a) + (SF_o \times IR_w)]} \qquad (1)$$

where:

Parameters	Definition (units)	Default Value
C	chemical concentration in water (mg/L)	—
TR	target excess individual lifetime cancer risk (unitless)	10^{-6}
SF_i	inhalation cancer slope factor ($(\text{mg/kg-day})^{-1}$)	chemical-specific
SF_o	oral cancer slope factor ($(\text{mg/kg-day})^{-1}$)	chemical-specific
BW	adult body weight (kg)	70 kg
AT	averaging time (yr)	70 yr
EF	exposure frequency (days/yr)	350 days/yr
ED	exposure duration (yr)	30 yr
IR_a	daily indoor inhalation rate (m^3/day)	15 m^3/day
IR_w	daily water ingestion rate (L/day)	2 L/day
K	volatilization factor (unitless)	0.0005 x 1000 L/m^3 (Andelman 1990)

REDUCED EQUATION: RESIDENTIAL WATER — CARCINOGENIC EFFECTS

$$\text{Risk-based PRG (mg/L; TR} = 10^{-6}) = \frac{1.7 \times 10^{-4}}{2(SF_o) + 7.5(SF_i)} \qquad (1')$$

where:

SF_o = oral slope factor in $(\text{mg/kg-day})^{-1}$
SF_i = inhalation slope factor in $(\text{mg/kg-day})^{-1}$

Concentrations Based on Noncarcinogenic Effects. Total HI would be calculated by combining the appropriate oral and inhalation RfDs with the two intakes from water:

$$HI = \frac{\text{Intake from oral ingestion}}{RfD_o} + \frac{\text{Intake from inhalation}}{RfD_i}$$

Adding appropriate parameters, and then rearranging the equation to solve for concentration, results in Equation (2).

Equation (2′) on the next page is the reduced version of Equation (2) using the standard default parameters, and is used to calculate the risk-based PRG at a prespecified HI of 1. It combines the toxicity information of a chemical with standard exposure parameters for residential land use to generate the concentration of that chemical that corresponds to an HI of 1. If either the RfD_o or RfD_i in Equation (2′) is not available for a particular chemical, the term containing that variable in the equation can be ignored or equated to zero (e.g., for a chemical that does not have RfD_i, the term $7.5/RfD_i$ in Equations (2′) is ignored).

RESIDENTIAL WATER — NONCARCINOGENIC EFFECTS

$$THI = \frac{C \times IR_w \times EF \times ED}{RfD_o \times BW \times AT \times 365\ \text{days/yr}} + \frac{C \times K \times IR_a \times EF \times ED}{RfD_i \times BW \times AT \times 365\ \text{days/yr}}$$

$$= \frac{EF \times ED \times C \times [(1/RfD_o \times IR_w) + (1/RfD_i \times K \times IR_a)]}{BW \times AT \times 365\ \text{days/yr}}$$

$$C\ (\text{mg/L; risk-based}) = \frac{THI \times BW \times AT \times 365\ \text{days/yr}}{EF \times ED \times [(1/RfD_i \times K \times IR_a) + (1/RfD_o \times IR_w)]} \qquad (2)$$

where:

Parameters	Definition	Default Value
C	chemical concentration in water (mg/L)	—
THI	target hazard index (unitless)	1
RfD_o	oral chronic reference dose (mg/kg-day)	chemical-specific
RfD_i	inhalation chronic reference dose (mg/kg-day)	chemical-specific
BW	adult body weight (kg)	70 kg
AT	averaging time (yr)	30 yr (for noncarcinogens, equal to ED)
EF	exposure frequency (days/yr)	350 days/yr
ED	exposure duration (yr)	30 yr
IR_a	daily indoor inhalation rate (m^3/day)	15 m^3/day
IR_w	daily water ingestion rate (L/day)	2 L/day
K	volatilization factor (unitless)	0.0005 x 1000 L/m^3 (Andelman 1990)

REDUCED EQUATION: RESIDENTIAL WATER — NONCARCINOGENIC EFFECTS

$$\text{Risk-based PRG (mg/L; THI = 1)} = \frac{73}{[7.5/RfD_i + 2/RfD_o]} \qquad (2')$$

where:

RfD_o = oral chronic reference dose in mg/kg-day
RfD_i = inhalation chronic reference dose in mg/kg-day

3.1.2 SOIL

Under residential land use, risk of the contaminant from soil is assumed to be due to direct ingestion of soil only.

Total risk from soil = Risk from ingestion of soil (child to adult)

Because the soil ingestion rate is different for children and adults, the risk due to direct ingestion of soil is calculated using an age-adjusted ingestion factor. The age-adjusted soil ingestion factor ($IF_{soil/adj}$) takes into account the difference in daily soil ingestion rates, body weights, and exposure durations for two exposure groups — children of one to six years and others of seven to 31 years. Exposure frequency (EF) is assumed to be identical for the two exposure groups. For convenience, this factor is calculated separately as a time-weighted soil intake, normalized to body weight, that can then be substituted in the total intake equation. Calculated in this manner, the factor leads to a more protective risk-based concentration compared to an adult-only assumption. Note that the ingestion factor is in units of mg-yr/kg-day, and therefore is not directly comparable to daily soil intake rate in units of mg/kg-day. See the box containing Equation (3) for the calculation of this factor.

Additional exposure pathways (e.g., inhalation of particulates, inhalation of volatiles, ingestion of foodcrops contaminated through airborne particulate deposits, consumption of ground water contaminated by soil leachate) are possible at some sites. The risk assessor should evaluate whether inhalation or other exposure pathways are significant at the site. Generally, for many undisturbed sites with vegetative cover such as those found in areas of residential land use, air pathways are relatively minor contributors of risk. Greater concern for baseline risk via air pathways exists under commercial/industrial land-use assumptions, given the increased activity levels likely (see Section 3.2.2). Air pathway risks also tend to be major concerns during remedial action (see RAGS/HHEM Part C). If these other pathways are known to be significant at scoping, Appendix B and/or other information should be used to develop site-specific equations for the risk-based PRGs.

Concentrations Based on Carcinogenic Effects. Total risk for carcinogenic effects would be calculated by combining the appropriate oral SF with the intake from soil:

Total risk = SF_o x Intake from ingestion of soil

Adding appropriate parameters, and then rearranging the equation to solve for concentration, results in Equation (4).

Equation (4′) below is the reduced version of Equation (4) using the standard default parameters, and is used to calculate the risk-based PRG at a prespecified cancer risk level of 10^{-6}. It combines the toxicity information of a chemical with standard exposure parameters for residential land use to generate the concentration of that chemical that corresponds to a 10^{-6} carcinogenic risk level due to that chemical.

AGE-ADJUSTED SOIL INGESTION FACTOR

$$IF_{soil/adj}\ (\text{mg-yr/kg-day}) = \frac{IR_{soil/age1\text{-}6} \times ED_{age1\text{-}6}}{BW_{age1\text{-}6}} + \frac{IR_{soil/age7\text{-}31} \times ED_{age7\text{-}31}}{BW_{age7\text{-}31}} \qquad (3)$$

Parameter	Definition	Default Value
$IF_{soil/adj}$	age-adjusted soil ingestion factor (mg-yr/kg-day)	114 mg-yr/kg-day
$BW_{age1\text{-}6}$	average body weight from ages 1-6 (kg)	15 kg
$BW_{age7\text{-}31}$	average body weight from ages 7-31 (kg)	70 kg
$ED_{age1\text{-}6}$	exposure duration during ages 1-6 (yr)	6 yr
$ED_{age7\text{-}31}$	exposure duration during ages 7-31 (yr)	24 yr
$IR_{soil/age1\text{-}6}$	ingestion rate of soil age 1 to 6 (mg/day)	200 mg/day
$IR_{soil/age7\text{-}31}$	ingestion rate of soil all other ages (mg/day)	100 mg/day

RESIDENTIAL SOIL — CARCINOGENIC EFFECTS

$$TR = \frac{SF_o \times C \times 10^{-6}\ kg/mg \times EF \times IF_{soil/adj}}{AT \times 365\ days/yr}$$

$$C\ (mg/kg;\ risk\text{-}based) = \frac{TR \times AT \times 365\ days/year}{SF_o \times 10^{-6}\ kg/mg \times EF \times IF_{soil/adj}} \quad (4)$$

where:

Parameters	Definition (units)	Default Value
C	chemical concentration in soil (mg/kg)	—
TR	target excess individual lifetime cancer risk (unitless)	10^{-6}
SF_o	oral cancer slope factor ($(mg/kg\text{-}day)^{-1}$)	chemical-specific
AT	averaging time (yr)	70 yr
EF	exposure frequency (days/yr)	350 days/yr
$IF_{soil/adj}$	age-adjusted ingestion factor (mg-yr/kg-day)	114 mg-yr/kg-day (see Equation (3))

REDUCED EQUATION: RESIDENTIAL SOIL — CARCINOGENIC EFFECTS

$$\text{Risk-based PRG } (mg/kg;\ TR = 10^{-6}) = \frac{0.64}{SF_o} \quad (4')$$

where:

SF_o = oral slope factor in $(mg/kg\text{-}day)^{-1}$

Concentrations Based on Noncarcinogenic Effects. Total HI would be calculated by combining the appropriate oral RfD with the intake from soil:

$$HI = \frac{\text{Intake from ingestion}}{RfD_o}$$

Adding appropriate parameters, and then rearranging the equation to solve for concentration, results in Equation (5).

Equation (5′) is the reduced version of Equation (5) using the standard default parameters, and is for calculating the risk-based PRG at a prespecified HI of 1. It combines the toxicity information of a chemical with standard exposure parameters for residential land use to generate the concentration of that chemical that corresponds to an HI of 1.

3.2 COMMERCIAL/INDUSTRIAL LAND USE

3.2.1 WATER

Once ground water is determined to be suitable for drinking, risk-based concentrations should be based on residential exposures. This is because the NCP seeks to require protection of ground water to allow for its maximum beneficial use (see Section 2.3). Thus, under the commercial/industrial land-use scenario, risk-based PRGs for ground water are calculated according to procedures detailed in Section 3.1.1. Similarly, for surface water that is to be used for drinking, the risk-based PRGs should be calculated for residential populations, and not simply worker populations.

RESIDENTIAL SOIL — NONCARCINOGENIC EFFECTS

$$THI = \frac{C \times 10^{-6}\ kg/mg \times EF \times IF_{soil/adj}}{RfD_o \times AT \times 365\ days/yr}$$

$$C\ (mg/kg;\ risk\text{-}based) = \frac{THI \times AT \times 365\ days/yr}{1/RfD_o \times 10^{-6}\ kg/mg \times EF \times IF_{soil/adj}} \quad (5)$$

where:

Parameters	Definition (units)	Default Value
C	chemical concentration in soil (mg/kg)	—
THI	target hazard index (unitless)	1
RfD_o	oral chronic reference dose (mg/kg-day)	chemical-specific
AT	averaging time (yr)	30 yr (for noncarcinogens, equal to ED [which is incorporated in $IF_{soil/adj}$])
EF	exposure frequency (days/yr)	350 days/yr
$IF_{soil/adj}$	age-adjusted ingestion factor (mg-yr/kg-day)	114 mg-yr/kg-day (see Equation (3))

REDUCED EQUATION: RESIDENTIAL SOIL — NONCARCINOGENIC EFFECTS

$$Risk\text{-}based\ PRG\ (mg/kg;\ THI = 1) = 2.7 \times 10^5\ (RfD_o) \quad (5')$$

where:

RfD_o = oral chronic reference dose in mg/kg-day

3.2.2 SOIL

Under commercial/industrial land use, risk of the contaminant from soil is assumed to be due to direct ingestion, inhalation of volatiles from the soil, and inhalation of particulates from the soil, and is calculated for an adult worker only. For this type of land use, it is assumed for calculating default risk-based PRGs that there is greater potential for use of heavy equipment and related traffic in and around contaminated soils and thus greater potential for soils to be disturbed and produce particulate and volatile emissions than in most residential land-use areas. Additional exposure pathways (e.g., dermal exposure) are possible at some sites, while perhaps only one exposure pathway (e.g., direct ingestion of soil only) may be relevant at others; Appendix B may be used to identify relevant exposure pathways to be combined. In such cases, the risk is calculated by considering all the relevant exposure pathways identified in the RI.

In the default case illustrated below, intakes from the three exposure pathways are combined and the risk-based PRG is derived to be protective for exposures from all three pathways. In this case, the risk for a specific chemical from soil due to the three exposure pathways would be calculated as follows:

Total risk from soil = Risk from ingestion of soil (worker)
+ Risk from inhalation of volatiles from soil (worker)
+ Risk from inhalation of particulates from soil (worker)

It is possible to consider only exposure pathways of site-specific importance by deriving a site-specific risk-based PRG (e.g., using the equations in Appendix B).

Concentrations Based on Carcinogenic Effects. Total risk for carcinogenic effects would be calculated by combining the appropriate inhalation and oral SFs with the three intakes from soil:

$$\text{Total risk} = SF_o \times \text{Intake from ingestion of soil (worker)}$$
$$+ SF_i \times \text{Intake from inhalation of volatiles from soil (worker)}$$
$$+ SF_i \times \text{Intake from inhalation of particulates (worker)}$$

Adding appropriate parameters, and then rearranging the equation to solve for concentration, results in Equation (6). As discussed in more detail in Section 3.3.1, Equation (6a) is used to test the results of Equation (6).

Equation (6′) is the reduced version of Equation (6) using the standard default parameters, and is used to calculate the risk-based PRG at a prespecified cancer risk level of 10^{-6}. It combines the toxicity information of a chemical with standard exposure parameters for commercial/industrial land use to generate the concentration of that chemical that corresponds to a 10^{-6} carcinogenic risk level due to that chemical.

Concentrations Based on Noncarcinogenic Effects. Total HI would be calculated by combining the appropriate oral and inhalation RfDs with the three intakes from soil:

$$HI = \frac{\text{Intake from ingestion}}{RfD_o} + \frac{\text{(Intake from inhalation of volatiles and particulates)}}{RfD_i}$$

Adding appropriate parameters, and then rearranging the equation to solve for concentration, results in Equation (7).

Equation (7′) is the reduced version of Equation (7) using the standard default parameters, and is used to calculate the risk-based PRG at a prespecified HI of 1. It combines the toxicity information of a chemical with standard exposure parameters for commercial/industrial land use to generate the concentration of that chemical that corresponds to an HI of 1.

3.3 VOLATILIZATION AND PARTICULATE EMISSION FACTORS

3.3.1 SOIL-TO-AIR VOLATILIZATION FACTOR

The volatilization factor (VF) is used for defining the relationship between the concentration of contaminants in soil and the volatilized contaminants in air. This relationship was established as a part of the Hwang and Falco (1986) model developed by EPA's Exposure Assessment Group (EAG). Hwang and Falco present a method intended primarily to estimate the permissible residual levels associated with the cleanup of contaminated soils. This method has been used by EPA in estimating exposures to PCBs and 2,3,7,8-TCDD from contaminated soil (EPA 1986; EPA 1988a). One of the pathways considered in this method is the intake by inhalation of volatilized contaminants.

The basic principle of the Hwang and Falco model is applicable only if the soil contaminant concentration is at or below saturation. Saturation is the soil contaminant concentration at which the adsorptive limits of the soil particles and the solubility limits of the available soil moisture have been reached. Above saturation, pure liquid-phase contaminant is present in the soil. Under such conditions, the partial pressure of the pure contaminant and the partial pressure of air in the interstitial soil pore spaces cannot be calculated without first knowing the mole fraction of the contaminant in the soil. Therefore, above saturation, the PRG cannot be accurately calculated based on volatilization. Because of this limitation, the chemical concentration in soil (C) calculated using the VF must be compared with the soil saturation concentration (C_{sat}) calculated using Equation (6a) or (7a). If C is greater than C_{sat}, then the PRG is set equal to C_{sat}.

The VF presented in this section assumes that the contaminant concentration in the soil is homogeneous from the soil surface to the depth of concern and that the contaminated material is not covered by contaminant-free soil material. For the purpose of calculating VF, depth of concern is defined as the depth at which a near impenetrable layer or the permanent ground-water level is reached.

COMMERCIAL/INDUSTRIAL SOIL — CARCINOGENIC EFFECTS

$$TR = \frac{SF_o \times C \times 10^{6}\ kg/mg \times EF \times ED \times IR_{soil}}{BW \times AT \times 365\ days/yr} + \frac{SF_i \times C \times EF \times ED \times IR_{air} \times (1/VF + 1/PEF)}{BW \times AT \times 365\ days/yr}$$

$$C\ (mg/kg;\ risk\text{-}based) = \frac{TR \times BW \times AT \times 365\ days/yr}{EF \times ED \times [(SF_o \times 10^{-6}\ kg/mg \times IR_{soil}) + (SF_i \times IR_{air} \times [1/VF + 1/PEF])]} \quad (6)$$

where:

Parameters	Definition (units)	Default Value
C	chemical concentration in soil (mg/kg)	—
TR	target excess individual lifetime cancer risk (unitless)	10^{-6}
SF_i	inhalation cancer slope factor ($(mg/kg\text{-}day)^{-1}$)	chemical-specific
SF_o	oral cancer slope factor ($(mg/kg\text{-}day)^{-1}$)	chemical-specific
BW	adult body weight (kg)	70 kg
AT	averaging time (yr)	70 yr
EF	exposure frequency (days/yr)	250 days/yr
ED	exposure duration (yr)	25 yr
IR_{soil}	soil ingestion rate (mg/day)	50 mg/day
IR_{air}	workday inhalation rate (m^3/day)	20 m^3/day
VF	soil-to-air volatilization factor (m^3/kg)	chemical-specific (see Section 3.3.1)
PEF	particulate emission factor(m^3/kg)	4.63×10^9 m^3/kg (see Section 3.3.2)

$$C_{sat} = (K_d \times s \times n_m) + (s \times \Theta_m) \quad (6a)$$

where:

Parameters	Definition (units)	Default Value
C_{sat}	soil saturation concentration (mg/kg)	—
K_d	soil-water partition coefficient (L/kg)	chemical-specific, or K_{oc} x OC
K_{oc}	organic carbon partition coefficient (L/kg)	chemical-specific
OC	organic carbon content of soil (fraction)	site-specific, or 0.02
s	solubility (mg/L-water)	chemical-specific
n_m	soil moisture content, expressed as a weight fraction	site-specific
Θ_m	soil moisture content, expressed as L-water/kg-soil	site-specific

REDUCED EQUATION: COMMERCIAL/INDUSTRIAL SOIL — CARCINOGENIC EFFECTS

$$\text{Risk-based PRG}\ (mg/kg;\ TR = 10^{-6}) = \frac{2.9 \times 10^{-4}}{[((5 \times 10^{-5}) \times SF_o) + (SF_i \times ((20/VF) + (4.3 \times 10^{-9})))]} \quad (6')$$

where:

SF_o = oral slope factor in $(mg/kg\text{-}day)^{-1}$
SF_i = inhalation slope factor in $(mg/kg\text{-}day)^{-1}$
VF = chemical-specific soil-to-air volatilization factor in m^3/kg (see Section 3.3.1)

If PRG > C_{sat}, then set PRG = C_{sat} (where C_{sat} = soil saturation concentration (mg/kg); see Equation (6a) and Section 3.3.1).

COMMERCIAL/INDUSTRIAL SOIL — NONCARCINOGENIC EFFECTS

$$THI = \frac{C \times 10^{-6}\ kg/mg \times EF \times ED \times IR_{soil}}{RfD_o \times BW \times AT \times 365\ days/yr} + \frac{C \times EF \times ED \times IR_{air} \times (1/VF + 1/PEF)}{RfD_i \times BW \times AT \times 365\ days/yr}$$

$$C\ (mg/kg;\ risk\text{-}based) = \frac{THI \times BW \times AT \times 365\ days/yr}{ED \times EF \times [((1/RfD_o) \times 10^{-6}\ kg/mg \times IR_{soil}) + ((1/RfD_i) \times IR_{air} \times (1/VF + 1/PEF))]} \quad (7)$$

where:

Parameters	Definition (units)	Default Value
C	chemical concentration in soil (mg/kg)	—
THI	target hazard index (unitless)	1
RfD_o	oral chronic reference dose (mg/kg-day)	chemical-specific
RfD_i	inhalation chronic reference dose (mg/kg-day)	chemical-specific
BW	adult body weight (kg)	70 kg
AT	averaging time (yr)	25 yr (always equal to ED)
EF	exposure frequency (days/yr)	250 days/yr
ED	exposure duration (yr)	25 yr
IR_{soil}	soil ingestion rate (mg/day)	50 mg/day
IR_{air}	workday inhalation rate (m^3/day)	20 m^3/day
VF	soil-to-air volatilization factor (m^3/kg)	chemical-specific (see Section 3.3.1)
PEF	particulate emission factor (m^3/kg)	4.63×10^9 m^3/kg (see Section 3.3.2)

$$C_{sat} = (K_d \times s \times n_m) + (s \times \Theta_m) \quad (7a)$$

where:

Parameters	Definition (units)	Default Value
C_{sat}	soil saturation concentration (mg/kg)	—
K_d	soil-water partition coefficient (L/kg)	chemical-specific, or K_{oc} x OC
K_{oc}	organic carbon partition coefficient (L/kg)	chemical-specific
OC	organic carbon content of soil (fraction)	site-specific, or 0.02
s	solubility (mg/L-water)	chemical-specific
n_m	soil moisture content, expressed as a weight fraction	site-specific
Θ_m	soil moisture content, expressed as L-water/kg-soil	site-specific

REDUCED EQUATION: COMMERCIAL/INDUSTRIAL SOIL — NONCARCINOGENIC EFFECTS

$$\text{Risk-based PRG (mg/kg; THI = 1)} = \frac{102}{[(5 \times 10^{-5}/RfD_o) + ((1/RfD_i) \times ((20/VF) + (4.3 \times 10^{-9})))]} \quad (7')$$

where:

RfD_o = oral chronic reference dose in mg/kg-day
RfD_i = inhalation chronic reference dose in mg/kg-day
VF = chemical-specific soil-to-air volatilization factor in m^3/kg (see Section 3.3.1)

If PRG > C_{sat}, then set PRG = C_{sat} (where C_{sat} = soil saturation concentration (mg/kg); see Equation (7a) and Section 3.3.1).

A chemical-specific value for VF is used in the standard default equations (Equations (6), (6´), (7), and (7´) in Section 3.2.2) and is developed in Equation (8). The VF value calculated using Equation (8) has been developed for specific use in the other equations in this guidance; it may not be applicable in other technical contexts. Equation (8) lists the standard default parameters for calculating VF. If site-specific information is available, Equation (8) may be modified to calculate a VF that is more appropriate for the particular site. Supporting references should be consulted when substituting site-specific data to ensure that the model and specific parameters can be appropriately applied to the given site.

3.3.2 PARTICULATE EMISSION FACTOR

The particulate emission factor (PEF) relates the contaminant concentration in soil with the concentration of respirable particles (PM_{10}) in the air due to fugitive dust emissions from surface contamination sites. This relationship is derived by Cowherd (1985) for a rapid assessment procedure applicable to a typical hazardous waste site where the surface contamination provides a relatively continuous and constant potential for emission over an extended period of time (e.g., years). The particulate emissions from contaminated sites are due to wind erosion and, therefore, depend on the erodibility of the surface

SOIL-TO-AIR VOLATILIZATION FACTOR

$$VF\ (m^3/kg) = \frac{(LS \times V \times DH)}{A} \times \frac{(3.14 \times \alpha \times T)^{1/2}}{(2 \times D_{ei} \times E \times K_{as} \times 10^{-3}\ kg/g)} \quad (8)$$

where:

$$\alpha\ (cm^2/s) = \frac{(D_{ei} \times E)}{E + (\rho_s)(1-E)/K_{as}}$$

Standard default parameter values that can be used to reduce Equation (8) are listed below. These represent "typical" values as identified in a number of sources. For example, when site-specific values are not available, the length of a side of the contaminated area (LS) is assumed to be 45 m; this is based on a contaminated area of 0.5 acre which approximates the size of an average residential lot. The "typical" values LS, DH, and V are from EPA 1986. "Typical" values for E, OC, and ρ_s are from EPA 1984, EPA 1988b, and EPA 1988f. Site-specific data should be substituted for the default values listed below wherever possible. Standard values for chemical-specific D_i, H, and K_{oc} can be obtained by calling the Superfund Health Risk Technical Support Center.

Parameter	Definition (units)	Default
VF	volatilization factor (m^3/kg)	—
LS	length of side of contaminated area (m)	45 m
V	wind speed in mixing zone (m/s)	2.25 m/s
DH	diffusion height (m)	2 m
A	area of contamination (cm^2)	20,250,000 cm^2
D_{ei}	effective diffusivity (cm^2/s)	$D_i \times E^{0.33}$
E	true soil porosity (unitless)	0.35
K_{as}	soil/air partition coefficient (g soil/cm^3 air)	$(H/K_d) \times 41$, where 41 is a units conversion factor
ρ_s	true soil density or particulate density (g/cm^3)	2.65 g/cm^3
T	exposure interval (s)	7.9×10^8 s
D_i	molecular diffusivity (cm^2/s)	chemical-specific
H	Henry's law constant (atm-m^3/mol)	chemical-specific
K_d	soil-water partition coefficient (cm^3/g)	chemical-specific, or $K_{oc} \times OC$
K_{oc}	organic carbon partition coefficient (cm^3/g)	chemical-specific
OC	organic carbon content of soil (fraction)	site-specific, or 0.02

material. The equation presented below, Equation (9), is representative of a surface with "unlimited erosion potential," which is characterized by bare surfaces of finely divided material such as sandy agricultural soil with a large number ("unlimited reservoir") of erodible particles. Such surfaces erode at low wind speeds, and particulate emission rates are relatively time-independent at a given wind speed.

This model was selected for use in RAGS/HHEM Part B because it represents a conservative estimate for intake of particulates; it is used to derive Equations (6) and (7) in Section 3.2.2.

Using the default parameter values given in the box for Equation (9), the default PEF is equal to 4.63×10^9 m^3/kg. The default values necessary to calculate the flux rate for an "unlimited reservoir" surface (i.e., G, U_m, U_t, and F(x)) are provided by Cowherd (1985), and the remaining default values (i.e., for LS, V, and DH) are "typical" values (EPA 1986). If site-specific information is available, Equation (9) may be modified to calculate a PEF that is more appropriate for the particular site. Again, the original reference should be consulted when substituting site-specific data to ensure applicability of the model to specific site conditions.

PARTICULATE EMISSION FACTOR

$$PEF\ (m^3/kg) = \frac{LS \times V \times DH \times 3600\ s/hr}{A} \times \frac{1000\ g/kg}{0.036 \times (1-G) \times (U_m/U_t)^3 \times F(x)} \quad (9)$$

where:

Parameter	Definition (units)	Default
PEF	particulate emission factor (m^3/kg)	4.63×10^9 m^3/kg
LS	width of contaminated area (m)	45 m
V	wind speed in mixing zone (m/s)	2.25 m/s
DH	diffusion height (m)	2 m
A	area of contamination (m^2)	2025 m^2
0.036	respirable fraction (g/m^2-hr)	0.036 g/m^2-hr
G	fraction of vegetative cover (unitless)	0
U_m	mean annual wind speed (m/s)	4.5 m/s
U_t	equivalent threshold value of wind speed at 10 m (m/s)	12.8 m/s
F(x)	function dependent on U_m/U_t (unitless)	0.0497 (determined using Cowherd 1985)

3.4 CALCULATION AND PRESENTATION OF RISK-BASED PRGs

The equations presented in this chapter can be used to calculate risk-based PRGs for both carcinogenic and noncarcinogenic effects. If both a carcinogenic and a noncarcinogenic risk-based PRG are calculated for a particular chemical, then the lower of the two values is considered the appropriate risk-based PRG for any given contaminant. The case-study box below illustrates a calculation of a risk-based PRG. A summary table — such as that in the final case-study box — should be developed to present both the risk-based PRGs and the ARAR-based PRGs. The table should be labeled as to whether it presents the concentrations that were developed during scoping or after the baseline risk assessment.

CASE STUDY: CALCULATE RISK-BASED PRGs[a]

Risk-based PRGs for ground water for isophorone, one of the chemicals detected in ground-water monitoring wells at the site, are calculated below. Initial risk-based PRGs for isophorone (carcinogenic and noncarcinogenic effects) are derived using Equations (1´) and (2´) in Section 3.1.1. Equations (1´) and (2´) combine the toxicity information of the chemical (oral RfD of 0.2 mg/kg-day and oral SF of 0.0039 $[mg/kg\text{-}day]^{-1}$; inhalation values are not available and, therefore, only the oral exposure route is considered) with standard exposure parameters. The calculated concentrations in mg/L correspond to a target risk of 10^{-6} and a target HQ of 1, as follows:

$$\text{Carcinogenic risk-based PRG} = \frac{1.7 \times 10^{-4}}{2(SF_o)} = \frac{1.7 \times 10^{-4}}{2(0.0039)} = 0.022 \text{ mg/L}$$

$$\text{Noncarcinogenic risk-based PRG} = \frac{73}{2/RfD_o} = \frac{73}{2/0.2} = 7.3 \text{ mg/L}$$

The lower of the two values (i.e., 0.022 mg/L) is selected as the appropriate risk-based PRG. Risk-based PRGs are calculated similarly for the other chemicals of concern.

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[a] All information in this example is for illustration purposes only.

CASE STUDY: PRESENT PRGs DEVELOPED DURING SCOPING[a]

Site: XYZ Co.
Location: Anytown, Anystate
Medium: Ground Water

Land Use: Residential
Exposure Routes: Water Ingestion, Inhalation of Volatiles

Chemical	Risk-based PRGs (mg/L)*		ARAR-based PRG	
	10^{-6}	HQ = 1	Type	Concentration (mg/L)
Benzene	—	—	MCL	0.005
Carbon Tetrachloride	—	—	MCL	0.005
Ethylbenzene	—	—	MCLG MCL	0.7*** 0.7
Hexane	—	0.33	—	—
Isophorone	0.022**	7.3	—	—
Triallate	—	0.47	—	—
1,1,2-Trichloroethane	—	—	MCLG MCL	0.003*** 0.005
Vinyl chloride	—	—	MCL	0.002

[a] All information in this example is for illustration purposes only.
* These concentrations were calculated using the standard default equations in Chapter 3.
** Of the two potential risk-based PRGs for this chemical, this concentration is the selected risk-based PRG.
*** Of the two potential ARAR-based PRGs for this chemical, this concentration is selected as the ARAR-based PRG.

CHAPTER 4

RISK-BASED PRGs FOR RADIOACTIVE CONTAMINANTS

This chapter presents standardized exposure parameters, derivations of risk equations, and "reduced" equations for calculating risk-based PRGs for radioactive contaminants for the pathways and land-use scenarios discussed in Chapter 2. In addition, a radiation site case study is provided at the end of the chapter to illustrate (1) how exposure pathways and radionuclides of potential concern (including radioactive decay products) are identified, (2) how initial risk-based PRGs for radionuclides are calculated using reduced equations based on information available at the scoping phase, and (3) how risk-based PRGs can be re-calculated using full risk equations and site-specific data obtained during the baseline risk assessment. Chapters 1 through 3 and Appendices A and B provide the basis for many of the assumptions, equations, and parameters used in this chapter, and therefore should be reviewed before proceeding further into Chapter 4. Also, Chapter 10 in RAGS/HHEM Part A should be consulted for additional guidance on conducting baseline risk assessments at sites contaminated with radioactive substances.

In general, standardized default exposure equations and parameters used to calculate risk-based PRGs for radionuclides are similar in structure and function to those equations and parameters developed in Chapter 3 for nonradioactive chemical carcinogens. Both types of risk equations:

- Calculate risk-based PRGs for each carcinogen corresponding to a pre-specified target cancer risk level of 10^{-6}. As mentioned in Section 2.8, target risk levels may be modified after the baseline risk assessment based on site-specific exposure conditions, technical limitations, or other uncertainties, as well as on the nine remedy selection criteria specified in the NCP.

- Use standardized default exposure parameters consistent with OSWER Directive 9285.6-03 (EPA 1991b). Where default parameters are not available in that guidance document, other appropriate reference values are used and cited.

- Incorporate pathway-specific default exposure factors that generally reflect RME conditions.

There are, however, several important areas in which risk-based PRG equations and assumptions for radioactive contaminants differ substantially from those used for chemical contaminants. Specifically, unlike chemical equations, risk equations for radionuclides:

- Accept input quantities in units of activity (e.g., picocuries (pCi)) rather than in units of mass (e.g., milligrams (mg)). Activity units are more appropriate for radioactive substances because concentrations of radionuclides in sample media are determined by direct physical measurements of the activity of each nuclide present, and because adverse human health effects due to radionuclide intake or exposure are directly related to the amount, type, and energy of the radiation deposited in specific body tissues and organs.

- Consider the carcinogenic effects of radionuclides only. EPA designates all radionuclides as Class A carcinogens based on their property of emitting ionizing radiation and on the extensive weight of epidemiological evidence of radiation-induced cancer in humans. At most CERCLA radiation sites, potential health risks are usually based on the radiotoxicity, rather than the chemical toxicity, of each radionuclide present.

- Use cancer slope factors that are best estimates (i.e., median or 50th percentile values) of the age-averaged, lifetime excess total cancer risk per unit intake of a radionuclide (e.g., per pCi inhaled or ingested) or per unit external radiation exposure (e.g., per microRoentgen) to gamma-emitting

radionuclides. Slope factors given in IRIS and HEAST have been calculated for individual radionuclides based on their unique chemical, metabolic, and radiological properties and using a non-threshold, linear dose-response model. This model accounts for the amount of each radionuclide absorbed into the body from the gastrointestinal tract (by ingestion) or through the lungs (by inhalation), the distribution and retention of each radionuclide in body tissues and organs, as well as the age, sex, and weight of an individual at the time of exposure. The model then averages the risk over the lifetime of that exposed individual (i.e., 70 years). Consequently, radionuclide slope factors are not expressed as a function of body weight or time, and do not require corrections for gastrointestinal absorption or lung transfer efficiencies.

Risk-based PRG equations for radionuclides presented in the following sections of this chapter are derived initially by determining the total risk posed by each radioactive contaminant in a given pathway, and then by rearranging the pathway equation to solve for an activity concentration set equal to a target cancer risk level of 10^{-6}. At the scoping phase, these equations are "reduced" — and risk-based PRGs are calculated for each radionuclide of concern — using standardized exposure assumptions for each exposure route within each pathway and land-use combination. After the baseline risk assessment, PRGs can be recalculated using full risk equations and site-specific exposure information obtained during the RI.

4.1 RESIDENTIAL LAND USE

4.1.1 GROUND WATER OR SURFACE WATER

Under the residential land-use scenario, risk from ground-water or surface water radioactive contaminants is assumed to be due primarily to direct ingestion and inhalation of volatile radionuclides released from the water to indoor air. However, because additional exposure routes (e.g., external radiation exposure due to immersion) are possible at some sites for some radionuclides, while only one exposure route may be relevant at others, the risk assessor always should consider all relevant exposure routes and add or modify exposure routes as appropriate.

In the case illustrated below, risks from the two default exposure routes are combined, as follows:

Total risk from water	=	Risk from ingestion of radionuclides in water (adult)
	+	Risk from indoor inhalation of volatile radionuclides released from water (adult)

At the scoping phase, risk from indoor inhalation of volatile radionuclides is assumed to be relevant only for radionuclides with a Henry's Law constant of greater than 1×10^{-5} atm-m^3/mole and a molecular weight of less than 200 g/mole. However, radionuclides that do not meet these criteria also may, under certain site-specific water-use conditions, be volatilized into the air from water, and thus pose significant site risks (and require risk-based goals). Therefore, the ultimate decision regarding which contaminants should be considered must be made by the risk assessor on a site-specific basis following completion of the baseline risk assessment.

Total carcinogenic risk is calculated for each radionuclide separately by combining its appropriate oral and inhalation SFs with the two exposure pathways for water, as follows:

Total risk	=	SF_o x	Intake from ingestion of of radionuclides
	+	SF_i x	Intake from inhalation of volatile radionuclides

By including appropriate exposure parameters for each type of intake, rearranging and combining exposure terms in the total risk equation, and setting the target cancer risk level equal to 10^{-6}, the risk-based PRG equation is derived as shown in Equation (10).

Equation (10′), presented in the next box, is the reduced version of Equation (10) based on the standard default values listed below. It is used to calculate risk-based PRGs for radionuclides in water at a pre-specified cancer risk level of 10^{-6} by combining each radionuclide's toxicity data with the standard default values for residential land-use exposure parameters.

After the baseline risk assessment, the risk assessor may choose to modify one or more of the exposure parameter default values or assumptions

RADIONUCLIDE PRGs: RESIDENTIAL WATER — CARCINOGENIC EFFECTS

Total risk $= [SF_o \times RW \times IR_w \times EF \times ED] + [SF_i \times RW \times K \times IR_a \times EF \times ED]$

RW (pCi/L; risk-based) $= \dfrac{TR}{EF \times ED \times [(SF_o \times IR_w) + (SF_i \times K \times IR_a)]}$ (10)

where:

Parameters	Definition (units)	Default Value
RW	radionuclide PRG in water (pCi/L)	—
TR	target excess individual lifetime cancer risk (unitless)	10^{-6}
SF_i	inhalation slope factor (risk/pCi)	radionuclide-specific
SF_o	oral (ingestion) slope factor (risk/pCi)	radionuclide-specific
EF	exposure frequency (days/yr)	350 days/yr
ED	exposure duration (yr)	30 yr
IR_a	daily indoor inhalation rate (m^3/day)	15 m^3/day
IR_w	daily water ingestion rate (L/day)	2 L/day
K	volatilization factor (unitless)	0.0005 x 1000 L/m^3 (Andelman 1990)

REDUCED EQUATION FOR RADIONUCLIDE PRGs: RESIDENTIAL WATER — CARCINOGENIC EFFECTS

Risk-based PRG (pCi/L; TR = 10^{-6}) $= \dfrac{9.5 \times 10^{-11}}{2(SF_o) + 7.5(SF_i)}$ (10′)

where:

SF_o = oral (ingestion) slope factor (risk/pCi)
SF_i = inhalation slope factor (risk/pCi)

in the risk equations to reflect site-specific conditions. In this event, radionuclide PRGs should be calculated using Equation (10) instead of Equation (10′).

4.1.2 SOIL

Under residential land-use conditions, risk from radionuclides in soil is assumed to be due to direct ingestion and external exposure to gamma radiation. Soil ingestion rates differ for children and adults, therefore age-adjusted ingestion rate factors are used in the soil pathway equation. Calculation of the risk from the external radiation exposure route assumes that any gamma-emitting radionuclide in soil is uniformly distributed in that soil within a finite soil depth and density, and dispersed in an infinite plane geometry.

The calculation of external radiation exposure risk also includes two additional factors, the gamma shielding factor (S_e) and the gamma exposure time factor (T_e), which can be adjusted to account for both attenuation of radiation fields due to shielding (e.g., by structures, terrain, or engineered barriers) and for exposure times of less than 24-hours per day, respectively. S_e is expressed as a fractional value between 0 and 1, delineating the possible risk reduction range from 0% to 100%, respectively, due to shielding. The default value of 0.2 for S_e for both residential and commercial/industrial land-use scenarios reflects the initial conservative assumption of a 20% reduction in external exposure due to shielding from structures (see EPA 1981). T_e is expressed as the quotient of the daily number of hours an individual is exposed directly to an external radiation field divided by the total number of exposure hours assumed each day for a given land-

use scenario (i.e., 24 hours for residential and 8 hours for commercial/industrial). The default value of 1 for T_e for both land-use scenarios reflects the conservative assumptions of a 24-hr exposure duration for residential populations (i.e., 24/24 = 1) and an 8-hr exposure duration for workers (i.e., 8/8 = 1). Values for both factors can (and, if appropriate, should) be modified by the risk assessor based on site-specific conditions.

In addition to direct ingestion of soil contaminated with radionuclides and exposure to external radiation from gamma-emitting radionuclides in soil, other soil exposure routes are possible, such as inhalation of resuspended radioactive particles, inhalation of volatile radionuclides, or ingestion of foodcrops contaminated by root or leaf uptake. The risk assessor should therefore identify all relevant exposure routes within the soil pathway and, if necessary, develop equations for risk-based PRGs that combine these exposure routes.

In the case illustrated below, the risk-based PRG is derived to be protective for exposure from the direct ingestion and external radiation routes. Total risk from soil due to ingestion and external radiation is calculated as follows:

Total risk from soil	=	Risk from direct ingestion of radionuclides in soil (child to adult)
	+	Risk from external radiation from gamma-emitting radionuclides in soil

Total risk for carcinogenic effects from each radionuclide of potential concern is calculated by combining the appropriate oral slope factor, SF_o, with the total radionuclide intake from soil, plus the appropriate external radiation slope factor, SF_e, with the radioactivity concentration in soil:

Total risk	=	SF_o	x	Intake from direct ingestion of soil
	+	SF_e	x	Concentration of gamma-emitting radionuclides in soil

Adding appropriate parameters, then combining and rearranging the equation to solve for concentration, results in Equation (11).

Equation (11′) is the reduced version of Equation (11) based on the standard default values listed below. Risk-based PRGs for radionuclides in soil are calculated for a pre-specified cancer risk level of 10^{-6}.

The age-adjusted soil ingestion factor ($IF_{soil/adj}$) used in Equation (11) takes into account the difference in soil ingestion for two exposure groups — children of one to six years and all other individuals from seven to 31 years. $IF_{soil/adj}$ is calculated for radioactive contaminants as shown in Equation (12). Section 3.1.2 provides additional discussion on the age-adjusted soil ingestion factor.

If any parameter values or exposure assumptions are adjusted after the baseline risk assessment to reflect site-specific conditions, soil PRGs should be calculated using Equation (11).

4.2 COMMERCIAL/INDUSTRIAL LAND USE

4.2.1 WATER

Under the commercial/industrial land use scenario, risk-based PRGs for radionuclides in ground water (and for radionuclides in surface water used for drinking water purposes) are based on residential exposures and calculated according to the procedures detailed in Section 4.1.1 (see Section 3.2.1 for the rationale for this approach). Risk-based PRGs should be calculated considering the possibility that both the worker and general population at large may be exposed to the same contaminated water supply.

4.2.2 SOIL

Under the commercial/industrial land use scenario, four soil exposure routes — direct ingestion, inhalation of volatile radionuclides, inhalation of resuspended radioactive particulates, and external exposure due to gamma-emitting radionuclides — are combined to calculate risk-based radionuclide PRGs in soil for adult worker exposures. Additional exposure routes (e.g., ingestion of foodcrops contaminated by radionuclide uptake) are possible at some sites, while only one exposure route (e.g., external radiation exposure only) may be relevant at others. The risk assessor should therefore consider and combine all relevant soil exposure routes, as necessary and appropriate, based on site-specific conditions.

RADIONUCLIDE PRGs: RESIDENTIAL SOIL — CARCINOGENIC EFFECTS

$$\text{Total risk} = RS \times [(SF_o \times 10^{-3}\text{g/mg} \times EF \times IF_{soil/adj}) + (SF_e \times 10^{3}\text{g/kg} \times ED \times D \times SD \times (1-S_e) \times T_e)]$$

$$\text{RS (pCi/g; risk-based)} = \frac{TR}{(SF_o \times 10^{-3} \times EF \times IF_{soil/adj}) + (SF_e \times 10^{3} \times ED \times D \times SD \times (1-S_e) \times T_e)} \quad (11)$$

where:

Parameters	Definition (units)	Default Value
RS	radionuclide PRG in soil (pCi/g)	—
TR	target excess individual lifetime cancer risk (unitless)	10^{-6}
SF_o	oral (ingestion) slope factor (risk/pCi)	radionuclide-specific
SF_e	external exposure slope factor (risk/yr per pCi/m^2)	radionuclide-specific
EF	exposure frequency (days/yr)	350 days/yr
ED	exposure duration (yr)	30 yr
$IF_{soil/adj}$	age-adjusted soil ingestion factor (mg-yr/day)	3600 mg-yr/day (see Equation (12))
D	depth of radionuclides in soil (m)	0.1 m
SD	soil density (kg/m^3)	1.43×10^3 kg/m^3
S_e	gamma shielding factor (unitless)	0.2 (see Section 4.1.2)
T_e	gamma exposure time factor (unitless)	1 (see Section 4.1.2)

REDUCED EQUATION FOR RADIONUCLIDE PRGs: RESIDENTIAL SOIL — CARCINOGENIC EFFECTS

$$\text{Risk-based PRG (pCi/g; TR} = 10^{-6}) = \frac{1 \times 10^{-6}}{1.3 \times 10^{3}(SF_o) + 3.4 \times 10^{6}(SF_e)} \quad (11')$$

where:

SF_o = oral (ingestion) slope factor (risk/pCi)
SF_e = external exposure slope factor (risk/yr per pCi/m^2)

AGE-ADJUSTED SOIL INGESTION FACTOR

$$IF_{soil/adj}\text{ (mg-yr/day)} = (IR_{soil/age\ 1\text{-}6} \times ED_{age\ 1\text{-}6}) + (IR_{soil/age\ 7\text{-}31} \times ED_{age\ 7\text{-}31}) \quad (12)$$

where:

Parameters	Definition (units)	Default Value
$IF_{soil/adj}$	age-adjusted soil ingestion factor (mg-yr/day)	3600 mg-yr/day
$IR_{soil/age\ 1\text{-}6}$	ingestion rate of soil ages 1-6 (mg/day)	200 mg/day
$IR_{soil/age\ 7\text{-}31}$	ingestion rate of soil ages 7-31 (mg/day)	100 mg/day
$ED_{age\ 1\text{-}6}$	exposure duration during ages 1-6 (yr)	6 yr
$ED_{age\ 7\text{-}31}$	exposure duration during ages 7-31 (yr)	24 yr

In the case illustrated below, total risk from radionuclides in soil is calculated as the summation of the individual risks from each of the four exposure routes listed above:

Total risk from soil	=	Risk from direct ingestion of radionuclides in soil (worker)
	+	Risk from inhalation of volatile radionuclides (worker)
	+	Risk from inhalation of resuspended radioactive particulates (worker)
	+	Risk from external radiation from gamma-emitting radionuclides (worker)

Total risk for carcinogenic effects for each radionuclide is calculated by combining the appropriate ingestion, inhalation, and external exposure SF values with relevant exposure parameters for each of the four soil exposure routes as follows:

Total risk	=	SF_o x	Intake from direct ingestion of radionuclides in soil (worker)
	+	SF_i x	Intake from inhalation of volatile radionuclides (worker)
	+	SF_i x	Intake from inhalation of resuspended radioactive particulates (worker)
	+	SF_e x	Concentration of gamma-emitting radionuclides in soil (worker)

Adding appropriate parameters, and then combining and rearranging the equation to solve for concentration, results in Equation (13).

Equation (13′) below is the reduced version of Equation (13) based on the standard default values below and a pre-specified cancer risk level of 10^{-6}. It combines the toxicity information of a radionuclide with standard exposure parameters for commercial/industrial land use to generate the concentration of that radionuclide corresponding to a 10^{-6} carcinogenic risk level due to that radionuclide.

If any parameter default values or assumptions are changed after the baseline risk assessment to reflect site-specific conditions, radionuclide soil PRGs should be derived using Equation (13).

4.2.3 SOIL-TO-AIR VOLATILIZATION FACTOR

The VF, defined in Section 3.3.1 for chemicals, also applies for radioactive contaminants with the following exceptions.

- Most radionuclides are heavy metal elements and are non-volatile under normal, ambient conditions. For these radionuclides, VF values need not be calculated and the risk due to the inhalation of volatile forms of these nuclides can be ignored for the purposes of determining PRGs.

- A few radionuclides, such as carbon-14 (C-14), tritium (H-3), phosphorus-32 (P-32), sulfur-35 (S-35), and other isotopes, are volatile under certain chemical or environmental conditions, such as when they are combined chemically with volatile organic compounds (i.e., the so-called radioactively-labeled or "tagged" organic compounds), or when they can exist in the environment in a variety of physical forms, such as C-14 labeled carbon dioxide (CO_2) gas and tritiated water vapor. For these radionuelides, VF values should be calculated using the Hwang and Falco (1986) equation provided in Section 3.3.1 based on the chemical species of the compound with which they are associated.

- The naturally occurring, non-volatile radioisotopes of radium, namely Ra-226 and Ra-224, undergo radioactive decay and form inert, gaseous isotopes of radon, i.e., Rn-222 (radon) and Rn-220 (thoron), respectively. Radioactive radon and thoron gases emanate from their respective parent radium isotopes in soil, escape into the air, and can pose cancer risks if inhaled. For Ra-226 and Ra-224 in soil, use the default values shown in the box on page 40 for VF and for SF_i in Equation (12) and Equation (12′).

4.3 RADIATION CASE STUDY

This section presents a case study of a hypothetical CERCLA radiation site, the ACME Radiation Co. site, to illustrate the process of calculating pathway-specific risk-based PRGs for radionuclides using the risk equations and assumptions presented in the preceding sections of this chapter. The radiation site case study is modeled after the XYZ Co. site study discussed in

RADIONUCLIDE PRGs: COMMERCIAL/INDUSTRIAL SOIL — CARCINOGENIC EFFECTS

$$\text{Total risk} = RS \times ED \times [(SF_o \times 10^{-3}g/mg \times EF \times IR_{soil}) + (SF_i \times 10^3 g/kg \times EF \times IR_{air} \times 1/VF) + (SF_i \times 10^3 g/kg \times EF \times IR_{air} \times 1/PEF) + (SF_e \times 10^3 g/kg \times D \times SD \times (1-S_e) \times T_e)]$$

$$\text{RS (pCi/g; risk-based)} = \frac{TR}{ED \times [(SF_o x10^{-3} xEFxIR_{soil}) + (SF_i x10^3 xEFxIR_{air}) \times (1/VF + 1/PEF) + (SF_e x10^3 xDxSDx(1-S_e)xT_e)]} \quad (13)$$

where:

Parameters	Definition (units)	Default Value
RS	**radionuclide PRG** in soil (pCi/g)	—
TR	target excess individual lifetime cancer risk (unitless)	10^{-6}
SF_i	inhalation slope factor (risk/pCi)	radionuclide-specific
SF_o	oral (ingestion) slope factor (risk/pCi)	radionuclide-specific
SF_e	external exposure slope factor (risk/yr per pCi/m^2)	radionuclide-specific
EF	exposure frequency (days/yr)	250 days/yr
ED	exposure duration (yr)	25 yr
IR_{air}	workday inhalation rate of air (m^3/day)	20 m^3/day
IR_{soil}	daily soil ingestion rate (mg/day)	50 mg/day
VF	soil-to-air volatilization factor (m^3/kg)	radionuclide-specific (see Section 4.2.3)
PEF	particulate emission factor (m^3/kg)	4.63 x 10^9 m^3/kg (see Section 3.3.2)
D	depth of radionuclides in soil (m)	0.1 m
SD	soil density (kg/m^3)	1.43 x 10^3 kg/m^3
S_e	gamma shielding factor (unitless)	0.2 (see Section 4.1.2)
T_e	gamma exposure factor (unitless)	1 (see Section 4.1.2)

REDUCED EQUATION FOR RADIONUCLIDE PRGs: COMMERCIAL/INDUSTRIAL SOIL — CARCINOGENIC EFFECTS*

$$\text{Risk-based PRG (pCi/g; TR} = 10^{-6}) = \frac{1 \times 10^{-6}}{[(3.1 \times 10^2 (SF_o)) + ((1.3 \times 10^8/VF + 2.7 \times 10^{-2})(SF_i)) + (2.9 \times 10^6 (SF_e))]} \quad (13')$$

where:

SF_o = oral (ingestion) slope factor (risk/pCi)
SF_i = inhalation slope factor (risk/pCi)
SF_e = external exposure slope factor (risk/yr per pCi/m^2)
VF = *radionuclide-specific soil-to-air volatilization factor in m^3/kg (see Section 3.3.1)*

*NOTE: See Section 4.2.3 when calculating PRGs for Ra-226 and Ra-224.

Chapters 2 and 3. It generally follows a two-phase format which consists of a "at the scoping stage" phase wherein risk-based PRGs for radionuclides of potential concern are calculated initially using reduced equations based on PA/SI data, and then a second, "after the baseline risk assessment" phase wherein radionuclide PRGs are recalculated using full equations and modified site-specific parameter values based on RI/FS data.

Following an overview of the history and current status of the site presented in Section 4.3.1, Section 4.3.2 covers a number of important steps taken early in the scoping phase to calculate preliminary risk-based PRGs assuming a specific

SOIL DEFAULT VALUES FOR VF AND SF, FOR Ra-226 AND Rn-224

Radium	Default VF Value $\left(\frac{pCi/kg\ Ra}{pCi/m^3\ Rn^*}\right)$	Inhalation Slope Factor, SF_i (risk/pCi)**
Ra-226	8	1.1E-11
Ra-224	200	4.7E-11

* Calculated using values taken from NCRP 1976 and UNSCEAR 1982: Assumptions: (1) an average Ra-226 soil concentration of 1 pCi/g associated with an average ambient Rn-222 air concentration of 120 pCi/m^3 and (2) an average Ra-224 soil concentration of 1 pCi/g associated with an average ambient Rn-220 air concentration of 5 pCi/m^3.

** Slope factor values are for Rn-222 (plus progeny) and for Rn-220 (plus progeny).

land-use scenario. Section 4.3.3 then discusses how initial assumptions and calculations can be modified when additional site-specific information becomes available.

4.3.1 SITE HISTORY

The ACME Radiation Co. site is an abandoned industrial facility consisting of a large factory building situated on ten acres of land surrounded by a high-density residential neighborhood. Established in 1925, the ACME Co. manufactured luminous watch dials and gauges using radium-based paint and employed approximately 100 workers, mostly women. With the declining radium market, ACME phased out dial production and expanded its operations in 1960 to include brokering (collection and disposal) of low-level radioactive waste (LLW). After the company was issued a state license in 1961, ACME began receiving LLW from various nearby hospitals and research laboratories. In 1975, acting on an anonymous complaint of suspected mishandling of radioactive waste, state officials visited the ACME Co. site and cited the company for numerous storage and disposal violations. After ACME failed to rectify plant conditions identified in initial and subsequent citations, the state first suspended, and then later revoked its operating license in 1978. Around the same time, officials detected radium-226 (Ra-226) contamination at a few neighboring locations off site. However, no action was taken against the company at that time. When ACME filed for bankruptcy in 1985, it closed its facility before completing cleanup.

In 1987, the state and EPA conducted an aerial gamma survey over the ACME Radiation Co. site and surrounding properties to investigate the potential extent of radioactive contamination in these areas. The overflight survey revealed several areas of elevated exposure rate readings, although individual gamma-emitting radionuclides could not be identified. When follow-up ground level surveys were performed in 1988, numerous "hot spots" of Ra-226 were pinpointed at various locations within and around the factory building. Three large soil piles showing enhanced concentrations of Ra-226 were discovered along the southern border. Approximately 20 rusting drums labelled with LLW placards also were discovered outside under a covered storage area. Using ground-penetrating radar, EPA detected subsurface magnetic anomalies in a few locations within the property boundary which suggested the possibility of buried waste drums. Based on interviews with people living near the site and with former plant workers, the state believes that radium contaminated soil may have been removed from the ACME site in the past and used locally as fill material for the construction of new homes and roadbeds. Site access is currently limited (but not entirely restricted) by an existing security fence.

In 1988, EPA's regional field investigation team completed a PA/SI. Based on the PA/SI data, the ACME Radiation Co. site scored above 28.50 using the HRS and was listed on the National Priorities List in 1989. Early in 1990, an RI/FS was initiated and a baseline risk assessment is currently in progress.

4.3.2 AT THE SCOPING PHASE

In this subsection, several steps are outlined to show by example how initial site data are used at the scoping phase to calculate risk-based PRGs for radionuclides in specific media of concern. Appropriate sections of Chapters 2 and 3 should be consulted for more detailed explanations for each step considered below.

Identify Media of Concern. A large stream runs along the western border of the site and feeds into a river used by some of the local residents for fishing and boating. Supplemental water intake ducts for the municipal water treatment plant are located approximately 300 yards downriver, and the site is situated over an aquifer which serves as the primary drinking water supply for a community of approximately 33,000 people.

Analyses of ground water, soil, and stream sediment samples taken during the PA/SI revealed significant levels of radionuclide contamination. Potential sources of contamination include the soil piles, process residues in soil, and radionuclides leaking from buried drums. Air filter samples and surface water samples from the stream and river showed only background levels of activity. (Background concentrations were determined from analyses conducted on a limited number of air, ground water, surface water, and soil samples collected approximately one mile from the site.)

The data show that the media of potential concern at this site include ground water and soil. Although stream water and river water were not found to be contaminated, both surface water bodies may become contaminated in the future due to the migration of radionuclides from sediment, from the exposed soil piles, or from leaking drums. Thus, surface water is another medium of potential concern.

For simplicity, only soil will be discussed as the medium of concern during the remainder of this case study. Procedures discussed for this medium can nevertheless be applied in a similar manner to all other media of concern.

Identify Initial List of Radionuclides of Concern. The PA/SI for the ACME Radiation Co. site identified elevated concentrations of five radionuclides in soil (Ra-226, tritium (H-3), carbon-14 (C-14), cesium (Cs-137), and strontium (Sr-90)). These comprise the initial list of radionuclides of potential concern.

Site records indicate that radioisotopes of cobalt (Co-60), phosphorus (P-32), sulfur (S-35), and americium (Am-241 and Am-243) were included on the manifests of several LLW drums in the storage area and on the manifests of other drums suspected to be buried onsite. Therefore, although not detected in any of the initial soil samples analyzed, Co-60, P-32, S-35, Am-241, and Am-243 are added to the list for this medium because of their potential to migrate from leaking buried drums into the surrounding soil.

Identify Probable Land Uses. The ACME Radiation Co. site is located in the center of a rapidly developing suburban community comprised of single and multiple family dwellings. The area immediately encircling the site was recently re-zoned for residential use only; existing commercial and light industrial facilities are currently being relocated. Therefore, residential use is determined to be the most reasonable future land use for this site.

Identify Exposure Pathways, Parameters, and Equations. During the scoping phase, available site data were neither sufficient to identify all possible exposure pathways nor adequate enough to develop site-specific fate and transport equations and parameters. Therefore, in order to calculate initial risk-based PRGs for radionuclides of potential concern in soil, the standardized default soil exposure equation and assumptions provided in this chapter for residential land use in Section 4.1.2 are selected. (Later in this case study, examples are provided to illustrate how the full risk equation (Equation (11)) and assumptions are modified when baseline risk assessment data become available.)

For the soil pathway, the exposure routes of concern are assumed to be direct ingestion of soil contaminated with radionuclides and exposure to external radiation from gamma-emitting radionuclides. Again, although soil is the only medium discussed throughout this case study, exposure pathways, parameters, equations, and eventually risk-based concentrations would need to be identified and developed for all other media and exposure pathways of potential concern at an actual site.

Identify Toxicity Information. To calculate media-specific risk-based PRGs, reference toxicity values for radiation-induced cancer effects are required (i.e., SFs). As stated previously, soil ingestion and external radiation are the exposure routes of concern for the soil pathway. Toxicity information (i.e., oral, inhalation, and external exposure SFs) for all radionuclides of potential concern at the ACME Radiation Co. site are obtained from IRIS or HEAST, and are shown in the box on the following page.

RADIATION CASE STUDY:
TOXICITY INFORMATION FOR RADIONUCLIDES OF POTENTIAL CONCERN*

Radionuclides	Radioactive Half-life (yr)	Decay Mode	ICRP Lung Classification	Inhalation Slope Factor (risk/pCi)	Ingestion Slope Factor (risk/pCi)	External Exposure Slope Factor (risk/yr per pCi/m^2)
H-3	12	beta	g	7.8E-14	5.5E-14	NA
C-14	5730	beta	g	6.4E-15	9.1E-13	NA
P-32	0.04	beta	D	3.0E-12	3.5E-12	NA
S-35	0.24	beta	D	1.9E-13	2.2E-13	NA
Co-60	5	beta/gamma	Y	1.6E-10	1.5E-11	1.3E-10
Sr-90	29	beta	D	5.6E-11	3.3E-11	NA
Cs-137	30	beta	D	1.9E-11	2.8E-11	NA
Ra-226	1600	alpha/gamma	W	3.0E-09	1.2E-10	4.2E-13
Am-241	432	alpha/gamma	W	4.0E-08	3.1E-10	1.6E-12
Am-243	7380	alpba/gamma	W	4.0E-08	3.1E-10	3.6E-12

* Sources: HEAST and Federal Guidance Report No. 11. All information in this example is for illustration only.

NA = Not applicable (i.e., these radionuclides are not gamma-emitters and the direct radiation exposure pathway can be ignored).

Calculate Risk-based PRGs. At this step, risk-based PRGs are calculated for each radionuclide of potential concern using the reduced risk Equation (11′) in Section 4.1.2, SF values obtained from IRIS and HEAST, and standardized default values for parameters for the residential land-use scenario. To calculate the risk-based PRG for Co-60 at a pre-specified target risk level of 10^{-6}, for example, its ingestion SF of 1.5×10^{-11} and its external exposure SF of 1.3×10^{-10} are substituted into Equation (11′), along with the standardized default values, as follows:

$$\text{Risk-based PRG for Co-60 (pCi/g; TR} = 10^{-6}) = \frac{1 \times 10^{-6}}{1.3 \times 10^{3}\,(SF_o) + 3.4 \times 10^{6}\,(SF_e)}$$

where:

SF_o = oral (ingestion) slope factor for Co-60 = 1.5×10^{-11} (risk/pCi)

SF_e = external exposure slope factor for Co-60 = 1.3×10^{-10} (risk/yr per pCi/m^2)

Substituting the values for SF_o and SF_e for Co-60 into Equation (11′) results in:

Risk-based PRG for Co-60 (pCi/g; TR = 10^{-6}) =

$$\frac{1 \times 10^{-6}}{[(1.3 \times 10^{3})(1.5 \times 10^{-11}) + (3.4 \times 10^{6})(1.3 \times 10^{-10})]}$$

= 0.002 pCi of Co-60/g of soil

In a similar manner, risk-based PRGs can be calculated for all other radionuclides of concern in soil at the ACME Radiation Co. site. These PRGs are presented in the next box.

RADIATION CASE STUDY: INITIAL RISK-BASED PRGs FOR RADIONUCLIDES IN SOIL*

Radionuclides	Risk-based Soil PRG (pCi/g)
H-3	14,000
Sr-90 (only)	23
P-32	220
S-35	3,500
C-14	850
Co-60	0.002
Cs-137 (only)	27
Ra-226 (only)	0.6
Am-241	0.2
Am-243 (only)	7.9×10^{-2}

* Calculated for illustration only using Equation (11′) in Section 4.1.2. Values have been rounded off.

4.3.3 AFTER THE BASELINE RISK ASSESSMENT

In this subsection, several steps are outlined which demonstrate how site-specific data obtained during the baseline risk assessment can be used to recalculate risk-based PRGs for radionuclides in soil. Appropriate sections of Chapters 2 and 3 should be consulted for more detailed explanations for each step considered below.

Review Media of Concern. During the RI/FS, gamma radiation surveys were conducted in the yards of several homes located within a two-block radius of the ACME Radiation Co. site. Elevated exposure rates, ranging from approximately two to four times the natural background rate, were measured on properties immediately bordering the site. Measurements onsite ranged from 10 to 50 times background. In both cases, enhanced soil concentrations of Ra-226 (and decay products) and several other gamma-emitting radionuclides were discovered to be the sources of these elevated exposure rates. Therefore, soil continues as a medium of potential concern.

Modify List of Radionuclides of Concern. During scoping, five radionuclides (Ra-226, H-3, C-14, Cs-137, and Sr-90) were detected in elevated concentrations in soil samples collected at the ACME Radiation Co. site. These made up the initial list of radionuclides of potential concern. Although not detected during the first round of sampling, five additional radionuclides (P-32, S-35, Co-60, Am-241, and Am-243) were added to this list because of their potential to migrate from buried leaking drums into the surrounding soil.

With additional RI/FS data, some radionuclides are now added to the list, while others are dropped. For example, soil analyses failed to detect P-32 (14-day half-life) or S-35 (87-day half-life) contamination. Decay correction calculations strongly suggest that these radionuclides should not be present onsite in detectable quantities after an estimated burial time of 30 years. Therefore, based on these data, P-32 and S-35 are dropped from the list. Soil data also confirm that decay products of Ra-226, Sr-90, Cs-137, and Am-243 (identified in the first box below)

are present in secular equilibrium (i.e., equal activity concentrations) with their respective parent isotopes.

Assuming secular equilibrium, slope factors for the parent isotope and each of its decay series members are summed. Parent isotopes are designated with a "+D" to indicate the composite slope factors of its decay chain (shown in bold face in the second box below). Thus, Ra-226+D, Sr-90+D, Cs-137+D, and Am-243+D replace their respective single-isotope values in the list of radionuclides of potential concern, and their composite SFs are used in the full soil pathway equation to recalculate risk-based concentrations.

RADIATION CASE STUDY: DECAY PRODUCTS

Parent Radionuclide	Decay Product(s) (Half-life)
Ra-226	Rn-222 (4 days), Po-218 (3 min), Pb-214 (27 min), Bi-214 (20 min), Po-214 (<1 s), Pb-210 (22 yr), Bi-210 (5 days), Po-210 (138 days)
Sr-90	Y-90 (14 hr)
Cs-137	Ba-137m (2 min)
Am-243	Np-239 (2 days)

RADIATION CASE STUDY: SLOPE FACTORS FOR DECAY SERIES[a]

	Slope Factors		
Decay Series	Inhalation	Ingestion	External
Ra-226	3.0E-09	1.2E-10	4.2E-13
Rn-222	7.2E-13	—	2.2E-14
Po-218	5.8E-13	2.8E-14	0.0E+00
Pb-214	2.9E-12	1.8E-13	1.5E-11
Bi-214	2.2E-12	1.4E-13	8.0E-11
Po-214	2.8E-19	1.0E-20	4.7E-15
Pb-210	1.7E-09	6.5E-10	1.8E-13
Bi-210	8.1E-11	1.9E-12	0.0E+00
Po-210	2.7E-09	2.6E-10	4.8E-16
Ra-226+D	**7.5E-09**	**1.0E-09**	**9.6E-11**
Sr-90	5.6E-11	3.3E-11	0.0E+00
Y-90	5.5E-12	3.2E-12	0.0E+00
Sr-90+D	**6.2E-11**	**3.6E-11**	**0.0E+00**
Cs-137	1.9E-11	2.8E-11	0.0E+00
Ba-137m	6.0E-16	2.4E-15	3.4E-11
Cs-137+D	**1.9E-11**	**2.8E-11**	**3.4E-11**
Am-243	4.0E-08	3.1E-10	3.6E-12
Np-239	1.5E-12	9.3E-13	1.1E-11
Am-243+D	**4.0E-08**	**3.1E-10**	**1.5E-11**

[a] All information in this example is for illustration purposes only.

Review Land-use Assumptions. At this step, the future land-use assumption chosen during scoping is reviewed. Since the original assumption of future residential land use is supported by RI/FS data, it is not modified.

Modify Exposure Pathways, Parameters, and Equations. Based on site-specific information, the upper-bound residence time for many of the individuals living near the ACME Radiation Co. site is determined to be 45 years rather than the default value of 30 years. Therefore, the exposure duration parameter used in Equation (11) in Section 4.1.2 is substituted accordingly. It is also determined that individuals living near the site are only exposed to the external gamma radiation field approximately 18 hours each day, and that their homes provide a shielding factor of about 0.5 (i.e., 50%). Therefore, values for T_e and S_e are changed to 0.75 (i.e., 18 hr/24 hr) and 0.5, respectively.

Modify Toxicity Information. As discussed above in the section on modifying the list of radionuclides of concern, oral, inhalation, and external exposure slope factors for Ra-226, Sr-90, Cs-137, and Am-243 were adjusted to account for the added risks (per unit intake and/or exposure) contributed by their respective decay series members that are in secular equilibrium.

Recalculate Risk-based PRGs. At this step, risk-based PRGs are recalculated for all remaining radionuclides of potential concern using the full risk equation for the soil pathway (i.e., Equation (11)) modified by revised site-specific assumptions regarding exposures, as discussed above.

To recalculate the risk-based PRG for Co-60 at a pre-specified target risk level of 10^{-6}, for example, its ingestion SF of 1.5×10^{-11}, and its external exposure SF of 1.3×10^{-10} are substituted into Equation (11), along with other site-specific parameters, as shown in the next box.

In a similar manner, risk-based PRGs can be recalculated for all remaining radionuclides of potential concern in soil at the ACME Radiation Co. site. These revised PRGs are presented in the box on the next page. In those cases where calculated risk-based PRGs for radionuclides are below current detection limits, risk assessors should contact the Superfund Health Risk Technical Support Center for additional guidance.

RADIATION CASE STUDY: REVISED RISK EQUATION FOR RESIDENTIAL SOIL

RS for Co-60 (pCi/g; *risk-based*)

$$= \frac{TR}{(SF_o \times 10^{-3} \times EF \times IF_{soil/adj}) + (SF_e \times 10^{3} \times ED \times D \times SD \times (1-S_e) \times T_e)}$$

$$= 0.003 \text{ pCi/g}$$

where:

Parameters	Definition (units)	Revised Value
RS	radionuclide PRG in soil (pCi/g)	—
TR	target excess individual lifetime cancer risk (unitless)	10^{-6}
SF_o	oral (ingestion) slope factor (risk/pCi)	1.5×10^{-11} (risk/pCi)
SF_e	external exposure slope factor (risk/yr per pCi/m^2)	1.3×10^{-10} (risk/yr per pCi/m^2)
EF	exposure frequency (days/yr)	350 days/yr
ED	exposure duration (yr)	45 yr
$IF_{soil/adj}$	age-adjusted soil ingestion factor (mg-yr/day)	5100 mg-yr/day
D	depth of radionuclides in soil (m)	0.1 m
SD	soil density (kg/m^3)	1.43×10^3 kg/m^3
S_e	gamma shielding factor (unitless)	0.5
T_e	gamma exposure time factor (unitless)	0.75

(Note: To account for the revised upper-bound residential residency time of 45 years, the age-adjusted soil ingestion factor was recalculated using the equation in Section 4.1.2 and an adult exposure duration of 39 years for individuals 7 to 46 years of age.)

RADIATION CASE STUDY:
REVISED RISK-BASED PRGs FOR RADIONUCLIDES IN SOIL*

Radionuclides	Risk-based Soil PRG (pCi/g)
H-3	10,200
Sr-90+D	20
C-14	620
Co-60	0.003
Cs-137+D	0.01
Ra-226+D	0.004
Am-241	0.2
Am-243+D	0.03

* Calculated for illustration only. Values have been rounded off.