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.

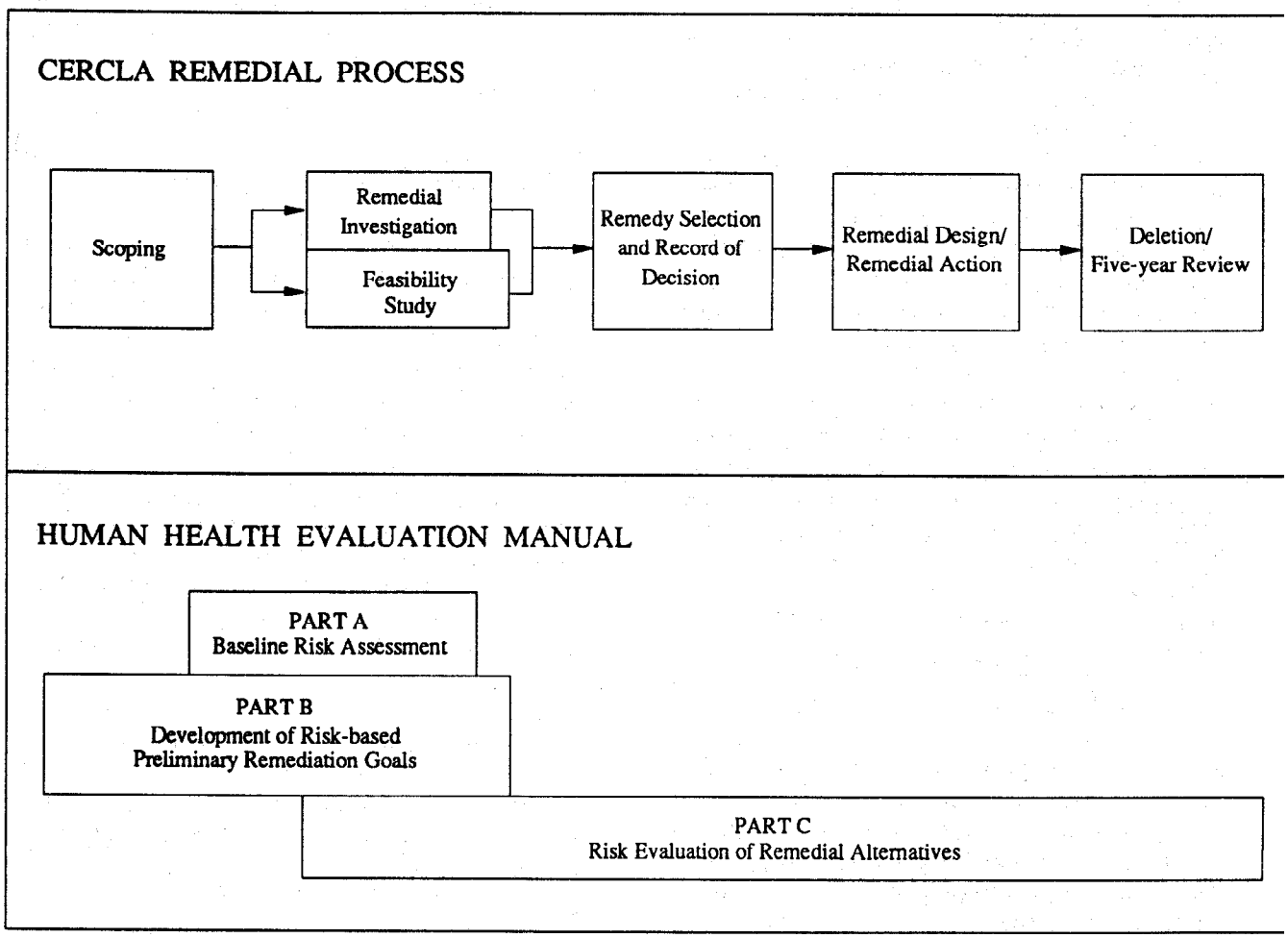
Chemical-specific PRGs are concentration goals for individual chemicals for specific medium and land use combinations at CERCLA sites. There are two general sources of chemical-specific PRGs: (1) concentrations based on ARARs and (2) concentrations based on risk assessment. ARARs include concentration 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.