CHAPTER 1

INTRODUCTION

This guidance has been developed by the U.S. Environmental Protection Agency (EPA) to assist remedial project managers (RPMs), risk assessors, site engineers, and others in conducting risk assessment planning, reporting, and review at Comprehensive Environmental Response Compensation and Liability Act (CERCLA) sites. This guidance could also be a useful tool for quantitative risk assessment for non-National Priorities List (Non-NPL), Base Realignment and Closure (BRAC), and Brownfields sites.

This guidance is the fourth part (Part D) in the five-part series *Risk Assessment Guidance for Superfund: Volume I -- Human Health Evaluation Manual* (RAGS/HHEM) (U.S. EPA, 1989c). Part A of this guidance addresses how to conduct a site-specific baseline risk assessment: the information in Part A is important background for Part D. Part B provides guidance for calculating risk-based concentrations that may be used, along with applicable or relevant and appropriate requirements (ARARs) and other information, to develop preliminary remediation goals (PRGs) during project scoping. PRGs (and final remediation levels set in the Record of Decision [ROD]) can be used throughout the analyses in Part C to assist in evaluating the human health risks of remedial alternatives. Part E provides guidance for evaluation of dermal exposure. Part D complements the guidance provided in Parts A, B, C, and E and presents recommended approaches to standardize risk assessment planning, reporting, and review. Part D guidance spans the CERCLA remedial process from project scoping to periodic review of the implemented remedial action. Exhibit 1-1 illustrates the major correspondence of RAGS/HHEM activities with the steps in the CERCLA remedial process.

The remainder of this chapter:

- presents an overview of Part D, including the background and elements of the Part D approach
- describes the applicability of Part D
- presents the organization of the remainder of this document
- describes where to find additional information regarding Part D.

1.1 OVERVIEW OF PART D

1.1.1 BACKGROUND

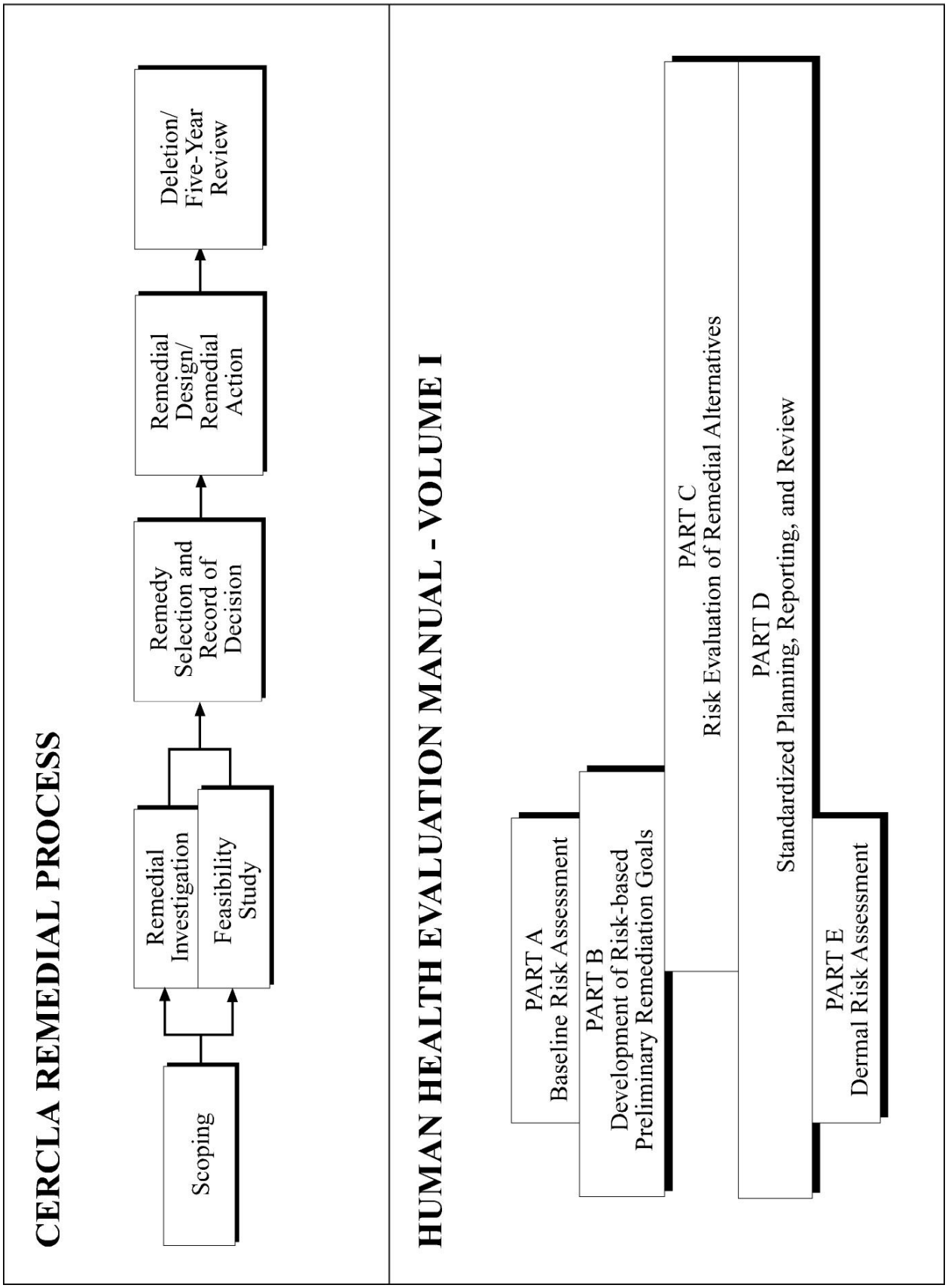
The March 21, 1995, memorandum on Risk Characterization Policy and Guidance from former EPA Administrator Browner directed improvement in the transparency, clarity, consistency, and reasonableness of risk assessments at EPA. EPA, over the years, has identified opportunities for improvement in presentation of Superfund risk assessments. Furthermore, the General Accounting Office (GAO), members of Congress, and others have called for betterment of Superfund risk assessments. The October 1995 Superfund Administrative Reform #6A directed EPA to: Establish National Criteria to Plan, Report, and Review Superfund Risk Assessments. EPA has developed an approach to respond to these challenges, which is presented in RAGS Part D.

1.1.2 GUIDANCE CHANGES

Released in January 1998 as interim guidance, RAGS Part D Revision 0 underwent field testing and evaluation for a 3-year period. This Final guidance incorporates changes based on the comments received from users of the Revision 0 guidance and provides recommended Planning Table format changes as appropriate.

Generally, changes were made to improve useability, transparency, clarity, or consistency with other risk guidance (e.g., RAGS Part E dermal guidance [U.S. EPA, 2001] and ROD guidance [U.S. EPA, 1999a]). These changes may also increase the efficiency of the risk assessor by decreasing the number of versions of each Planning Table associated with certain sites.

EXHIBIT 1-1
RELATIONSHIP OF THE HUMAN HEALTH EVALUATION TO THE CERCLA PROCESS



In addition to Planning Table format changes, the Final guidance provides standard formats to document radionuclide and lead risk evaluations, neither of which was addressed in the Revision 0 guidance. This final guidance also provides more robust and diverse examples than were included in Revision 0. These examples address comments and questions received from users of the Revision 0 guidance and are provided as suggested approaches to address complex situations. In all cases, the EPA risk assessor and the RPM (when appropriate) should be consulted to discuss the appropriate approach for a site. Revisions associated with each Planning Table may be found in Exhibit 3-3.

1.1.3 ELEMENTS OF PART D APPROACH

The *Risk Assessment Guidance for Superfund* (RAGS) Part D approach consists of three basic elements: Use of Planning Tools, Continuous Involvement of EPA Risk Assessors, and Information Transfer to a National Superfund Risk Data Repository. Brief descriptions of the three components follow:

- **Use of Planning Tools** - The Planning Tools developed by the EPA RAGS Part D Workgroup and refined through regional review include a Technical Approach for Risk Assessment or TARA, Planning Tables, and Instructions for the Planning Tables.

  -- The Technical Approach for Risk Assessment (TARA) is a road map for incorporating continuous involvement of the EPA risk assessor throughout the CERCLA remedial process for a particular site. Risk-related activities, beginning with scoping and problem formulation, extending through collection and analysis of risk-related data, and supporting risk management decision making and remedial design/remedial action issues are addressed.

  Chapters 2 through 5 of this guidance document present the TARA in the four CERCLA remedial process phases: During Scoping, During the Remedial Investigation, During the Feasibility Study, and After the Feasibility Study. It is recommended that the elements identified in the TARA in Chapters 2 through 5 be customized for each site-specific human health risk assessment, as appropriate. These elements should be included in project workplans to better define that risk assessment and facilitate more standardized planning. A planning worksheet that can be used to summarize the TARA for a particular site (the TARA Schedule Worksheet) is found in Appendix C.

  -- The Planning Tables have been developed to more clearly and consistently document important parameters, data, calculations, and conclusions from all stages of human health risk assessment development. Electronic templates for the Planning Tables have been developed in Lotus® and Excel® for ease of use by risk assessors. For site-specific risk assessments, the Planning Tables, related Worksheets, and Supporting Information should first be prepared as Interim Deliverables for EPA risk assessor review, and should later be included in the Draft and Final Baseline Risk Assessment Reports. The Planning Tables, both a blank set and a fully completed example set, may be found in Appendix A. Additional example scenarios and selected Planning Tables are provided in Appendix D. Use of the Planning Tables will help standardize the reporting of human health risk assessments and improve communication with stakeholders.

  -- Instructions for the Planning Tables have been prepared corresponding to each row and column on each Planning Table. Definitions of each field are supplied in the Glossary and example data or selections for individual data fields are provided. The Instructions should be used to complete and/or review Planning Tables for each site-specific human health risk assessment, where appropriate. The Instructions may be found in Appendix B.

- **Continuous Involvement of EPA Risk Assessors** - The EPA risk assessor is a critical

participant in the CERCLA remedial process for any site, from scoping through completion and periodic review of the remedial action. EPA risk assessors support reasonable and consistent risk analysis and risk-based decision making. Early and continuous involvement by the EPA risk assessors should include scoping, workplan review, and customization of the TARA for each site to identify all risk-related requirements. The EPA risk assessors should review Interim Deliverables and identify corrections needed prior to preparation of the Draft and Final Baseline Risk Assessment Reports. Participation of the EPA risk assessors in all other phases of the CERCLA remedial process will help ensure human health risk issues are appropriately incorporated in the remedy selection and implementation processes.

- **Information Transfer to a Superfund Risk Data Collection -** Summary-level site-specific risk information should be contained in a Superfund Risk Data Repository to provide information access and evaluation capabilities to EPA staff.

1.2 APPLICABILITY OF PART D APPROACH

The approach contained in RAGS Part D is strongly recommended for all CERCLA human health risk assessments.

Exhibit 1-2 provides guidelines regarding RAGS Part D applicability as a function of site lead and site type, so that site-specific applicability may be defined by each region.

1.3 PROCESS IMPROVEMENTS RESULTING FROM PART D APPROACH

The RAGS Part D approach provides advantages over previous practices in the Superfund program at both the site level and the overall Superfund program level.

A brief discussion of the process improvements associated with each RAGS Part D element follows:

- **Use of Planning Tools** - Planning Tools facilitate planning with TARA, reporting with Planning Table formats, and reviewing with Interim Deliverables. The Planning Tools are designed to provide more consistent content and clarity of data, parameters, and assumptions. Transparency for the public and others to understand the risk assessment should be improved by the Planning Tables, and review is facilitated because the basis for conclusions should be more clear. Because Interim Deliverables are integral parts of the baseline risk assessment, their early review and resolution by EPA risk assessors should minimize rework and may reduce project schedules and budgets, while improving consistency.

- **Continuous Involvement of EPA Risk Assessor** - Involvement of the EPA risk assessor throughout the CERCLA remedial process should result in holistic consideration of risk issues during scoping and helps ensure that appropriate and adequate data are collected. Planning for special evaluations can also be conducted efficiently at project inception rather than at a later point with associated schedule delays and additional costs. Ongoing review of Interim Deliverables by the EPA risk assessor should provide direction regarding reasonable assumptions and should eliminate rework requirements, particularly for those deliverables that build on previous analyses (e.g., the Baseline Risk Assessment Report).

Exhibit 1-2 goes here

At later stages of the project (e.g., after the feasibility study), continuous involvement of the EPA risk assessor promotes reasonableness and consistency in risk management decision-making by clearly providing risk managers with the information they need. Preparation of draft ROD risk information as an interim deliverable in the format specified in Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents (U.S. EPA, 1999a) will further support risk managers' efficiency. The ROD Risk Worksheets found in Appendix C match the ROD guidance formats.

- **Information Transfer to Superfund Risk Data Collection** - Submission of the electronic Planning Tables and Worksheets to the Superfund Risk Data Collection fulfills the review objectives of Superfund Administrative Reform #6A. Use of the information by EPA risk assessors will help improve consistency in future risk assessments.

1.4 ORGANIZATION OF DOCUMENT

The remainder of this guidance is organized into four additional chapters, references, and four appendices as follows:

- Chapter 2: Risk Considerations During Project Scoping;
- Chapter 3: Risk Assessment Data Needs and Tasks During the Remedial Investigation;
- Chapter 4 Risk Evaluations During the Feasibility Study;
- Chapter 5: Risk Evaluations After the Feasibility Study;
- References
- Appendix A: Planning Tables
- Appendix B: Instructions for Completion of Planning Tables
- Appendix C: Worksheets
- Appendix D: Example Scenarios.

In addition, other useful information has been presented in highlight boxes placed throughout the document.

Exhibit 1-3 depicts the continuous involvement of the EPA risk assessor during scoping, during the remedial investigation, and during and after the feasibility study. The various activities the risk assessor conducts are listed, as well as the Part D chapter that addresses that phase.

1.5 ADDITIONAL INFORMATION

This guidance will be updated periodically in response to user comments and suggestions and to address new human health risk assessment guidance as appropriate.

The Part D guidance and corresponding information may be accessed electronically on the RAGS Part D website, at http://www.epa.gov/superfund/programs/risk/ragsd/index.htm . Updates to Part D will also appear on the website along with an index of the current version of each Chapter or Appendix.

Questions or comments regarding Part D usage for a particular risk assessment should be directed to your EPA risk assessor. General Part D questions or comments should be directed to the RAGS Part D website. Questions or comments received through the website will be considered and a response will be developed and forwarded via telephone or email as appropriate. Frequently asked questions will be assembled and displayed on the website with corresponding responses to provide Part D user support.

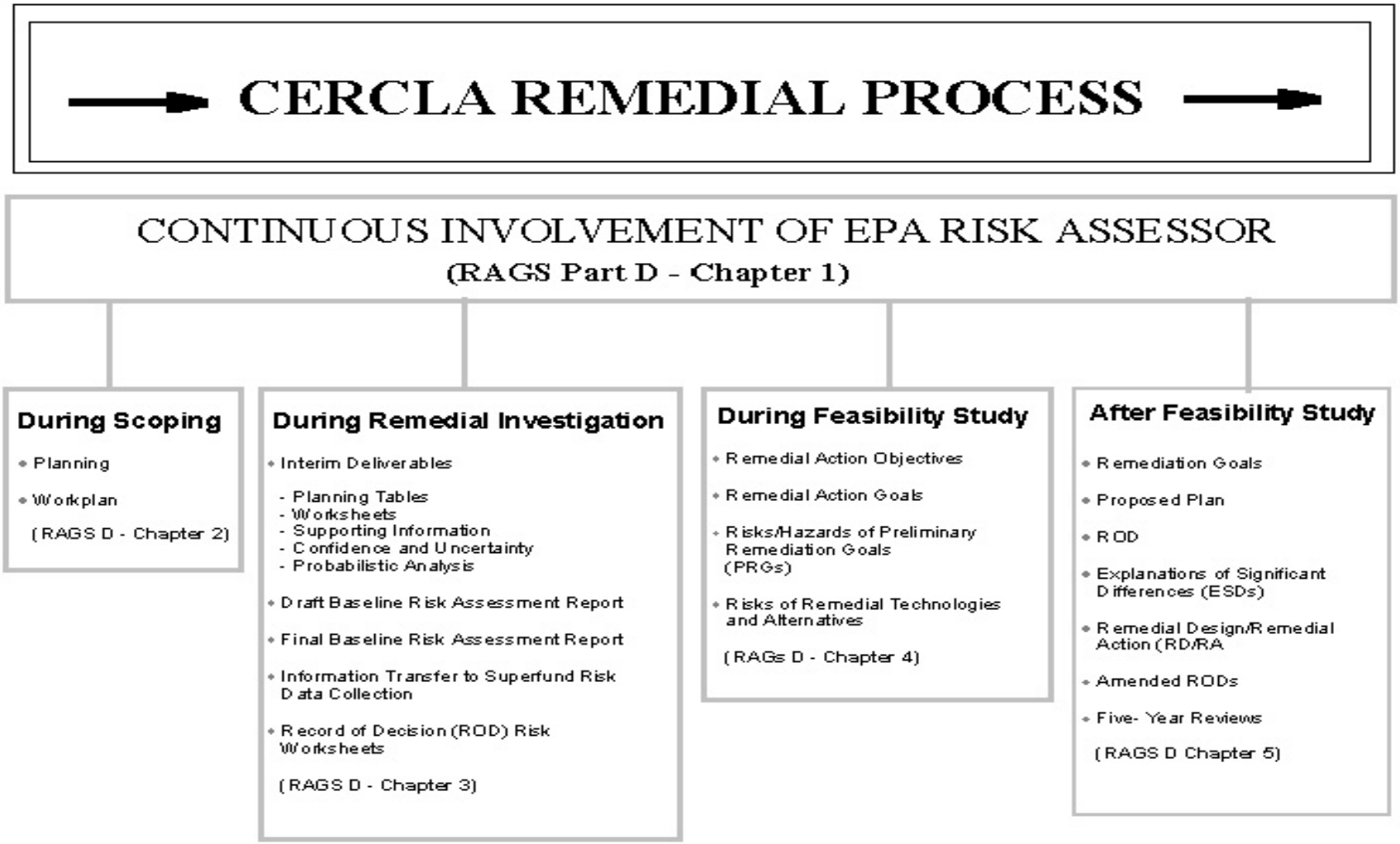



EXHIBIT 1-3
ROLE OF RISK ASSESSOR IN THE CERCLA REMEDIAL PROCESS