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# Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments)

## Final

**Office of Emergency and Remedial Response**
**U.S. Environmental Protection Agency**
**Washington, DC 20460**

# NOTICE

This document provides guidance to EPA Regions regarding National policy on the planning, reporting, and review of Superfund risk assessments Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular situation will be made based on the statute and regulations, and EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future, as appropriate.

This guidance is based on 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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# CONTENTS (Continued)

# EXHIBITS

# DEFINITIONS

| Term | Definition |
|---|---|
| Applicable or Relevant and Appropriate Requirements (ARARs) | "Applicable" requirements are those clean-up 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. |
| 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." |
| Deterministic Analysis | Calculation and expression of health risks as single numerical values or "single point" estimates of risk. In risk assessments, the uncertainty and variability are discussed in a qualitative manner. |
| EPA Risk Assessor | The risk assessor responsible for reviewing the risk assessment on behalf of EPA. The individual may be an EPA employee or contractor, a State employee, or some other party, as appropriate for an individual site. |
| Exposure Medium | The contaminated environmental medium to which an individual may be exposed. Includes the transfer of contaminants from one Medium to another. |

## DEFINITIONS (Continued)

| Term | Definition |
|---|---|
| Exposure Pathway | The course a chemical or radionuclide takes from the source to the exposed individual. An exposure pathway analysis links the sources, locations, and types of environmental releases with population locations and activity patterns to determine the significant pathways of human exposure. Within the Standard Tables, an Exposure Pathway is defined as each unique combination of Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, Receptor Age, and Exposure Route. |
| Exposure Point | An exact location of potential contact between a person and a chemical or radionuclide within an Exposure Medium. |
| Exposure Point Concentration | The value, based on either a statistical derivation of measured data or modeled data, that represents an estimate of the chemical or radionuclide concentration available from a particular Medium or route of exposure. |
| Exposure Route | The way a chemical or radionuclide comes in contact with a person (e.g., by ingestion, inhalation, dermal contact). |
| Interim Deliverables | A series of Standard Tables, Worksheets, and Supporting Information, identified in the Workplan for each site, that should be developed by the risk assessment author, and evaluated by the EPA risk assessor, prior to development of the Draft Baseline Risk Assessment Report. After review and revision, as necessary, these documents should be included in the Baseline Risk Assessment Report. The Standard Tables should be prepared for each site to achieve standardization in risk assessment reporting. The Worksheets and Supporting Information should also be prepared to further improve transparency, clarity, consistency, and reasonableness of risk assessments. |
| Medium | The environmental substance (e.g, air, water, soil) that is a potential source of contaminants in the Exposure Medium. (The Medium will sometimes equal the Exposure Medium.) Usually the Medium is that targeted for possible remediation. |

## DEFINITIONS (Continued)

| Term | Definition |
|---|---|
| Preliminary Remediation Goals (PRGs) | Initial cleanup goals that (1) are protective of human health and the environment and (2) comply with ARARs They are developed early in the remedy selection 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). Remedial goals, selected as part of the risk management decision, replace PRGs in the Record of Decision. |
| Probabilistic Analysis | Calculation and expression of health risks using multiple risk descriptors to provide the likelihood of various risk levels. Probabilistic risk results approximate a full range of possible outcomes and the likelihood of each, which often are presented as a frequency distribution graph, thus allowing uncertainty or variability to be expressed quantitatively. |
| Risk Assessment Author | The risk assessor responsible for preparing the risk assessment. This individual may be an EPA employee or contractor, a State employee, à PRP employee or contractor, or some other party, as appropriate for an individual site. |
| Receptor Age | The description of the exposed individual as defined by the EPA Region or dictated by the site. |
| Receptor Population | The exposed individual relative to the Exposure Pathway considered. |
| Scenario Timeframe | The time period (current and/or future) being considered for the Exposure Pathway. |

## DEFINITIONS (Continued)

| Term | Definition |
|---|---|
| Standard Tables | One of the Standard Tools under the RAGS Part D approach. The Standard Tables have been developed to clearly and consistently document important parameters, data, calculations, and conclusions from all stages of human health risk assessment development. Electronic templates for the Standard Tables have been developed in Lotus® and Excel® for ease of use by risk assessors. For each site-specific risk assessment, the Standard 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 Standard Tables may be found in Appendix A. Use of the Standard Tables will standardize the reporting of human health risk assessments. The Standard Table formats should not be altered (i.e., columns should not be added, deleted, or changed); however, rows and footnotes may be added as appropriate. Standardization of the Tables is needed to achieve Superfund program-wide reporting consistency. |
| Standard Tools | A basic element of the RAGS Part D approach. The Standard Tools have been developed to standardize the planning, reporting, and review of Superfund risk assessments. The three Standard Tools contained in the Part D approach include the Technical Approach for Risk Assessment (TARA), the Standard Tables, and Instructions for the Standard Tables. |
| Supporting Information | Information submissions that substantiate or summarize detailed data analysis, calculations, or modeling and associated parameters and assumptions. Examples of recommended Supporting Information include: derivations of background values, exposure point concentrations, modeled intakes, and chemical-specific parameters. Supporting Information should be provided as Interim Deliverables for EPA risk assessor review prior to the development of the Draft Baseline Risk Assessment Report. |

## DEFINITIONS (Continued)

| Term | Definition |
|---|---|
| Technical Approach for Risk Assessment (TARA) | One of the Standard Tools under the RAGS Part D approach The TARA is a road map for incorporating continuous involvement of the EPA risk assessor throughout the CERCLA remedial process. 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. The TARA should be customized for each site and the requirements identified should be included in project workplans so that risk assessment requirements and approaches are clearly defined. The TARA Schedule Worksheet may be found in Appendix C with the other worksheets. Chapters 2 through 5 of Part D present the TARA. |
| Worksheets | Formats for documenting assumptions, input parameters, and conclusions regarding complex risk assessment issues. Data Useability, TARA Schedule, Lead, Dermal, Radiation Dose Assessment, and ROD Risk Worksheets are found in Appendix C and should be developed as Interim Deliverables for all risk assessments, as applicable. |

# ACRONYMS/ABBREVIATIONS

| Acronym/ Abbreviation | Definition |
|---|---|
| ARARs | Applicable or Relevant and Appropriate Requirements |
| BRAC | Base Realignment and Closure |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act |
| COPCs | Chemicals of Potential Concern |
| CSF | Cancer Slope Factor |
| CT | Central Tendency |
| CWA | Clean Water Act |
| DQOs | Data Quality Objectives |
| EPA | U.S. Environmental Protection Agency |
| EPC | Exposure Point Concentration |
| ESD | Explanation of Significant Differences |
| FS | Feasibility Study |
| FY | Fiscal Year |
| GAO | General Accounting Office |
| HEAST | Health Effects Assessment Summary Tables |
| HI | Hazard Index |
| HQ | Hazard Quotient |
| IEUBK | Integrated Exposure Uptake Biokinetic Model |
| IRIS | Integrated Risk Information System |
| MCLs | Maximum Contaminant Levels |
| NCEA | National Center for Environmental Assessment |
| NCP | National Contingency Plan |
| NPL | National Priorities List |
| non-TCL | non-Target Compound List |
| OSWER | Office of Solid Waste and Emergency Response |
| PAHs | Polynuclear Aromatic Hydrocarbons |
| PCBs | Polychlorinated Biphenyls |
| PQLs | Procedure Quantitation Limits |
| PRGs | Preliminary Remediation Goals |
| PRP | Potentially Responsible Party |
| QA/QC | Quality Assurance/Quality Control |
| QAPP | Quality Assurance Project Plan |
| RAGS | *Risk Assessment Guidance for Superfund* |
| RAGS/HHEM | *Risk Assessment Guidance for Superfund. Volume I -- Human Health Evaluation Manual* |
| RAOs | Remedial Action Objectives |
| RfC | Reference Concentration |
| RfD | Reference Dose |
| RI/FS | Remedial Investigation/Feasibility Study |

| Acronym/ Abbreviation | Definition |
|---|---|
| RI | Remedial Investigation |
| RME | Reasonable Maximum Exposure |
| ROD | Record of Decision |
| RPM | Remedial Project Manager |
| SAP | Sampling and Analysis Plan |
| SDWA | Safe Drinking Water Act |
| TARA | Technical Approach for Risk Assessment |
| UCL | Upper Confidence Level |
| URF | Unit Risk Factor |
| UTL | Upper Tolerance Limit |

# ACKNOWLEDGMENTS

This manual was developed by EPA's Office of Emergency and Remedial Response A large number of EPA regional technical staff (see below) participated in the Workgroup that developed the RAGS Part D Revision 1 approach presented in this manual.

CDM Federal Programs Corporation provided technical assistance to EPA in the development of this guidance, under contract No. 68-W5-0022.

## RAGS PART D REVISION 1 WORKGROUP

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# PREFACE

*Risk Assessment Guidance for Superfund Volume I -- Human Health Evaluation Manual* (RAGS/HHEM) Part D is the fourth part in the five-part series of guidance manuals on Superfund human health risk assessment. Part A addresses the baseline risk assessment; Part B addresses the development of risk-based preliminary remediation goals; Part C addresses the human health risk evaluations of remedial alternatives; and Part E addresses dermal exposure. Part D provides guidance on standardized risk assessment planning, reporting, and review throughout the CERCLA remedial process, from scoping through remedy selection and completion and periodic review of the remedial action. Thus, Part D strives for effective and efficient implementation of Superfund risk assessment practice described in Parts A, B, C, and E, and in supplemental Office of Solid Waste and Emergency Response (OSWER) directives and other Agency risk assessment guidance. The potential users of Part D are persons involved in the risk evaluation, remedy selection, and implementation process, including risk assessors, risk assessment reviewers, remedial project managers, and other decisionmakers.

Released in January 1998 as interim guidance, RAGS Part D Revision 0 underwent field testing and evaluation for a 3-year period. This Revision 1 guidance considers the comments received from users of the Revision 0 guidance and provides Standard Table format changes as appropriate.

Generally, changes were made to improve useability, transparency, clarity, and/or consistency with other risk guidance (e.g., RAGS Part E dermal guidance [U.S. EPA, 2001], adult lead exposures technical fact sheet [U.S. EPA, 1996d], and Record of Decision guidance [U.S. EPA, 1999a]). These changes may also increase the efficiency of the risk assessor by decreasing the number of versions of each Standard Tables associated with certain sites.

In addition to Standard Table format changes, the Revision 1 guidance provides standard formats to document radionuclide and lead risk evaluations, neither of which was addressed in the Revision 0 guidance. The Revision 1 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 regional risk assessor should be consulted to discuss the appropriate approach for a site.

This guidance does not discuss the standardization of ecological risk assessments. EPA will provide standard tables for ecological evaluation under separate cover. This guidance does not discuss the risk management decisions that are necessary at a CERCLA site (e g., selection of final remediation goals).

Upon issuance, RAGS Part D Revision 1 will be effective for all new CERCLA risk assessments. Consult the EPA risk assessor for applicability of Revision 1 to ongoing risk assessments and non-CERCLA risk assessments. Any updates to this guidance will be posted at the RAGS Part D website at http://www.epa.gov/superfund/programs/risk/ragsd/index.htm.

Comments addressing usefulness, changes, and additional areas where guidance is needed should be addressed to the RAGS Part D website or to:

Senior Process Manager for Risk (RAGS Part D)
U.S. Environmental Protection Agency
Office of Emergency and Remedial Response (5202G)
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington, DC 20460

# 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 standardizing 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 (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 describes how to conduct a site-specific baseline risk assessment: the information in Part A is necessary 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 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

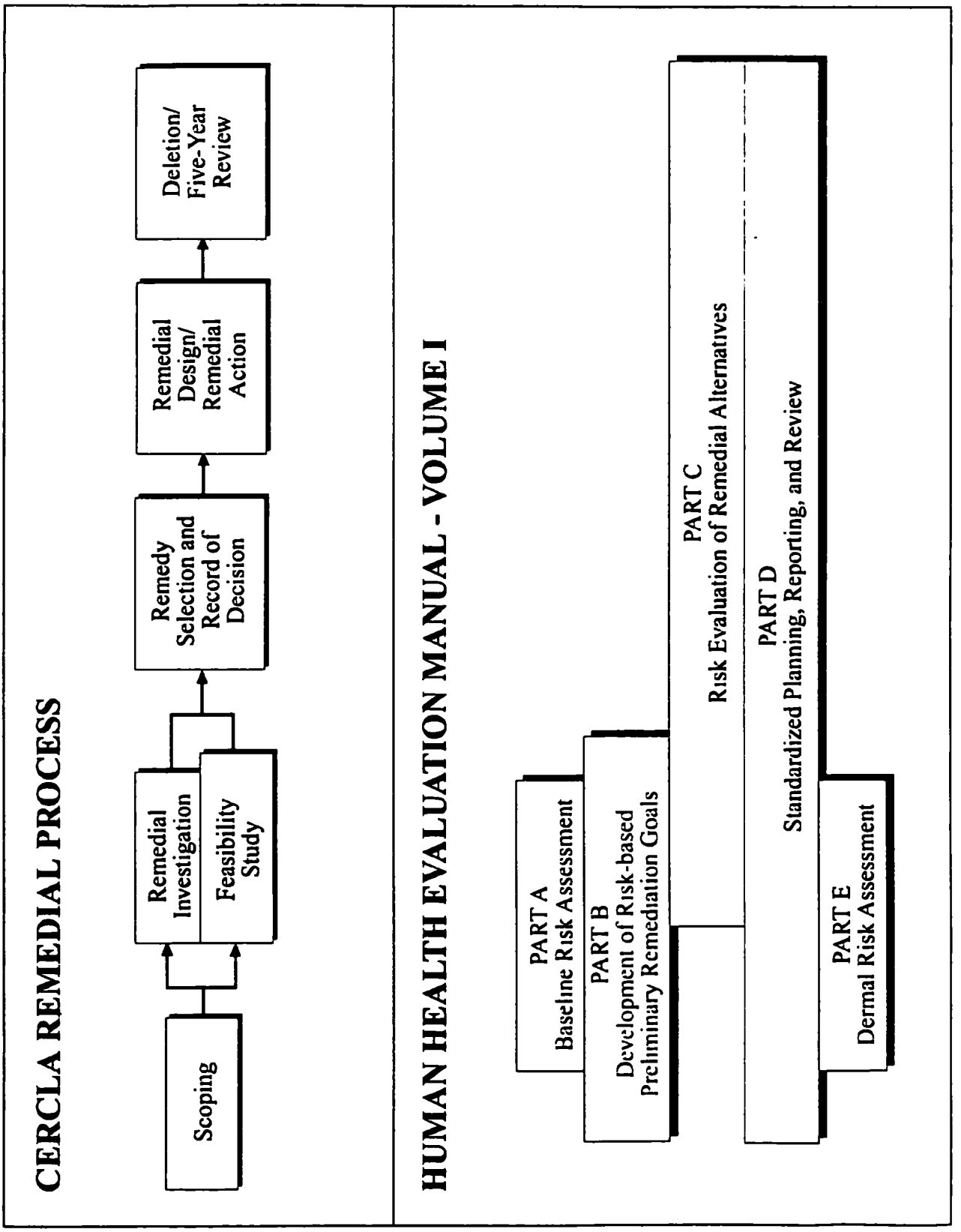
The March 21, 1995, memorandum on Risk Characterization Policy and Guidance from former EPA Administrator Browner directed improvement in the transparency, clarity, consistency, and reasonableness of risk assessments at EPA. EPA, over the years, has identified opportunities for improvement in presentation 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 REVISION 1 CHANGES

Released in January 1998 as interim guidance, RAGS Part D Revision 0 underwent field testing and evaluation for a 3-year period. This Revision 1 guidance considers the comments received from users of the Revision 0 guidance and provides Standard 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

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



guidance [U.S. EPA, 1999a]). These changes may also increase the efficiency of the risk assessor by decreasing the number of versions of each Standard Table associated with certain sites.

In addition to Standard Table format changes, the Revision 1 guidance provides standard formats to document radionuclide and lead risk evaluations, neither of which was addressed in the Revision 0 guidance. The Revision 1 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 Standard 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 Standard 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 Standard Tools** - The Standard Tools developed by the EPA RAGS Part D Workgroup and refined through regional review include a Technical Approach for Risk Assessment or TARA, Standard Tables, and Instructions for the Standard 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 requirements identified in the TARA in Chapters 2 through 5 be customized for each site-specific human health risk assessment, as appropriate. These requirements should be included in project workplans so that risk assessment requirements are clearly defined and standardized planning will occur. A worksheet that can be used to summarize the TARA for a particular site (the TARA Schedule Worksheet) is found with the other Worksheets in Appendix C.

  -- The Standard Tables have been developed to clearly and consistently document important parameters, data, calculations, and conclusions from all stages of human health risk assessment development. Electronic templates for the Standard Tables have been developed in Lotus® and Excel® for ease of use by risk assessors. For each site-specific risk assessment, the Standard 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 Standard Tables, both a blank set and a fully completed example set, may be found in Appendix A. Additional example scenarios and selected Standard Tables are provided in Appendix D. Use of the Standard Tables will standardize the reporting of human health risk assessments.

  -- Instructions for the Standard Tables have been prepared corresponding to each row and column on each Standard 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 Standard Tables for each site-specific human health risk assessment. 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 will 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 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 will 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 Standard Tools** - Standard Tools facilitate planning with TARA, reporting with Standard Table formats, and reviewing with Interim Deliverables. The Standard Tools provide consistent content and clarity of data, parameters, and assumptions. Transparency for the public and others to understand the risk assessment is improved by the Standard Tables, and review is facilitated because the basis for conclusions is clear. Because Interim Deliverables are integral parts of the baseline risk assessment, their early review and resolution by EPA risk assessors 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 results in holistic consideration of risk issues during scoping and ensures 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 provides direction regarding reasonable assumptions and eliminates rework requirements, particularly for those deliverables that build on previous analyses (e.g., the Baseline Risk Assessment Report).

## EXHIBIT 1- 2
## GUIDELINES FOR PART D APPLICABILITY

| SITE LEAD | PART D APPLICABLE |
|---|---|
| Fund Lead | ✓ |
| Federal Facility Lead | ✓ |
| PRP Lead | ✓ |
| State Lead | ✓ |
| **SITE TYPE[1]** | |
| Remedial<br>Scoping, RI/FS, Risk Assessment, Proposed Plan, ROD, RD/RA, Presumptive Remedy | ✓ |
| Post-Remedial.<br>ESD, Amended ROD,<br>Five-Year Review | ✓ |
| Removal:<br>Non-time Critical, Time-Critical, Streamlined | –[2] |
| SACM[3] | ✓ |
| RCRA Corrective Action[4] | –[2] |

Notes
1 The RAGS Part D Workgroup also suggests that RAGS Part D could be a useful tool for quantitative risk assessment for non-NPL, BRAC, and Brownfields sites and encourages its use
2 RAGS Part D use is encouraged as appropriate
3 Superfund Accelerated Cleanup Model
4 As described in the September 1996 EPA memorandum on Coordination Between Resource Conservation and Recovery Act (RCRA) Corrective Action and Closure and CERCLA Site Activities, EPA is " committed to the principle of parity between the RCRA corrective action and CERCLA programs "

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 Standard 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: Standard Tables
- Appendix B: Instructions for Completion of Standard 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.

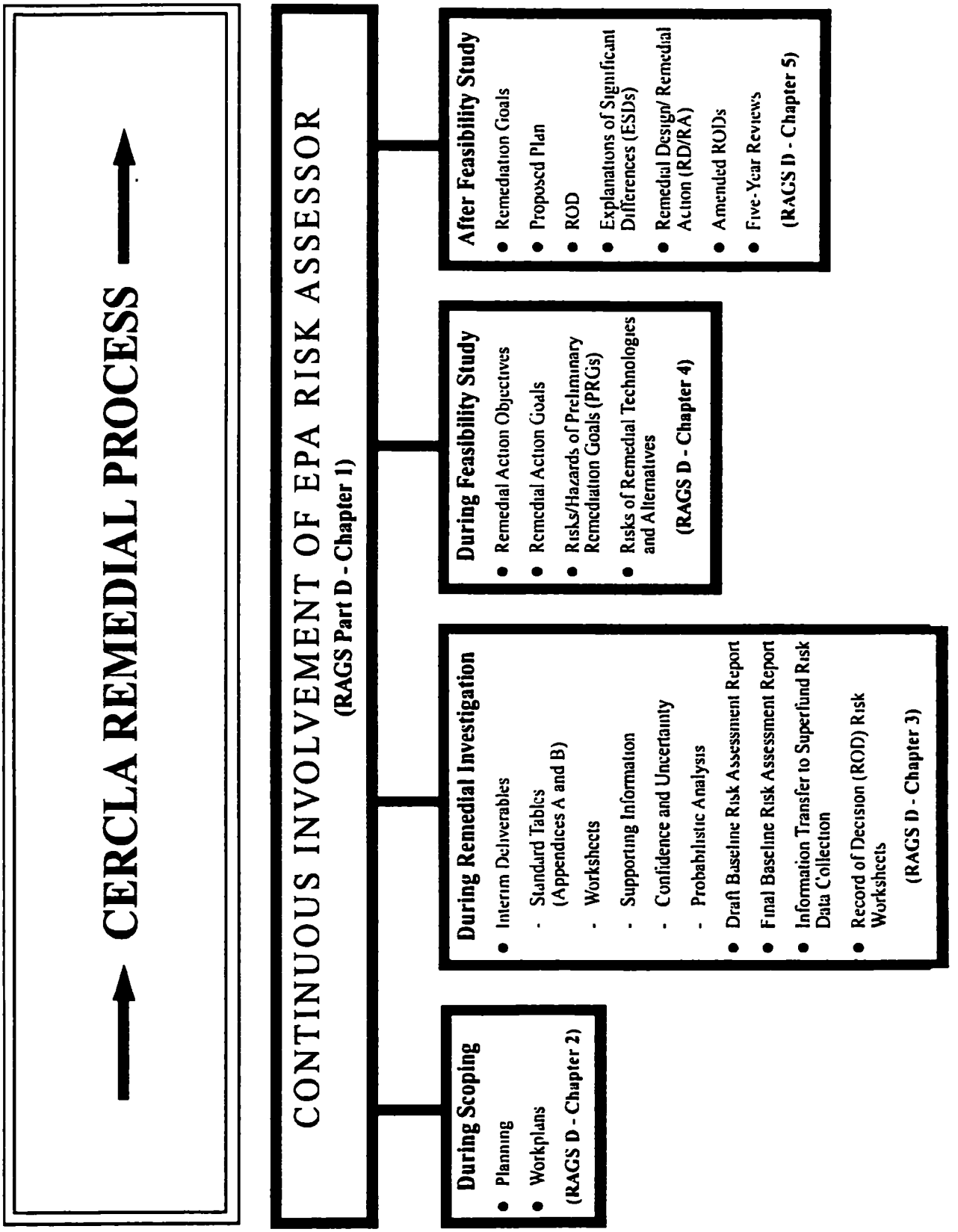
## 1.5 ADDITIONAL INFORMATION

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**



# CHAPTER 2

# RISK CONSIDERATIONS DURING PROJECT SCOPING

The project scoping stage of the remedial investigation (RI) and baseline risk assessment is critical to the success of a Superfund project. The EPA risk assessor should be involved in the project scoping discussions and meetings to ensure that the planning and workplan development tasks incorporate risk assessment data needs and achieve standardization in risk assessment planning.

## 2.1 PLANNING

The following planning activities should be performed at the beginning of the project. These activities should involve the EPA RPM and EPA risk assessor, as decisionmakers, and the risk assessment author and other resources tasked with preparing the Remedial Investigation Report, to support planning. Pertinent information should be incorporated, as appropriate, into the Remedial Investigation Report or Site Characterization Report and the Baseline Risk Assessment Report:

- Provide site background information, site maps, sample location map; discuss historical site activity and chronology of land use.
- Discuss historical data and data useability, previous studies and actions, and an overview of the nature and extent of contamination.
- Discuss the purpose of the investigation.
- Prepare the preliminary site conceptual model which clearly identifies all potential sources of contamination (soil, groundwater, surface water, leachate, air, etc.), release mechanisms, and receptor routes and identifies all potential exposure pathways (including secondary pathways) and the media and receptors associated with each.
- Discuss PRGs and ARARs for the site.

WHEN PREPARING THE SITE CONCEPTUAL MODEL, CONSIDER THE FOLLOWING

- Sensitive populations, including but not limited to the elderly, pregnant or nursing women, infants and children, and people suffering from chronic illnesses
- People exposed to particularly high levels of contaminants
- Circumstances where a disadvantaged population is exposed to hazardous materials (i.e., Environmental Justice situations)
- Significant contamination sources
- Potential contaminant release mechanisms (e g , volatilization, fugitive dust emission, surface runoff/overland flow, leaching to groundwater, tracking by humans/animals, soil gas generation, biodegradation and radioactive decay)
- Contaminant transport pathways such as direct air transport downwind, diffusion in surface water, surface water flow, groundwater flow, soil gas migration, and biomagnification in the food chain
- Cross media transfer effects, such as volatilization to air; wet deposition, dry deposition, groundwater discharge to surface water, groundwater recharge from surface water, and bioaccumulation by aquatic species

- Involve the risk assessor in discussions with the stakeholders concerning land use,

groundwater use, and exposure pathways and variables. If possible, the risk assessor should also visit the site.

- Identify interim deliverables for the risk assessment.

INTERIM DELIVERABLES SHOULD INCLUDE THE FOLLOWING:

- Standard Tables 0 through 10
- Worksheets on Data Useability, TARA Schedule, Dermal, Radiation Dose Assessment, and Lead (as applicable)
- Supporting Information (Section 3.1.1)
- Assessment of Confidence and Uncertainty (Section 3.1.2) and Probabilistic Analysis information, as applicable (Section 3.1 3).

- Identify Draft and Final deliverables for the risk assessment. Draft and Final deliverables include the Draft and Final Baseline Risk Assessment Reports, which also incorporate the Interim Deliverables.
- Prepare a preliminary version of Standard Table 1.
- During project scoping, the EPA RPM and EPA risk assessor may also meet to discuss the potential need for including a Probabilistic Analysis (Monte Carlo) in the RI and the need for a separate Workplan. This preliminary discussion is necessary to determine whether funds need to be allocated to carry out a Probabilistic Analysis. This decision should be revisited throughout Workplan development and the risk assessment process.

## 2.2 WORKPLAN DEVELOPMENT

Tasks to be conducted during the remedial investigation/feasibility study (RI/FS) are identified and documented in several workplans. These usually include the RI/FS Workplan, a Sampling and Analysis Plan (SAP), and a Quality Assurance Project Plan (QAPP). Tasks related to development of the baseline risk assessment are sometimes presented in a separate Risk Assessment Workplan or incorporated into the RI/FS Workplan.

WHEN EVALUATING WHETHER TO CONDUCT PROBABILISTIC ANALYSIS, CONSIDER THE FOLLOWING

- Extent of site remediation
- Potential costs of remediation
- Degree of uncertainty associated with the exposure information available for each portion of the site conceptual model

Risk assessment needs should be considered not only in tasks related to development of the baseline risk assessment but also in tasks related to sampling and analysis (i.e., those in the SAP and the QAPP) in the RI and tasks needing risk assessment input in the feasibility study (FS) (e.g., development of remedial goals and estimates of potential risk from remediation options).

### 2.2.1 RI/FS WORKPLAN/BASELINE RISK ASSESSMENT WORKPLAN

The RI/FS Workplan summarizes site background, the current and potential problems posed by site contaminants, and the objectives and scope of the RI/FS. It also includes a description of the tasks to be performed and the information and work products that will be produced from each task. Deliverables for specific tasks are included. Tasks and deliverables for the baseline risk assessment may be included as a part of the RI/FS Workplan or in a separate Risk Assessment Workplan.

Within these Workplans, it should be clear that risk assessment needs are being considered in the RI/FS objectives. The site-specific objectives and scope of the risk assessment should be included in the Workplan. This includes information needed to complete the baseline risk assessment in the RI as well as information needed for the FS, such as that

needed to develop risk-based remedial goals (e.g , PRGs), and to assess risks from remediation (e.g., incineration).

These Workplans should also reference the methods (e.g., National guidance such as RAGS/HHEM [U.S. EPA, 1989c]; RAGS Probabilistic Guidance [U.S. EPA, 1997e and g and 2001d.]), that will be used to prepare the Interim, Draft, and Final risk assessment deliverables and define the schedule for submission. These deliverables are described in more detail in Chapter 3. Deliverables related to development of risk-based remedial goals and assessment of risk from remediation should also be included in the Workplan (see Chapter 4).

The EPA risk assessor and EPA RPM may revisit the question of the potential value added by using Probabilistic Analyses in the risk assessment. If these analyses are to be used, the issues concerning the time, expense, and possible benefit associated with the collection of additional exposure information or sampling data should be considered to identify those exposure parameters with the greatest uncertainty, where collection of additional data and/or information may be warranted. A separate Probabilistic Analysis Workplan identifying associated deliverables should be prepared and approved by the EPA RPM and risk assessor.

### 2.2.2 SAP AND QAPP

Sampling and analysis activities undertaken during the RI should provide adequate data to evaluate all appropriate exposure pathways. Therefore, risk assessors should be involved in the development of the data quality objectives (DQOs) for sampling and analysis and in selecting the types of sampling and analyses that will be done. The DQOs should address the qualitative and quantitative nature of the sampling data in terms of relative quality and intent for use, to ensure that the data collected will be appropriate for the intended objectives. Note that the data quality evaluation should be recorded in the Data Useability Worksheet in Appendix C.

**Sampling.** The SAP should discuss how the types, numbers, and locations of samples to be collected will be adequate to evaluate each exposure pathway (both current and future) and medium. The SAP should be accompanied by detailed sampling maps showing the location and type of samples (e.g., grab, composite, or duplicate) It is important to consider how sample results will be used to estimate exposure point concentrations Background samples should be collected from appropriate areas (e.g., areas proximate to the site, free of potential contamination by site chemicals and similar to the site in topography, geology, meteorology, and other characteristics)

If models will be used to evaluate exposure pathways and estimate exposure point concentrations, these models should be identified in the Workplan. Site-specific data collection needed for these models should also be discussed.

WHEN DEVELOPING THE SAP, CONSIDER THE FOLLOWING

- How will data from multiple groundwater wells collected over time be used to calculate exposure?
- At what depths will soil samples be taken and how will they be combined to describe exposures for different scenarios (e g , industrial versus residential) or to characterize hotspots?
- What type of sampling design (e.g , random versus purposive) will be used?
- Are SAPs adequate to distinguish site contamination from background contamination for each medium and for organic and inorganic parameters?

**Analysis.** Development of the DQOs for analysis should not be limited to concern for the precision, accuracy, representativeness, completeness, and comparability of the data. DQOs that are important for risk assessment should consider types of laboratory analyses used, sensitivity of detection limits of the analytical techniques (especially for non-Target Compound List [non-TCL] chemicals and non-standard matrices), resulting data quality, and the employment of adequate quality assurance/quality control (QA/QC) measures.

In some cases, risk assessment data needs may be best supported by additional chemicals, different analytical methods, and/or lower detection limits than are being used for the RI. Based upon the values of the risk-based PRGs calculated during scoping, detection limits may need to be lower than those obtained by the standard Superfund methods. The adequacy of detection limits for conducting the baseline risk assessment and for comparing to PRGs should be evaluated in the Workplan (QAPP). For example, a table listing expected contaminants and comparing the method detection limit or quantitation limit for each compound with the appropriate risk-based goal for that chemical could be presented. This information along with issues of cost and other data uses should affect the methods and detection limits finally selected.

Analytical data should be evaluated and reviewed in accordance with the criteria to evaluate data (e.g., the National Functional Guidelines) Also refer to your regional Agency office for guidance on data validation and/or chemical-specific other guidance, as applicable.

The Workplan should also discuss how split samples, duplicates, blanks (trip, field, and laboratory), and qualified and rejected data will be used in assessing site risks. The Workplan should describe the analysis for each medium and how the types of analyses were selected based on site history.

# CHAPTER 3

# RISK ASSESSMENT DATA NEEDS AND TASKS DURING THE REMEDIAL INVESTIGATION

**Project Management Guidelines.** Remedial project managers will establish the schedule of submission for the deliverables for the RI Reports and Baseline Risk Assessment Reports. The schedule may vary from site to site, as appropriate. Interested parties (States, Commonwealths, tribes and other stakeholders) may be involved in the scheduling and review process, as appropriate. Refer to your regional office for guidance regarding the order of the deliverables. These deliverables should also be defined in the Workplan.

**General RI Guidelines.** RI guidance should be followed in performing the remedial investigation. The following items are of particular importance to risk assessments. If the risk assessment is being prepared as a stand-alone document, the following items should be included. If, instead, the risk assessment is a section of the RI Report, the items which follow should be addressed in the RI Report and clearly referenced in the Baseline Risk Assessment Report.

- Present a general map of the site depicting boundaries and surface topography, which illustrates site features, such as fences, ponds, structures, as well as geographical relationships between potential receptors and the site.
- Discuss historical site activity.
- Discuss chronology of land use (specify agriculture, industry, recreation, waste deposition, and residential development at the site).
- Present an overview of the nature and extent of contamination, including when samples were collected and the kinds of contaminants and media potentially contaminated.
- Describe the analytical and data validation methods used.
- If modeling was used to estimate exposure point concentrations, document the parameters related to soil/sediment, hydrogeology, hydrology, and meteorology either in the risk assessment or the RI Report.

**Risk Assessment Guidelines.** The risk assessment should be conducted in accordance with all appropriate guidance and policies. Consult with your EPA risk assessor regarding the most appropriate guidance.

Interim Deliverables should be prepared as described in Section 3.1.1 and should ultimately be incorporated into the Baseline Risk Assessment Report. The Interim Deliverables prepared by the risk assessment author should be reviewed by the EPA risk assessor prior to submission of the Baseline Risk Assessment Report. Hazard identification and exposure parameters, among others, may require discussion, refinement, and revision. Review and modification of Interim Deliverables will greatly reduce the Baseline Risk Assessment Report preparation and review time. Discussions of the three categories of risk assessment deliverables (Interim Deliverables, Draft Baseline Risk Assessment Report, and Final Baseline Risk Assessment Report) follow

## 3.1 INTERIM DELIVERABLES

This section presents an outline of the Standard Tables, Worksheets, and Supporting Information that should be prepared as Interim Deliverables for each site. The Workplan discussed in Section 2.2.1 should also describe the

Standard Tables, Worksheets, and Supporting Information for a particular site. Exhibit 3-1 presents a list of the Interim Deliverables. Use of these deliverables for each site should improve standardization in risk assessment reporting by improving the transparency, clarity, consistency, and reasonableness of risk assessments.

### 3.1.1 STANDARD TABLES, WORKSHEETS, AND SUPPORTING INFORMATION

Standardized reporting of Superfund human health risk assessments will be achieved through the preparation of Standard Tables, Worksheets, and Supporting Information. These documents should be prepared as Interim Deliverables and reviewed by the EPA risk assessor prior to preparation of the Baseline Risk Assessment Report. After review and revision, as necessary, these documents should be included in the Baseline Risk Assessment Report.

This section describes the Standard Table formats for use in all future risk assessments. The Standard Table formats should not be altered (i.e., columns should not be added, deleted, or changed); however, rows and footnotes should be added as appropriate. Standardization of the Tables is needed to achieve Superfund program-wide reporting consistency. Note that multiple versions of some Standard Tables may be needed to address different Media, different Exposure Pathways, or different Exposures (i.e., reasonable maximum exposure [RME] versus central tendency [CT]). Exhibit 3-2 summarizes the relationship between five traditional risk assessment activities and the corresponding Standard Tables that standardize risk assessment reporting. The five risk assessment activities follow:

- Data collection
- Data evaluation
- Exposure assessment
- Toxicity assessment
- Risk characterization.

Copies of the blank Standard Tables are provided in both Lotus® and Excel® spreadsheet formats associated with the Part D guidance. Blank Standard Table templates and completed examples of typical Standard Tables are provided in Appendix A. Detailed Instructions for the completion of the Standard Tables are provided in Appendix B. Additional example scenarios and selected Standard Tables are provided in Appendix D.

In addition to the Standard Tables, six Standard Worksheets are provided in Appendix C These include Worksheets for Data Useability, TARA Schedule, Dermal, Radiation Dose Assessment, Lead, and ROD Risk. Use of the Worksheets is strongly encouraged to improve transparency, clarity, consistency, and reasonableness.

The Standard Tables and Worksheets document the majority of the data and assumptions used to evaluate risk, as well as the risks and hazards calculated. In most cases, other data and rationale are used to support the information presented in the Standard Tables. This additional Supporting Information should also be provided to the EPA risk assessor as an Interim Deliverable and later incorporated in the Baseline Risk Assessment Report.

Refer to Exhibit 3-3 for a brief summary of the Revision 1 improvements to the Standard Tables and Worksheets as compared to Revision 0. Descriptions of the RAGS Part D Revision 1 Standard Tables, Worksheets, and Supporting Information follow:

**STANDARD TABLE 0: Site Risk Assessment Identification Information.** The purposes of **Standard Table 0** are:

- To uniquely identify the risk assessment
- To identify the relevant contacts for the risk assessment.

The information documented in **Standard Table 0** includes:

- Site Information
- Contact information
- Risk assessment document information.

The data elements presented in **Standard Table 0** are listed in the Standard Table 0 highlight box.

DATA ELEMENTS IN
STANDARD TABLE 0

Provide the following information: Site Name/OU, Region, EPA ID Number, State, Status, Federal Facility (Y/N), EPA Project Manager, EPA Risk Assessor, Prepared by, Prepared for, Document Title, Document Date, Probabilistic Risk Assessment (Y/N), and Comments.

Perform the following steps associated with the preparation of **Standard Table 0:**

1. Provide the identification information for the risk assessment.

2. Include Standard Table 0 with the other Standard Tables, Worksheets, and Supporting Information to facilitate tracking of the relevant contacts.

**TARA SCHEDULE WORKSHEET.** The **TARA Schedule of Risk-Related Activities Worksheet** (TARA Schedule Worksheet) is the first Worksheet that should be developed for each risk assessment to document the applicability, responsibility, and schedule for each risk-related activity. As the first interim deliverable, the Worksheet documents the plan for a particular site, identifying which Standard Tables, Worksheets, and Supporting Information will be provided as interim deliverables for EPA risk assessor review, and when they are expected to be available. The TARA Schedule Worksheet should be prepared in consultation with the EPA risk assessor assigned to the site.

Perform the following steps associated with the preparation of the TARA Schedule Worksheet:

1. **Complete the TARA Schedule Worksheet** prior to initiation of any other Standard Tables, Worksheets, or Supporting Information.

2. **Obtain EPA risk assessor consensus** regarding which interim deliverables will be submitted and the schedules for each.

The blank TARA Schedule Worksheet may be found in Appendix C. An example TARA Schedule Worksheet accompanies the Dean Company example in Appendix A

**STANDARD TABLE 1:** Selection of Exposure Pathways. The purposes of **Standard Table 1** are:

- To assist in project planning
- To accompany the site conceptual model
- To present possible Receptors, Exposure Routes, and Exposure Pathways
- To present the rationale for selection or exclusion of each Exposure Pathway
- To communicate risk information to interested parties outside EPA
- To establish a framework for the generation of subsequent Standard Tables. All subsequent tables should be built from the information contained in Standard Table 1.

The information documented in **Standard Table 1** includes:

- Exposure Pathways that were examined and excluded from analysis
- Exposure Pathways that will be qualitatively or quantitatively evaluated in the risk assessment.

The data elements presented in **Standard Table 1** are listed in the Standard Table 1 highlight box.

DATA ELEMENTS IN
STANDARD TABLE 1

Provide the following information: Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, Receptor Age, Exposure Route, Type of Analysis, Rationale for Selection or Exclusion of Exposure Pathway

Perform the following steps associated with the preparation of **Standard Table 1**:

1. Refine site conceptual model which identifies all potential sources of contamination, all potential Exposure Pathways, the Medium associated with each, and the potentially exposed populations (Receptors).

2. Select realistic Exposure Pathways for detailed analyses.

3. Include rationale for exclusion of potential Exposure Pathways.

4. **Modify Standard Table 1, if necessary.**

5. **Standard Table 1** should later be incorporated in the Baseline Risk Assessment Report.

**DATA USEABILITY WORKSHEET.** Data quality is an important component of the risk assessment and the evaluation of data quality should be documented. The Data Useability Worksheet is included to address this need.

The EPA risk assessor and the EPA document *Guidance for Data Useability in Risk Assessment (Part A,* U.S. EPA 1990a*),* should be consulted before completing the Data Useability Worksheet to define the appropriate level of detail to be reflected in the comment fields in the Worksheet. This Worksheet should be prepared as soon as all data validation reports have been completed for each medium. A medium-specific Data Useability Worksheet should be completed only after the project team (i.e., lead chemist, lead hydrogeologist, risk assessor, etc.) has collectively discussed the data useability criteria. The Worksheet should be used to record and identify the impact of data quality issues as they relate to data useability. For example, deviations from approved site Workplans which occurred during sample collection, laboratory analysis, or data review should be assessed. Also refer to your regional office for guidance on data validation when preparing the Worksheet.

Perform the following steps associated with the preparation of the **Data Useability Worksheet**:

1. **Complete the *Data Useability Worksheet*** for each Medium prior to screening of chemicals of potential concern (COPCs).

2. The **Data Useability Worksheet** should later be incorporated in the Baseline Risk Assessment Report.

The blank Data Useability Worksheet may be found in Appendix C. An example Data Useability Worksheet accompanies the Dean Company example in Appendix A.

**STANDARD TABLE 2: Occurrence, Distribution, and Selection of COPCs.** The purposes of **Standard Table 2** are:

- To provide information useful for data evaluation of chemicals and radionuclides detected
- To provide adequate information so the user/reviewer gets a sense of the chemicals and radionuclides detected at the site and the potential magnitude of the potential problems at the site
- To provide chemical screening data and rationale for selection of COPCs.

The information documented in **Standard Table 2** includes:

- Statistical information about chemicals and radionuclides detected in each Medium
- The detection limits of chemicals and radionuclides analyzed
- The toxicity screening values for COPC selection
- The chemicals and radionuclides selected and deleted as COPCs.

The data elements presented in **Standard Table 2** are listed in the Standard Table 2 highlight box.

Perform the following steps associated with the preparation of **Standard Table 2**. Refer to the regional office for guidance when performing these steps.

DATA ELEMENTS IN
STANDARD TABLE 2

For each unique combination of Scenario Timeframe, Medium, and Exposure Medium, provide the following information: Exposure Point, CAS Number, Chemical, Minimum Concentration (Qualifier), Maximum Concentration (Qualifier), Units, Location of Maximum Concentration, Detection Frequency, Range of Detection Limits, Concentration Used for Screening, Background Value, Screening Toxicity Value (N/C), Potential ARAR/TBC Value, Potential ARAR/TBC Source, COPC Flag (Y/N), and Rationale for Selection or Deletion.

1. Discuss selection criteria for COPCs; including toxicity screening values, frequency of detection, and background comparison, as appropriate.

2. Perform screening; select COPCs that will be carried into the risk assessment (include comparison to regulatory standards and criteria where appropriate).

3. **Submit Supporting Information to substantiate the available Background Value shown for each chemical in Standard Table 2** and to enable verification of those values by EPA. The format of the summary will be determined by each region. The Supporting Information should provide relevant information for each chemical used to determine the background concentration, including (but not limited to) average, maximum, hypothesis testing of equality of the mean, and other information that may be required to fully describe the background selection process.

4. The Background Supporting Information should later be incorporated in the Baseline Risk Assessment Report.

5. **Complete Standard Table 2** for each combination of Scenario Timeframe, Medium, and Exposure Medium.

6. **Standard Table 2** should later be incorporated in the Baseline Risk Assessment Report.

**STANDARD TABLE 3: Exposure Point Concentration Summary.** The purposes of **Standard Table 3** are:

- To provide the EPCs for measured and modeled values
- To provide statistical information on the derivation of the EPCs.

The information documented in **Standard Table 3** includes:

- Statistical information which was used to calculate the EPCs for chemicals and radionuclides detected in each Medium
- EPCs (RME and/or CT)
- The statistics which were used to make the determinations as well as the rationale for the selection of the statistics for each chemical or radionuclide (i.e., discuss statistical derivation of measured data or approach for modeled data).

The data elements presented in **Standard Table 3** are listed in the Standard Table 3 highlight box.

DATA ELEMENTS IN
STANDARD TABLE 3

For each unique combination of Scenario Timeframe, Medium, and Exposure Medium, provide the following information: Exposure Point, Chemical of Potential Concern, Units, Arithmetic Mean, 95% upper confidence level (UCL), Maximum Concentration (Qualifier), EPC Value, EPC Units, EPC Statistic, and EPC Rationale

Perform the following steps associated with the preparation **of Standard Table 3.**

1. Discuss how samples will be grouped (e.g., how hot spots in soil will be considered; how groundwater data will be combined; how temporal and chemical phases will be addressed; how upgradient, downgradient, and cross gradient samples will be addressed).

2. Discuss approach to determine how data are distributed (e.g., normal, log-normal).

3. Discuss evaluation of lead, total chromium and any other special chemicals.

4. **Submit Supporting Information to document the EPC summary presented in Standard Table 3** and to enable verification of those values by EPA. The format of the summary will be determined by each region. The Supporting Information should discuss EPCs statistically derived from measured data, including identification of the samples used in each calculation, results of distribution testing (Wilk-Shapiro, D'Agostino), mean (transformed if appropriate), maximum (transformed if appropriate), standard deviation (transformed if appropriate), t- or H-statistic, 95% UCL (including non-parametric methods, where applicable), and other protocols as required. The Supporting Information should also present information for EPCs, including derivation of modeled values, assumptions and values used, statistical derivation of measured values and associated calculations, and other protocols as required.

5. The **EPC Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

6. **Complete Standard Table 3** for each combination of Scenario Timeframe, Medium, Exposure Medium, and Exposure Point. Create separate sets of Standard Table 3 for RME and CT, when appropriate.

7. **Standard Table 3** should later be incorporated in the Baseline Risk Assessment Report.

**STANDARD TABLE 4: Values Used for Daily Intake Calculations.** The purposes of **Standard Table 4** are:

- To provide the exposure parameters used for intake calculations for each Exposure Pathway (Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, Receptor Age, and Exposure Route)
- To provide the intake equations or models used for each Exposure Route/Pathway.

The information documented in **Standard Table 4** includes

- Values used for each intake equation for each Exposure Pathway and the reference/rationale for each
- Intake equation or model used to calculate the intake for each Exposure Pathway

The data elements presented in **Standard Table 4** are listed in the Standard Table 4 highlight box.

DATA ELEMENTS IN STANDARD TABLE 4

For each unique combination of Scenario Timeframe, Medium, and Exposure Medium, provide the following information Exposure Route, Receptor Population, Receptor Age, Exposure Point, Parameter Code, Parameter (Definition, Value, and Units), Rationale/Reference, and Intake Equation/Model Name.

Perform the following steps associated with the preparation of **Standard Table 4.**

1. Provide references for all exposure parameters.

2. **Submit Supporting Information to summarize the Modeled Intake Methodology and Parameters used to calculate modeled intake values** and to enable verification of those values by EPA. The Supporting Information should be limited to summary level information. The format of the summary should be structured to accommodate the variability and complexity associated with different models.

3. The **Modeled Intake Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

4. **Submit Supporting Information on Chemical-Specific Parameters**, which apply to all Standard Tables to be completed for the risk assessment and to enable verification of those values by EPA. The summary should identify and display chemical parameters and constants that are used to calculate risks and hazards, but are not included on Standard Tables. The format of the summary will be determined by each region. The values and constants that are used to calculate risk and hazards, including molecular weight, vapor pressure, $K_{oc}$, $K_{ow}$, dermal permeability constant, Henry's Law constant, and other information that the reader would find useful for understanding the risk assessment discussion should be included.

5. The **Chemical-Specific Parameter Supporting Information** summary should later be incorporated into the Baseline Risk Assessment Report.

6. **Complete Standard Table 4** for each combination of Scenario Timeframe, Medium, and Exposure Medium. Create separate sets of Standard Table 4 for RME and CT, where appropriate.

7. **Standard Table 4** should later be incorporated into the Baseline Risk Assessment Report.

**DERMAL WORKSHEET.** The Dermal Worksheet presents intermediate variables for calculating absorbed dose per event DA (event). A version of this Worksheet should be developed for each medium for which the dermal exposure route will be quantitatively assessed. Available data should be provided for each COPC under evaluation.

Perform the following steps associated with preparation of the **Dermal Worksheet**:

1. **Complete the Dermal Worksheet** prior to calculation of risks and hazards.

2. Provide interim deliverables to the EPA risk assessor, as appropriate

3. The **Dermal Worksheet** should later be incorporated in the Baseline Risk Assessment Report.

The blank Dermal Worksheet may be found in Appendix C. An example Dermal Worksheet accompanies the Dean Company example in Appendix A.

**STANDARD TABLES 5 AND 6: Non-Cancer and Cancer Toxicity Data.** The purposes of **Standard Tables 5.1, 5.2, and 5.3** are:

- To provide information on reference doses (RfDs), reference concentrations (RfCs), Target organs, and adjustment factors for chemicals
- To provide oral to dermal adjustment factors
- To provide RfC to RfD adjustment factors
- To verify references for non-cancer toxicity data
- To provide non-cancer toxicity information for "special-case" chemicals.

DATA ELEMENTS IN STANDARD TABLE 5.1

Provide the following information. Chemical of Potential Concern, Chronic/Subchronic, Oral RfD Value and Units, Oral Absorption Efficiency for Dermal, Absorbed RfD for Dermal Value and Units, Primary Target Organ(s), Combined Uncertainty/Modifying Factors, Source(s) RfD-Target Organ(s), and Dates of RfD Target Organ(s).

The information documented in **Standard Tables 5.1, 5.2, and 5.3** includes:

- The RfDs for each of the COPCs, as well as modifying factors and reference concentration (RfC) to RfD adjustments
- The organ effects of each of the COPCs
- References for RfCs and organ effects.

The data elements presented in **Standard Tables 5.1, 5.2, and 5.3** are listed in the Standard Tables 5.1, 5.2, and 5.3 highlight boxes.

DATA ELEMENTS IN
STANDARD TABLE 5.2

Provide the following information: Chemical of Potential Concern, Chronic/Subchronic, Inhalation RfC Value and Units, Extrapolated RfD Value and Units, Primary Target Organ(s), Combined Uncertainty/Modifying Factors, Source(s) of RfC. Target Organ(s), and Date(s) of RfC: Target Organ(s).

DATA ELEMENTS IN
STANDARD TABLE 5.3

Provide the following information: Chemical of Potential Concern, Chronic/Subchronic, Parameter Name, Value, and Units), Primary Target Organ(s), Combined Uncertainty/Modifying Factors, Source(s) of Parameter: Target Organ(s), and Date(s) of Parameter: Target Organ(s).

The purposes of **Standard Tables 6.1, 6.2, 6.3, and 6.4** are:

- To provide the oral, dermal, and inhalation cancer toxicity information (values and sources of information) for chemicals and radionuclides of potential concern
- To provide the methodology and adjustment factors used to convert oral cancer toxicity values to dermal toxicity values and to convert inhalation unit risks to inhalation cancer slope factors
- To provide weight of evidence/cancer guideline descriptions for each chemical and radionuclide of potential concern
- To provide cancer toxicity information for "special case" chemicals.

The information documented in **Standard Tables 6.1, 6.2, 6.3, and 6.4** includes:

- Oral, dermal, and inhalation toxicity values for chemicals and radionuclides of potential concern
- Weight of evidence/cancer guidelines descriptions for chemicals of potential concern
- The source/reference for each toxicity value.

The data elements presented in **Standard Tables 6.1, 6.2, 6.3, and 6.4** are listed in the Standard Tables 6.1, 6.2, 6.3, and 6.4 highlight box.

DATA ELEMENTS IN
STANDARD TABLE 6.1

Provide the following information: Chemical of Potential Concern, Oral Cancer Slope Factor Value and Units, Oral Absorption Efficiency for Dermal, Absorbed Cancer Slope Factor for Dermal Value and Units, Weight of Evidence/Cancer Guideline Description, Source(s) and Date(s) of Oral CSF

DATA ELEMENTS IN
STANDARD TABLE 6.2

Provide the following information: Chemical of Potential Concern, Unit Risk Value and Units, Inhalation Cancer Slope Factor Value and Units, Weight of Evidence/Cancer Guideline Description, Source(s) and Date(s) of Unit Risk: Inhalation CSF

DATA ELEMENTS IN
STANDARD TABLE 6.3

Provide the following information: Chemical of Potential Concern, Parameter (Name, Value, and Units), Source(s), and Dates(s).

DATA ELEMENTS IN
STANDARD TABLE 6.4

Provide the following information: Chemical of Potential Concern, Cancer Slope Factor Value and Units, Source(s), and Dates(s).

Perform the following steps associated with the preparation of **Standard Tables 5 and 6.**

1. Refer to the end of Section 3.1.1 for Lead Worksheets.

2. Ensure that chronic and subchronic toxicity values are applied correctly based on the duration of exposure. Provide rationale for selection of surrogate toxicity values not in IRIS or HEAST, or provided by NCEA. (EPA may require additional review.)

3. **Submit Supporting Information regarding Toxicity Data for Special Case Chemicals** (i.e., those chemicals with cancer risks and non-cancer hazards calculated using methods or toxicity parameters different from those presented on Standard Tables 5.1, 5.2, 6.1, or 6.2). The Supporting Information will be used to enable verification of those values by EPA. Examples may include selection of potency factors for polychlorinated biphenyls (PCBs), use of relative potencies for polynuclear aromatic hydrocarbons (PAHs) and chlorinated dioxins and furans, and valence species assumptions for metals. Consult the EPA risk assessor regarding the use of these tables.

4. The **Special Case Chemicals Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

5. **Complete Standard Tables 5 and 6** for the exposure routes and chemicals under evaluation.

   **Standard Table 5.1**: Non-Cancer Toxicity Data - Oral/Dermal
   **Standard Table 5.2**: Non-Cancer Toxicity Data - Inhalation
   **Standard Table 5.3**: Non-Cancer Toxicity Data - Special Case Chemicals
   **Standard Table 6.1**: Cancer Toxicity Data - Oral/Dermal
   **Standard Table 6.2**: Cancer Toxicity Data - Inhalation
   **Standard Table 6.3**: Cancer Toxicity Data - Special Case Chemicals
   **Standard Table 6.4**: Cancer Toxicity Data -External (Radiation).

6. **Standard Tables 5 and 6** should later be incorporated in the Baseline Risk Assessment Report.

**STANDARD TABLE 7: Calculation of Chemical Cancer Risks and Non-Cancer Hazards.** The purposes of **Standard Table 7** are:

- To provide a summary of the variables used to calculate chemical cancer risks and non-cancer hazards
- To show the EPC and intake used in the non-cancer hazard and cancer risk calculations
- To present the result of the calculation for each Exposure Route/Pathway for each COPC
- To provide the total hazard index and cancer risks for all Exposure Routes/Pathways for the Scenario Timeframe and Receptor presented in this table.

The information documented in **Standard Table 7** includes:

- The non-cancer hazard quotient (HQ) and cancer risk value for each COPC for each Exposure Route/Pathway
- The values used for EPC, non-cancer intake, cancer intake, reference doses and concentrations, and cancer slope factors for each COPC for each Exposure Route.

The data elements presented in **Standard Table 7** are listed in the Standard Table 7 highlight box.

DATA ELEMENTS IN STANDARD TABLE 7

For each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, provide the following information: Medium, Exposure Medium, Exposure Point, Exposure Route, Chemical of Potential Concern, EPC Value and Units, Cancer Risk Calculations (Intake Exposure Concentration Value and Units, CSF/Unit Risk Value and Units, and Cancer Risk), and Non-Cancer Hazard Calculations (Intake/Exposure Concentration Value and Units, RfD/RfC Value and Units, and Hazard Quotient)

Perform the following steps associated with the preparation of **Standard Table 7.**

1. Address non-cancer hazards and cancer risks

including the calculations and supporting information by Exposure Route.

2. Include RME and CT results in separate tables. Ensure that risks and hazards from multiple chemicals are combined appropriately across Pathways that affect the same individual or population subgroup, for all site-related chemicals.

3. Definitions of Standard Tables
   **Standard Table 7.n.RME**: Calculation of Chemical Cancer Risks and Non-Cancer Hazards (RME)
   **Standard Table 7.n.CT**: Calculation of Chemical Cancer Risks and Non-Cancer Hazards (CT)

4. If it is preferred to segregate cancer and non-cancer evaluations, see the blank Standard Tables 7.a.1 and 7.b.1 shown in Appendix A as well as Example Scenario 7 in Appendix D.

5. **Submit Supporting Information that summarizes the approach used to perform Special Chemical Risk and Hazard Calculations** and to enable verification of those values by EPA. This summary should address the calculation of non-cancer hazards and cancer risks for chemicals that do not use RfD or cancer slope factor (CSF) values, respectively. The format of the summary will be determined by each region.

6. The **Special Chemical Risk and Hazard Calculations Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

7. **Complete Standard Table 7** for each combination of Scenario Timeframe, Receptor Population, and Receptor Age.

8. **Standard Table 7** should later be incorporated in the Baseline Risk Assessment Report.

**STANDARD TABLE 8: Calculation of Radiation Cancer Risks.** The purposes of **Standard Table 8** are:

- To provide a summary of the variables used to calculate radiation cancer risks
- To show the EPC used in the radiation cancer risk calculations
- To show, based on the documented risk calculation approach, the intake and cancer slope factors
- To present the result of the calculation for each Exposure Route/Pathway for each COPC
- To provide the radiation cancer risks for all Exposure Routes/Pathways for the Scenario Timeframe and Receptor presented in this table.

The information documented in **Standard Table 8** includes:

- The approach for calculating the radiation cancer risk for each COPC for each Exposure Route/Pathway
- The values used for EPC, intake, and cancer slope factor for each COPC for each Exposure Route
- The Cancer risk value for each COPC for each Exposure Route/Pathway
- Total cancer risk values by Exposure Route, Exposure Point, and across all media for the Scenario Timeframe and Receptor presented in this table.

The data elements presented in **Standard Table 8** are listed in the Standard Table 8 highlight box.

DATA ELEMENTS IN
STANDARD TABLE 8

For each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, provide the following information: Medium, Exposure Medium, Exposure Point, Exposure Route, Radionuclide of Potential Concern, EPC Value and Units, Risk Calculation Approach, and Cancer Risk Calculations (Intake/Activity Value and Units, CSF Value and Units, and Cancer Risk).

Perform the following steps associated with the preparation of **Standard Table 8**.

1. Address radiation cancer risks including the

calculations and supporting information by Exposure Route.

2. Include RME and CT results in separate tables. Ensure that risks from multiple radionuclides are combined appropriately across Pathways that affect the same individual or population subgroup, for all site-related radionuclides.

3. Definitions of Standard Tables
   **Standard Table 8.n.RME**: Calculation of Cancer Radiation Risks (RME)
   **Standard Table 8.n.CT**: Calculation of Cancer Radiation Risks (CT)

4. **Complete Standard Table 8** for each combination of Scenario Timeframe, Receptor Population, and Receptor Age.

5. **Standard Table 8** should later be incorporated in the Baseline Risk Assessment Report.

**RADIATION DOSE ASSESSMENT WORKSHEET.** The Radiation Dose Assessment Worksheet has been provided to document alternate radionuclide cancer risk calculations, performed using a dose approach rather than the standard CERCLA risk calculation method.

Perform the following steps associated with preparation of the **Radiation Dose Assessment Worksheet,** if applicable to the risk assessment:

1. Complete the **Radiation Dose Assessment Worksheet** for each Receptor.

2. Provide interim deliverables to the EPA risk assessor, as appropriate.

3. The **Radiation Dose Assessment Worksheet** should later be incorporated in the Baseline Risk Assessment Report.

The blank Radiation Dose Assessment Worksheet may be found in Appendix C. An example Radiation Dose Assessment Worksheet is presented in Appendix D, Example Scenario 11.

**STANDARD TABLE 9: Summary of Receptor Risk and Hazards for COPCs.**

The purpose of **Standard Table 9** is

- To provide a summary of cancer risks and non-cancer hazards for each Receptor, by Medium, Exposure Medium, Exposure Route, and Exposure Point.

The information documented in **Standard Table 9** includes:

- The cancer risk and non-cancer hazard to each Receptor for each COPC by Exposure Route and Exposure Point
- The total cancer risk and non-cancer hazard for each Exposure Point, Exposure Medium and Medium across all Exposure Routes
- The total cancer risk and non-cancer hazard for a Receptor across all media
- The primary target organs for non-carcinogenic hazard effects.

The data elements presented in **Standard Table 9** are listed in the Standard Table 9 highlight box.

DATA ELEMENTS IN STANDARD TABLE 9

For each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, provide the following information: Medium, Exposure Medium, Exposure Point, Chemical of Potential Concern, Carcinogenic Risk (Ingestion, Inhalation, Dermal, External (Radiation) and Exposure Routes Total), and Non-Carcinogenic Hazard Quotient (Primary Target Organ(s), Ingestion, Inhalation, Dermal, and Exposure Routes Total).

Perform the following steps associated with the preparation of **Standard Table 9.**

1. Address non-cancer hazards and cancer risks including the calculations and supporting information by Exposure Route.

2. Include RME and CT results. Ensure that risks and hazards from multiple chemicals are combined appropriately across Pathways that affect the same individual or population subgroup, for all site-related chemicals.

3. Definitions of Standard Tables
   **Standard Table 9.n.RME**: Summary of Receptor Risks and Hazards for COPCs (RME)
   **Standard Table 9.n.CT**: Summary of Receptor Risks and Hazards for COPCs (CT)

4. **Complete Standard Table 9** for each combination of Scenario Timeframe, Receptor Population, and Receptor Age.

5. **Standard Table 9** should later be incorporated in the Baseline Risk Assessment Report.

**STANDARD TABLE 10: Risk Summary.** The purpose of **Standard Table 10** is:

- To provide a summary of cancer risks and non-cancer hazards for each Receptor, by Medium, Exposure Medium, Exposure Route, and Exposure Point, that may trigger the need for remedial action.

The information documented in **Standard Table 10** includes:

- The cancer risk and non-cancer hazard to each Receptor for each chemical or radionuclide by Exposure Route and Exposure Point for risk drivers
- The total cancer risk and non-cancer hazard for each Exposure Point, Exposure Medium, and Medium across all Exposure Routes for risk drivers
- The total cancer risk and non-cancer hazard for a Receptor across all media for risk drivers
- The primary target organs for non-carcinogenic hazard effects for risk drivers.

The data elements presented in **Standard Table 10** are listed in the Standard Table 10 highlight box.

DATA ELEMENTS IN STANDARD TABLE 10

For each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, provide the following information Medium, Exposure Medium, Exposure Point, Chemical, Carcinogenic Risk (Ingestion, Inhalation, Dermal, External (Radiation) and Exposure Routes Total), and Non-Carcinogenic Hazard Quotient (Primary Target Organ(s), Ingestion, Inhalation, Dermal, and Exposure Routes Total).

Perform the following steps associated with the preparation of **Standard Table 10.**

1. Address non-cancer hazards and cancer risks including the calculations and supporting information by Exposure Route.

2. Include RME and CT results. Ensure that risks and hazards from multiple chemicals are combined appropriately across Pathways that affect the same individual or population subgroup, for all site-related chemicals.

3. Definitions of Standard Tables
   **Standard Table 10.n.RME**: Risk Summary (RME)
   **Standard Table 10.n.CT**: Risk Summary (CT)

4. **Complete Standard Table 10** for each combination of Scenario Timeframe, Receptor Population, and Receptor Age.

5. **Standard Table 10** should later be incorporated in the Baseline Risk Assessment Report.

**LEAD WORKSHEETS.** Two Lead Worksheets have been provided to document lead risk evaluations performed for young children and adult receptors at a site.

Perform the following steps associated with the preparation of **Lead Worksheets**:

1. **Complete the Lead Worksheets** for Child and Adult. Also attach the appropriate graphs and results from the Integrated Exposure Uptake Biokinetic Model (IEUBK) model (if used) to the Child Worksheet. Also attach results from the adult lead spreadsheet to the Adult Worksheet.

2. The **Lead Worksheets** should later be incorporated in the Baseline Risk Assessment Report.

Blank Lead Worksheets may be found in Appendix C. Example Lead Worksheets are presented in Appendix D Example Scenario 10.

### 3.1.2 ASSESSMENT OF CONFIDENCE AND UNCERTAINTY

Uncertainty assessment is important in risk assessment. Although the risk assessment should indicate sources of variability and uncertainty throughout the process, it will generally be appropriate to include a separate section of the Baseline Risk Assessment Report that also focuses on the uncertainties associated with data evaluation, toxicity assessment, exposure assessment, and risk characterization, as well as overall uncertainty of the final risk numbers. The region may choose to defer presentation of this specific section to the Draft Baseline Risk Assessment Report.

Perform the following steps associated with the **Assessment of Confidence and Uncertainty**:

1. **Summarize the Assessment of Confidence and Uncertainty.**

2. The **Assessment of Confidence and Uncertainty** should later be incorporated in the Baseline Risk Assessment Report.

### 3.1.3 PROBABILISTIC ANALYSIS INFORMATION

Based upon the results from a deterministic risk characterization calculation (Standard Table 7) a decision should be made if a Probabilistic Analysis will be performed to calculate cancer risks and non-cancer hazards in accordance with Agency policy.

Perform the following steps associated with the **Probabilistic Analysis:**

1 **Summarize the Probabilistic Analysis** (if performed) in a non-standard format. (Standard formats have not been developed to document probalistic analysis ) Refer to probabilistic analysis guidance (U S EPA 1997e, 1997g and 2001d) to determine the information to be documented.

2. The **Probabilistic Analysis** summary should later be incorporated in the Baseline Risk Assessment Report.

## 3.2 DRAFT BASELINE RISK ASSESSMENT REPORT

**Submit the Draft Baseline Risk Assessment Report** after the completion and acceptance of the Interim Deliverables described above. EPA guidance should be consulted in preparing the Draft Baseline Risk Assessment Report EPA anticipates that this report preparation will be greatly expedited, since it should incorporate the following Interim Deliverables:

- Standard Tables 0 through 10
- Worksheets on Data Useability, Dermal, Radiation Dose Assessments, and Lead, as applicable
- Supporting Information
- The Assessment of Confidence and Uncertainty
- Probabilistic Analysis information (if applicable).

However, the report should not consist exclusively of the Interim Deliverables, because additional narrative will be necessary for a clear and comprehensible Baseline Risk Assessment Report. For example, information such as definition of hazard indices and cancer slope factors, toxicological profiles for COPCs, and other information indicated by risk assessment guidance should be incorporated.

Every risk assessment should contain a Risk

Characterization appropriate to the assessment. Risk assessments submitted to the Agency or performed by the Agency should incorporate any current Agency guidance applicable on Risk Characterization (e.g., RAGS/HHEM, EPA 1989c; Memorandum from Carol Browner on Risk Characterization, EPA 1995b).

## 3.3 FINAL BASELINE RISK ASSESSMENT REPORT

**Submit the Final Baseline Risk Assessment Report** as a revision of the draft, incorporating review comments as necessary and appropriate.

**Prepare Draft ROD Risk Worksheet (ROD Risk Highlights)** as directed by the EPA RPM and EPA risk assessor, upon completion of the Final Baseline Risk Assessment Report. Refer to the ROD guidance (U.S. EPA, 1999a) for human health risk data needs. The draft ROD Risk Worksheets present the Exposure Pathways and Chemicals that justify the need for remedial action. Preparation of these Worksheets is recommended when the Final Baseline Risk Assessment Report is completed, in order to facilitate the EPA risk manager's preparation of the ROD at a later date.

Exhibit 3-4 identifies the RAGS Part D information sources (Standard Table and column) for ROD Risk Worksheets (Highlights) 6-15, 6-16A, 6-16B, 6-18A, and 6-18B. Blank templates for the five ROD Risk Worksheets (Highlights) may be found in Appendix C.

## 3.4 INFORMATION TRANSFER TO SUPERFUND RISK DATA COLLECTION

Upon the completion of the Final Baseline Risk Assessment Report, provide the Lotus® or Excel® version of the Standard Tables and Worksheets to the EPA risk assessor, who will submit them to the EPA Headquarters Risk Information Manager responsible for the Superfund Risk Data Collection.

## EXHIBIT 3-1

## INTERIM DELIVERABLES FOR EACH SITE

| Interim Deliverable | Scope of Deliverable |
|---|---|
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLE 0** | |
| **TARA Schedule Worksheet** | One Worksheet for each Risk Assessment |
| **Standard Table 0** - Site Risk Assessment Identification Information | One Standard Table for each Risk Assessment |
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLE 1** | |
| **Standard Table 1** - Selection of Exposure Pathways | One Standard Table for each Risk Assessment. |
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLE 2** | |
| **Data Useability Worksheet** | One Worksheet for each Medium. |
| **Supporting Information on Background Values** | Information for all Chemicals listed in Standard Table 2. |
| **Standard Table 2** - Occurrence, Distribution, and Selection of Chemicals of Potential Concern (COPCs) | One Standard Table for each unique combination of Scenario Timeframe, Medium, and Exposure Medium |
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLE 3** | |
| **Supporting Information on EPCs** | Information for all EPCs presented in Standard Table 3. |
| **Standard Table 3** - Exposure Point Concentration (EPC) Summary | One Standard Table for each unique combination of Scenario Timeframe, Medium, and Exposure Medium |
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLE 4** | |
| **Supporting Information on Modeled Intake Methodology and Parameters** | Information for all Modeled Intake calculations that are not presented in Standard Table 4. |
| **Supporting Information on Chemical-Specific Parameters** | Information for all Chemical-Specific Parameters used |
| **Dermal Worksheet** | Information for calculation of DA(event) |
| **Standard Table 4** - Values Used for Daily Intake Calculations | One Standard Table for each unique combination of Scenario Timeframe, Medium, and Exposure Medium |
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLES 5 AND 6** | |
| **Supporting Information on Toxicity Data for Special Case Chemicals** | Information for each Special Case Chemical |
| **Standard Table 5** - Non-Cancer Toxicity Data | Three Standard Tables - 5.1 for Oral/Dermal, 5 2 for Inhalation, and 5 3 for Special Case Chemicals. |

## EXHIBIT 3-1

## INTERIM DELIVERABLES FOR EACH SITE (continued)

| Interim Deliverable | Scope of Deliverable |
|---|---|
| **Standard Table 6** - Cancer Toxicity Data | Four Standard Tables - 6 1 for Oral/Dermal, 6 2 for Inhalation, 6 3 for Special Case Chemicals, and 6 4 for External (Radiation) |
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLES 7 AND 8** | |
| **Supporting Information on Special Chemical Risk and Hazard Calculations** | Information for each Special Case Chemical. |
| **Standard Table 7** - Calculation of Chemical Cancer Risks and Non-Cancer Hazards | One Standard Table for each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, for RME and for CT. |
| **Radiation Dose Assessment Worksheet** | One Worksheet for each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age (as appropriate). |
| **Standard Table 8** - Calculation of Radiation Cancer Risks | One Standard Table for each unique combination of Scenario Timeframe, Receptor Population and Receptor Age. |
| **INTERIM DELIVERABLES ASSOCIATED WITH STANDARD TABLES 9 AND 10** | |
| **Standard Table 9** - Summary of Receptor Risks and Hazards for COPCs | One Standard Table for each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, for RME and CT. |
| **Standard Table 10** - Risk Summary | One Standard Table for each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, for RME and CT |
| **INTERIM DELIVERABLES ASSOCIATED WITH LEAD** | |
| **Lead Worksheets** (if applicable) | Separate Worksheets for Residential and Non-Residential Scenarios for each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age |
| **INTERIM DELIVERABLES ASSOCIATED WITH UNCERTAINTY ASSESSMENT** | |
| **Assessment of Confidence and Uncertainty** | One Assessment for each Risk Assessment. |
| **INTERIM DELIVERABLES ASSOCIATED WITH PROBABILISTIC ANALYSIS** | |
| **Summary of Probabilistic Analysis** (if applicable) | One Summary for each Risk Assessment. |

## EXHIBIT 3-1

## INTERIM DELIVERABLES FOR EACH SITE (continued)

| Interim Deliverable | Scope of Deliverable |
|---|---|
| **INTERIM DELIVERABLES ASSOCIATED WITH THE ROD** | |
| **ROD Risk Worksheets** | As appropriate to document (in draft form) the need for remedial action. |

Notes
1 Each Interim Deliverable should be reviewed and verified by EPA prior to submission of the Draft Baseline Risk Assessment Report
2 Each Interim Deliverable should later be incorporated in the Draft and Final Baseline Risk Assessment Reports
3 The Interim Deliverables are needed for each risk assessment to achieve standardization in risk assessment reporting

## EXHIBIT 3-2

## STANDARDIZED RISK ASSESSMENT REPORTING

| Risk Assessment Activity | Corresponding Standard Table/Worksheet |
|---|---|
| **Data Collection** | |
| Provide identification information for the risk assessment | Standard Table 0 - Site Risk Assessment Identification Information |
| Plan the risk assessment review process | TARA Schedule Worksheet |
| Develop a conceptual site model | Standard Table 1 - Selection of Exposure Pathways |
| Gather and report appropriate data | Standard Table 2 - Occurrence, Distribution, and Selection of Chemicals of Potential Concern |
| **Data Evaluation** | |
| Evaluate detection frequency, background data, and site data | Data Useability Worksheet<br><br>Standard Table 2 - Occurrence, Distribution, and Selection of Chemicals of Potential Concern |
| Identify chemicals of potential concern and provide rationale for selection and deletion | Standard Table 2 - Occurrence, Distribution, and Selection of Chemicals of Potential Concern |
| **Exposure Assessment** | |
| Characterize physical setting, identify potential pathways and exposed population | Standard Table 1 - Selection of Exposure Pathways |
| Identify exposure assumptions | Standard Table 4 - Values Used for Daily Intake Calculations<br><br>Dermal Worksheet |
| Estimate exposure point concentrations | Standard Table 3 - Exposure Point Concentration Summary |
| Estimate exposure intakes | Standard Table 7 - Calculation of Chemical Cancer Risks and Non-Cancer Hazards<br><br>Standard Table 8 - Calculation of Radiation Cancer Risks |
| **Toxicity Assessment** | |
| Determine toxicity values for carcinogenic and non-carcinogenic effects and provide source information | Standard Table 5 - Non-Cancer Toxicity Data<br><br>Standard Table 6 - Cancer Toxicity Data |

## EXHIBIT 3-2

## STANDARDIZED RISK ASSESSMENT REPORTING (continued)

| Risk Assessment Activity | Corresponding Standard Table/Worksheet |
|---|---|
| **Risk Characterization** | |
| Quantify cancer and non-cancer risk by pathway | Standard Table 7 - Calculation of Chemical Cancer Risks and Non-Cancer Hazards<br><br>Standard Table 8 - Calculation of Radiation Cancer Risks<br><br>Radiation Dose Assessment Worksheet |
| Combine risks by media for different receptors | Standard Table 9 - Summary of Receptor Risks and Hazards for COPCs |
| Summarize risk drivers for different receptors | Standard Table 10 - Risk Summary |
| Prepare draft risk documentation for ROD | ROD Risk Worksheets |

## EXHIBIT 3-3

## SUMMARY OF RAGS PART D
## REVISION 1 CHANGES

| STANDARD TABLE/WORKSHEET | REVISION 1 CHANGES |
|---|---|
| **Standard Table 0** | This is a new Standard Table |
| **TARA Schedule Worksheet** | This is a new Worksheet. |
| **Standard Table 1** | Revision 1 does not include the On-Site/Off-Site field from Revision 0 |
| **Data Useability Worksheet** | The Revision 1 Worksheet is the same as the Revision 0 Worksheet. |
| **Standard Table 2** | Exposure Point was moved from the last row of the Summary Box (Revision 0) to the first column of the table (Revision 1). This may reduce the number of versions of Standard Table 2 needed for some sites. The Qualifier information for Minimum and Maximum Concentrations has been moved to the corresponding Concentration fields. |
| **Standard Table 3** | In Revision 1, separate versions of this table should be prepared for RME and CT. Exposure Point was moved from the last row of the Summary Box (Revision 0) to the first column of the table (Revision 1). This may reduce the number of versions of Standard Table 3 needed for some sites. The Qualifier information has been moved to the corresponding Maximum Concentration field. |
| **Standard Table 4** | In Revision 1, separate versions of this table should be prepared for RME and CT Receptor Population, Receptor Age, and Exposure Point were moved from the Summary Box (Revision 0) to columns in Revision 1. This may reduce the number of versions of Standard Table 4 needed for some sites. |
| **Standard Tables 5.1, 5.2, and 5.3** | The Revision 1 Standard Tables are essentially the same as Revision 0. Some column headings have been slightly reworded, but the data needs are the same |
| **Standard Table 6.1, 6.2, 6.3, and 6.4** | The Revision 1 Standard Tables 6.1, 6.2, and 6.3 are essentially the same as Revision 0 Some column headings have been slightly reworded, but the data needs are the same. Revision 1 Standard Table 6.4 for radionuclides was not included in Revision 0. |

## EXHIBIT 3-3

## SUMMARY OF RAGS PART D
## REVISION 1 CHANGES (continued)

| STANDARD TABLE/WORKSHEET | REVISION 1 CHANGES |
|---|---|
| **Standard Table 7** | Medium, Exposure Medium, and Exposure Point were moved from the Summary Box (Revision 0) to columns in the table (Revision 1) This may reduce the number of versions of Standard Table 7 needed for some sites Standard Table 7, which previously contained only non-cancer information (Revision 0), now presents cancer and non-cancer information for chemicals. |
| **Standard Table 8** | Standard Table 8 (Revision 1) focuses exclusively on the calculation of radiation cancer risks Standard Table 8 (Revision 0) focused on cancer risk calculations for all chemicals Medium, Exposure Medium, and Exposure Point were moved from the Summary Box (Revision 0) to columns in the table (Revision 1) This may reduce the number of versions of Standard Table 8 needed for some sites. Medium EPC and Route EPC information (Revision 0) was replaced by EPC information (Revision 1) |
| **Radiation Dose Assessment Worksheet** | This is a new Worksheet. |
| **Standard Tables 9 and 10** | A column for Exposure Route External (Radiation) has been added to the cancer calculations in Revision 1 The second COPC (Standard Table 9) or Chemical (Standard Table 10) column from Revision 0 has been deleted in Revision 1<br><br>Accommodations have been made for summing risks and hazards at the Exposure Point, Exposure Medium, Medium, and Receptor Levels. |
| **Lead Worksheets** | These are new Worksheets. |
| **ROD Risk Worksheets (ROD Risk Highlights)** | These are new Worksheets that copy the ROD Guidance (U S EPA, 1999a) Risk Highlights. |

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-15 | Summary of Chemicals of Concern and Medium-Specific Exposure Point Concentrations | Scenario Timeframe | Standard Tables 2 & 3 | Scenario Timeframe |
| | | Medium | Standard Tables 2 & 3 | Medium |
| | | Exposure Medium | Standard Tables 2 & 3 | Exposure Medium |
| | | Exposure Point | Standard Tables 2 & 3 | Exposure Point |
| | | Chemical of Concern | Significant Chemicals from Standard Table 2 (site specific definition) | Chemical |
| | | Concentration Detected - Min | Standard Table 2 | Minimum Concentration |
| | | Concentration Detected - Max | Standard Table 2 | Maximum Concentration |
| | | Units | Standard Table 2 | Units |
| | | Frequency of Detection | Standard Table 2 | Detection Frequency |
| | | Exposure Point Concentration | Standard Table 3 | Exposure Point Concentration Value |
| | | Exposure Point Concentration Units | Standard Table 3 | Exposure Point Concentration Units |
| | | Statistical Measure | Standard Table 3 | Exposure Point Concentration Statistic |

Notes:
-A version of ROD Highlight 6-15 is to be prepared for each combination of Scenario Timeframe, Medium, and Exposure Medium with "significant routes of exposure". The definition of "significant" will be site specific.
-Only Exposure Points with "Significant Routes of Exposure" are to be included.

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS (continued)

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-16A | Cancer Toxicity Data Summary | Pathway. Ingestion, Dermal | Standard Table 6 1 (Cancer Toxicity Data-Oral/Dermal) | |
| | | Chemical of Concern | Chemicals of Concern from Standard Table 6.1 (site specific definition) | Chemical of Potential Concern |
| | | Oral Cancer Slope Factor | Standard Table 6 1 | Oral Cancer Slope Factor |
| | | Dermal Cancer Slope Factor | Standard Table 6.1 | Absorbed Cancer Slope Factor for Dermal Value |
| | | Slope Factor Units | Standard Table 6.1 | Oral Cancer Slope Factor Units and Absorbed Cancer Slope Factor for Dermal Units |
| | | Weight of Evidence/ Cancer Guideline Description | Standard Table 6.1 | Weight of Evidence/Cancer Guideline Description |
| | | Source | Standard Table 6.1 | Oral CSF Source(s) |
| | | Date | Standard Table 6.1 | Oral CSF Date(s) |
| | | Pathway: Inhalation | Standard Table 6.2 (Cancer Toxicity Data - Inhalation) | |
| | | Chemical of Concern | Chemicals of Concern from Standard Table 6 2 (site specific definition) | Chemical of Potential Concern |
| | | Unit Risk | Standard Table 6.2 | Unit Risk Value |
| | | Units | Standard Table 6.2 | Unit Risk Units |

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS (continued)

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-16A (continued) | Cancer Toxicity Data Summary (continued) | Inhalation Cancer Slope Factor | Standard Table 6 2 | Inhalation Cancer Slope Factor Value |
| | | Units | Standard Table 6 2 | Inhalation Cancer Slope Factor Units |
| | | Weight of Evidence/ Cancer Guideline Description | Standard Table 6 2 | Weight of Evidence/Cancer Guideline Description |
| | | Source | Standard Table 6 2 | Unit Risk Inhalation CSF Source(s) |
| | | Date | Standard Table 6 2 | Unit Risk . Inhalation CSF Date(s) |
| | | Pathway: External (Radiation) | Standard Table 6 4 (Cancer Toxicity Data - Radiation) | |
| | | COC | Chemicals of Concern from Standard Table 6 4 (site specific definition) | Chemical of Potential Concern |
| | | Cancer Slope or Conversion Factor | Standard Table 6 4 | Cancer Slope Factor Value |
| | | Exposure Route | Standard Table 1 | Exposure Route |
| | | Units | Standard Table 6 4 | Cancer Slope Factor Units |
| | | Weight of Evidence/ Cancer Guideline Description | Not Available | Not Available |
| | | Source | Standard Table 6 4 | Source(s) |
| | | Date | Standard Table 6 4 | Date(s) |

Note:
-A version of ROD Highlight 6-16A is to be prepared for the Chemicals of Concern. This definition will be site specific.

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS (continued)

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-16B | Non-Cancer Toxicity Data Summary | Pathway Ingestion, Dermal | Standard Table 5 1 (Non-Cancer Toxicity Data - Oral/Dermal) | |
| | | Chemical of Concern | Chemicals of Concern fiom Standard Table 5 1 (site specific definition) | Chemical of Potential Concern |
| | | Chronic/ Subchronic | Standard Table 5 1 | Chronic/Subchronic |
| | | Oral RfD Value | Standard Table 5.1 | Oral RfD Value |
| | | Oral RfD Units | Standard Table 5.1 | Oral RfD Units |
| | | Dermal RfD | Standard Table 5.1 | Absorbed RfD for Dermal Value |
| | | Dermal RfD Units | Standard Table 5 1 | Absorbed RfD for Dermal Units |
| | | Primary Target Organ | Standard Table 5.1 | Primary Target Organ(s) |
| | | Combined Uncertainty/ Modifying Factors | Standard Table 5 1 | Combined Uncertainty/ Modifying Factors |
| | | Sources of RfD:Target Organ | Standard Table 5 1 | RfD Target Organ(s) Source(s) |
| | | Dates of RfD.Target Organ | Standard Table 5.1 | RfD Target Organ(s) Date(s) |
| | | Pathway: Inhalation | Standard Table 5.2 (Non-Cancer Toxicity Data - Inhalation) | |
| | | Chemical of Concern | Chemicals of Concern from Standard Table 5 2 (site specific definition) | Chemical of Potential Concern |

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS (continued)

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-16B (continued) | Non-Cancer Toxicity Data Summary (continued) | Chronic/ Subchronic | Standard Table 5 2 | Chronic/ Subchronic |
| | | Inhalation RfC | Standard Table 5 2 | Inhalation RfC Value |
| | | Inhalation RfC Units | Standard Table 5 2 | Inhalation RfC Units |
| | | Inhalation RfD | Standard Table 5 2 | Extrapolated RfD Value |
| | | Inhalation RfD Units | Standard Table 5.2 | Extrapolated RfD Units |
| | | Primary Target Organ | Standard Table 5 2 | Primary Target Organ(s) |
| | | Combined Uncertainty/ Modifying Factors | Standard Table 5 2 | Combined Uncertainty/ Modifying Factors |
| | | Sources of RfC:RfD: Target Organ | Standard Table 5 2 | RfC.Target Organ(s) Source(s) |
| | | Dates | Standard Table 5 2 | RfC.Target Organ(s) Date(s) |

Notes:
-A version of ROD Highlight 6-16B is to be prepared for the Chemicals of Concern. This definition will be site specific.

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS (continued)

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-18A | Risk Characterization Summary - Carcinogens | Scenario Timeframe | Standard Table 9 or 10 | Scenario Timeframe |
| | | Receptor Population | Standard Table 9 or 10 | Receptor Population |
| | | Receptor Age | Standard Table 9 or 10 | Receptor Age |
| | | Medium | Standard Table 9 or 10 | Medium |
| | | Exposure Medium | Standard Table 9 or 10 | Exposure Medium |
| | | Exposure Point | Standard Table 9 or 10 | Exposure Point |
| | | Chemical of Concern | Chemicals of Concern from Standard Table 9 or 10 (site specific definition) | Chemical |
| | | Carcinogenic Risk–Ingestion | Standard Table 9 or 10 | Carcinogenic Risk–Ingestion |
| | | Carcinogenic Risk–Inhalation | Standard Table 9 or 10 | Carcinogenic Risk–Inhalation |
| | | Carcinogenic Risk–Dermal | Standard Table 9 or 10 | Carcinogenic Risk–Dermal |
| | | Carcinogenic Risk–External (Radiation) | Standard Table 9 or 10 | Carcinogenic Risk–External (Radiation) |
| | | Carcinogenic Risk Exposure Routes Total | Standard Table 9 or 10 | Carcinogenic Risk - Exposure Routes Total |
| | | Medium Risk Total | Standard Table 9 or 10 | Medium Total (Risk) |
| | | Total Risk | Standard Table 9 or 10 | Receptor Risk Total |

Notes:
-A version of Highlight 6-18A is to be prepared for each Receptor (combination of Scenario Timeframe, Receptor Population, and Receptor Age) with "Significant Exposure". The definition of "Significant Exposure" will be site specific.

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS (continued)

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-18B | Risk Characterization Summary - Non-Carcinogens | Scenario Timeframe | Standard Table 9 or 10 | Scenario Timeframe |
| | | Receptor Population | Standard Table 9 or 10 | Receptor Population |
| | | Receptor Age | Standard Table 9 or 10 | Receptor Age |
| | | Medium | Standard Table 9 or 10 | Medium |
| | | Exposure Medium | Standard Table 9 or 10 | Exposure Medium |
| | | Exposure Point | Standard Table 9 or 10 | Exposure Point |
| | | Chemical of Concern | Chemicals of Concern from Standard Table 9 or 10 (site specific definition) | Chemical |
| | | Primary Target Organ | Standard Table 9 or 10 | Non-Carcinogenic Hazard Quotient - Primary Target Organ(s) |
| | | Non-Carcinogenic Hazard Quotient - Ingestion | Standard Table 9 or 10 | Non-Carcinogenic Hazard Quotient - Ingestion |
| | | Non-Carcinogenic Hazard Quotient - Inhalation | Standard Table 9 or 10 | Non-Carcinogenic Hazard Quotient - Inhalation |
| | | Non-Carcinogenic Hazard Quotient - Dermal | Standard Table 9 or 10 | Non-Carcinogenic Hazard Quotient - Dermal |
| | | Non-Carcinogenic Hazard Quotient - Exposure Routes Total | Standard Table 9 or 10 | Non-Carcinogenic Hazard Quotient - Exposuse Routes Total |

## EXHIBIT 3-4

## RAGS PART D INFORMATION SOURCES FOR ROD RISK GUIDANCE HIGHLIGHTS (continued)

| ROD RISK HIGHLIGHT | PURPOSE OF ROD RISK HIGHLIGHT | ROD FIELDS | ASSOCIATED RAGS D TABLE | ASSOCIATED RAGS D FIELDS |
|---|---|---|---|---|
| Highlight 6-18B (continued) | Risk Characterization Summary - Non-Carcinogens (continued) | Medium Hazard Index Total | Standard Table 9 or 10 | Medium Total (Hazard) |
| | | Receptor Hazard Index | Standard Table 9 or 10 | Receptor HI Total |
| | | Organ Hazard Index | Standard Table 9 or 10 | Total Organ HI Across All Media |

Notes:
-A version of Highlight 6-18B is to be prepared for each Receptor (combination of Scenario Timeframe, Receptor Population, and Receptor Age) with "Significant Exposure" The definition of "Significant Exposure" will be site specific.

# CHAPTER 4

# RISK EVALUATIONS DURING THE FEASIBILITY STUDY

Continuous involvement of the EPA risk assessor during the FS has the benefit of. 1) supporting the development of remedial action objectives (RAOs) and PRGs, 2) identifying risks and hazards associated with PRGS, and 3) supporting comparison of risks associated with various remedial alternatives. For these reasons, EPA risk assessor involvement in FS preparation and review is strongly encouraged.

## 4.1 INTRODUCTION

The purpose of the FS is to evaluate waste management remedial alternatives. The *National Oil and Hazardous Substances Pollution Contingency Plan (NCP)* (U.S. EPA, 1990c) specifies that a detailed analysis be performed that involves nine criteria. The NCP specifies that for screening of remedial alternatives, the long-term and short-term aspects of three criteria - effectiveness, implementability, and cost - should be used to guide the development and screening of remedial alternatives. Consideration of effectiveness involves evaluating the long-term and short-term human health risks. Long-term risks associated with a remedial alternative are those risks that will remain after the remedy is complete; short-term risks associated with a remedial alternative are those risks that occur during implementation of the remedial alternative.

Evaluating long-term risks ideally includes an assessment of the risks associated with treatment of residuals and untreated wastes for a treatment-based remedy, or an evaluation of the remedy's ability to provide protectiveness over time for a containment-based remedy. For short-term human health risks associated with a remedial alternative, a risk assessor may need to evaluate the risks that occur during implementation of the remedial alternative (e.g., risks associated with emissions from an onsite air stripper). Because some remedies may take many years to complete, some "short-term" risks may actually occur over a period of many years Populations that may be exposed to chemicals during remedy implementation include people who live and work in the vicinity of the site

The NCP also requires that RAOs and remediation goals be developed. These serve as objectives and goals that can be used to identify and assess remedial alternatives at Superfund sites. The remainder of this chapter defines and discusses RAOs and remediation goals. As also discussed in the NCP, final remediation goals are not determined until a final remedy for the site is selected in the ROD (see Chapter 5).

### 4.1.1 REMEDIAL ACTION OBJECTIVES

As discussed in the NCP, RAOs describe, in general terms, what any remedial action needs to accomplish in order to be protective of human health and the environment. They are typically narrative statements that specify the contaminants and environmental media of concern, the potential exposure pathways to be addressed by remedial actions, the exposed populations and environmental receptors to be protected, and the acceptable contaminant concentrations or concentration ranges (remediation goals) in each environmental medium.

### 4.1.2 REMEDIATION GOALS

Remediation goals are a subset of the RAOs They provide the acceptable contaminant concentrations in each medium for remedial actions to meet.

EPA explained in the preamble to the final NCP that remediation goals are based on ARARs unless ARARs are not available or are not protective. ARARs do not always exist for all chemicals and all environmental media

SELECTION OF REMEDIATION GOALS

The NCP [U S. EPA, 1990c, Section 300.430(e) (2)(I)] states that the selection of remediation goals should consider the following.

"...remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed considering the following...

ARARs under Federal environmental or State environmental or facility siting laws, if available, 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 the presence of multiple contaminants at a site or multiple pathways of exposure;

3. Factors related to technical limitations such as detection/quantification limits for contaminants;

4. Factors related to uncertainty; and

5 Other pertinent information."

Therefore, according to the NCP, there are two major sources for the acceptable exposure levels used for remediation goals: a) concentrations found in Federal and State ARARs and, if these are not available or not protective, (b) risk-based concentrations that are determined to be protective of human health and the environment. These risk-based concentrations are calculated using, at a minimum, the criteria sited in numbers 1 and 2 in the Remediation Goals highlight box. Other factors mentioned in the highlight box [i e . limits of detection (number 3). uncertainty (number 4), and background concentration levels (number 5)] are also considered.

Risk-based concentrations may need to be developed even if ARARs are available to ensure that these ARARs are protective of human health and the environment.

**ARAR-Based Remediation Goals**. Potential chemical-specific ARARs include concentration limits set by Federal environmental regulations such as Maximum Contaminant Levels (MCLs) established under the Safe Drinking Water Act (SDWA), ambient water quality criteria established under the Clean Water Act (CWA), and State regulations (e g , State drinking water laws) Action-specific and location-specific ARARs must also be complied with or waived according to the NCP.

**Risk-Based Remediation Goals**. In general, remediation goals based on risk-based calculations are determined using cancer or non-cancer toxicity values with specific exposure assumptions For chemicals with carcinogenic effects, the NCP has described the development of remediation goals, as a practical matter, as a two-step process [U S. EPA, 1990c, Section 300.430(e)(2)(I)(D)]. A concentration equivalent to a lifetime cancer risk of $10^{-6}$ is first established as a point of departure Then, other factors are taken into account to determine where within the acceptable range the remediation goals for a given contaminant at a specific site will be established.

The NCP discusses a generally acceptable risk range of $10^{-4}$ to $10^{-6}$. EPA has further clarified the extent of the acceptable risk range by stating that the upper boundary is not a discrete line at $1x10^{-4}$ Risks slightly greater than $1x10^{-4}$ may be considered to be acceptable (i.e., protective) if justified based on site-specific conditions, including any uncertainties about the nature and extent of contamination and associated

risks. [See *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (U.S. EPA, 1991d)].

For non-cancer effects, the NCP states that an acceptable exposure level must be defined. (See "Selection of Remediation Goals" highlight box in this section.) According to EPA guidance, (RAGS Part A, U.S. EPA, 1989c), generally, if the Hazard Index (HI) (Intake/RfD) is above 1 (i.e., the site exposure is estimated to be above the RfD) there may be a concern for potential non-cancer effects [see *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (U.S. EPA, 1991d)]. Therefore, in calculating remediation goals at a site to protect for non-cancer effects, remediation goals are generally set at a Hazard Index at or below 1.

### 4.1.3 PRELIMINARY REMEDIATION GOALS

PRGs for a site are established as early in the RI/FS process as possible during project scoping (see Chapter 2). These initial PRGs can then be modified as necessary during the FS, based on site-specific information from the baseline risk assessment. The PRGs will then be used to establish the goals to be met by the remedial alternatives in the FS. The PRGs also guide the development of the Proposed Plan for remedial action and the selection of remediation levels in the Record of Decision. During the FS, both risk-based and ARAR-based PRGs are considered. (See Section 4.1.2 for more discussion on ARAR-based PRGs).

Risk-based PRGs (non-ARARs) may be modified within the acceptable risk range during the remedy selection process based on a balancing of the major trade-offs among the alternatives as well as the public and Agency comments on the Proposed Plan (RAGS Part B, U.S. EPA, 1991a). Such balancing among alternatives and consideration of community and State acceptance will establish the specific level of protection the remedy will achieve (i.e., the final remediation levels).

The dialogue begun during Scoping between the EPA risk assessor and the EPA RPM should continue during the FS and beyond to ensure that risk assessment information is used appropriately in the risk management decision process

The primary guidance on development of the FS is available in *"Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (U.S EPA, 1988) RAGS Part B (U.S EPA, 1991a) also presents guidance for the role of risk assessment in the FS Consult the EPA RPM for guidance

## 4.2 DEVELOP REMEDIAL ACTION OBJECTIVES

The risk assessor should be involved in the preparation or review of the following

- A narrative description of the Medium, Exposure Point and Exposure Routes, and chemicals and radionuclides that will be the focus of the remedial action

- A narrative identifying the remedial action objectives for prevention of exposure and restoration of each contaminated Medium (e.g., restoring groundwater to a potable water source)

A format such as Example Table 1 in Exhibit 4-1 may be a useful approach to present these data for each Medium.

## 4.3 DEVELOP REMEDIATION GOALS

The risk assessor should be involved in the preparation or review of a short narrative or tables which provide the goals of the remediation. First, all values considered as PRGs should be identified. Then the PRGs selected for each chemical to be used in the FS should be presented.

### 4.3.1 IDENTIFY VALUES CONSIDERED AS PRELIMINARY REMEDIATION GOALS

The risk assessor should be involved in the following activities:

- Identify which chemicals and/or radionuclides will have PRGs developed.

- Identify ARAR-based PRGs and associated risks/hazards.

- If ARAR-based PRGs are not protective, calculate risk-based PRGs using EPA methods.

- Identify other values to consider as PRGs [e.g., background, detection limits, Procedure Quantitation Limits (PQLs)].

A format such as Example Table 2 in Exhibit 4-1 may be a useful approach to present these values, for each Medium and Receptor Population combination.

### 4.3.2 SELECT PRELIMINARY REMEDIATION GOALS

The risk assessor should be involved in the following activities:

- Select PRG(s) for each chemical from among the values considered (e.g., risk-based for cancer and non-cancer, ARAR-based, other), modifying values as appropriate. Note that the PRG should be ARAR-based unless there is no ARAR available or the ARAR is not protective.

- Provide the rationale for the selected PRG. Include the source of the value.

A format such as Example Table 3 in Exhibit 4-1 may be a useful approach to present these values for each Medium and Receptor Population combination.

## 4.4 SUMMARIZE RISKS AND HAZARDS ASSOCIATED WITH PRELIMINARY REMEDIATION GOALS

The risk assessor should be involved in the preparation or review of a short narrative or tables which summarize the risks and hazards associated with the PRGs. The risk assessor should be involved in the following activities:

- Identify the chemical and/or radionuclide of concern, maximum concentration, PRG, basis of PRG, and calculated risks and hazards associated with the PRG for each Medium and Receptor Population.

- Summarize the total risk and total hazard among all chemicals for each Medium and Receptor Population combination

A format such as Example Table 3 in Exhibit 4-1 may be a useful approach to present these values for each Medium and Receptor Population combination.

## 4.5 EVALUATE REMEDIAL TECHNOLOGIES AND ALTERNATIVES FOR RISK CONSIDERATIONS

The risk assessor may provide input in the process of evaluating remedial technologies and alternatives for risk considerations beginning in the development and screening stage of the FS and extending into the detailed analysis stage. The major goal for the risk evaluation during these steps is to provide the FS team and the EPA RPM with specific long-term and short-term human health risk information to consider when identifying and screening technologies and alternatives and performing detailed analysis of alternatives.

The long-term human health risks associated with a remedial technology or alternative are those risks that will remain after the remedy is complete (i.e., residual risks). The risk issues to be considered may include an assessment of the risks associated with treatment residuals, untreated wastes, or contained wastes.

The short-term human health risks associated with a remedial technology or alternative are those risks that occur during implementation of the technology or alternative, which may occur over a period of years. Populations to be considered include people who live and work in the vicinity of the site and workers involved in site remediation.

### 4.5.1 IDENTIFICATION AND SCREENING OF TECHNOLOGIES AND ALTERNATIVES

The risk assessor may contribute to the identification and screening of technologies and alternatives and focus on evaluating associated short-term and long-term human health risks to ensure that they meet RAOs and PRGs. The goal of the risk assessor is to assist in identifying, and eliminating from further consideration, technologies and/or alternatives with clearly unacceptable risks. This evaluation is typically qualitative, based on simplifying assumptions and professional judgment rather than detailed analysis. The risk assessor's evaluation is associated with the consideration of effectiveness, one of three criteria specified by the NCP. (Implementability and cost are the other two criteria evaluated at this screening stage, but they do not typically involve risk assessor participation.)

### 4.5.2 DETAILED ANALYSIS OF ALTERNATIVES

The overall objective of the risk assessor's role in the detailed analysis of alternatives is to support the preparation and evaluation of the risk information needed for RPMs to select a remedial alternative for a site. See the highlight box for the nine remedial alternative evaluation criteria specified by the NCP. The risk assessor contributes to the analysis of three of the nine criteria specified by the NCP:

- Overall Protection of Human Health and the Environment
- Long-term Effectiveness and Permanence
- Short-term Effectiveness.

The detailed analysis of short-term and long-term risks may be qualitative or quantitative depending on the "perceived risk" associated with the alternative based on both professional judgment and community concerns. The risk analysis follows the same general steps as the baseline risk assessment; however, the steps will typically not be conducted in the same level of detail for the FS.

**NCP CRITERIA FOR REMEDIAL ALTERNATIVE DETAILED EVALUATION**

1. Overall Protection of Human Health and Environment
2. Compliance with ARARs
3. Long-term Effectiveness and Permanence
4. Reductions in Toxicity, Mobility, and Volume Through Treatment
5. Short-term Effectiveness
6. Implementability
7. Cost
8. State Acceptance
9. Community Acceptance

The detailed analysis of short-term risks includes the following components for each alternative:

- Evaluate short-term exposure
- Evaluate short-term toxicity
- Characterize short-term risks to the community (including people who live or work on or near the site)
- Characterize short-term risks to remediation workers (a qualitative assessment may be appropriate if the risks to remediation workers are addressed adequately in the site-specific Health and Safety Plan)

The detailed analysis of long-term risks includes the following components for each alternative.

- Evaluate residual risk
- Evaluate protectiveness over time.

# EXHIBIT 4-1
# EXAMPLE TABLES TO STANDARDIZE REPORTING OF FS RISK EVALUATIONS

**Example Table 1**
**REMEDIAL ACTION OBJECTIVES**

| Medium |
|---|

| Exposure Point | Chemical | Exposure Route | Receptor Population | Remedial Action Objectives |
|---|---|---|---|---|
| | | | | |

**Example Table 2**
**VALUES CONSIDERED AS PRGs**

| Medium·<br>Receptor Population. |
|---|

| Chemical | Most Restrictive ARAR | Most Restrictive ARAR Source | Risk/Hazard at ARAR | Risk-Based PRG Cancer* | Risk-Based PRG Non-Cancer* | Other Value** | Other Value** Source |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

*Provide the associated risk and hazard levels in the footnotes
**(e g , detection limits, background)

**Example Table 3**
**RISKS AND HAZARDS ASSOCIATED WITH PRGs**

| Medium.<br>Receptor Population |
|---|

| Chemical | Site Concentration | PRG | Basis for PRG* | Risk at PRG Cancer | Hazard at PRG Non-Cancer | Target Endpoint |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | Totals | | | |

*TBC (Federal ARARs, State ARARs), Risk-based
Background Concentrations, method detection limits

# CHAPTER 5

# RISK EVALUATIONS AFTER THE FEASIBILITY STUDY

After completion of the FS, EPA risk assessor involvement in risk evaluations should be conducted as necessary to support the EPA RPM in ensuring that the remedy is protective. While these risk evaluations may not always require a significant level of quantitation, continuous involvement of EPA risk assessors is essential to ensure consistency in risk evaluation and risk communication. Post-FS activities benefitting from EPA risk assessor involvement typically include the Proposed Plan, the Record of Decision (ROD), the Remedial Design/Remedial Action, and Five-Year Reviews.

## 5.1 RISK EVALUATION FOR THE PROPOSED PLAN

The Proposed Plan should include sufficient risk assessment information to support the basis for the proposed remedial action. EPA risk assessor support is recommended during the preparation of the Proposed Plan to ensure the consistency of risk information with the Baseline Risk Assessment Report and the FS Report. The level of detail in the Proposed Plan should be appropriate to the needs of the community. Additional EPA risk assessor support required at this time may be qualitative or quantitative, typically focusing on refinement of previous analyses, based on newly developed information.

## 5.2 RISK EVALUATION ASSOCIATED WITH THE RECORD OF DECISION

EPA risk assessor involvement in preparation of the risk evaluation in the ROD is strongly recommended. A summary of the relevant information from the Baseline Risk Assessment Report should be presented in a mixture of text format and table format. In addition, the risks (short-term and residual) associated with each alternative should be discussed

### 5.2.1 BASELINE RISK SUMMARY IN THE RECORD OF DECISION

To support the preparation of the Record of Decision, the EPA risk assessor should prepare or review a summary of the Baseline Risk Assessment Report which supports the basis for the remedial action. The primary focus should be on those exposure pathways and chemicals of concern found to pose actual or potential threats to human health or the environment. Chemicals included in the risk assessment but determined not to contribute significantly to an unacceptable risk need not be included in the Risk Characterization Summary in the ROD (e.g., chemicals with risk levels less than $1x10^{-6}$ or HQ less than 0.1) unless they are needed to justify a No Action ROD

Refer to *Interim Final Guidance on Preparing Superfund Decision Documents* (U.S EPA, 1989b) and *Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents* (U S EPA, 1999a) for a recommended format for summarizing human health risk assessment information in the ROD.

Other risk information may also be included in the ROD depending upon the level of detail preferred. Information related to values used for intake calculations and non-cancer and cancer toxicity data and exposure point concentrations are summarized on Standard Tables 4, 5, 6, 7, and 8, which could be placed in appendices to the ROD Section 3 3 provides ROD Risk Worksheets that correspond to ROD guidance highlights 6-15, 6-16A, 6-16B, 6-18A and 6.18B. Preparation of these Worksheets previously, as interim deliverables (see Section 3.3), is strongly recommended because it greatly facilitates risk

evaluation in the ROD. If these Worksheets were not previously prepared, refer to Exhibit 3-4 for RAGS Part D Standard Table sources for this information.

### 5.2.2 RISKS ASSOCIATED WITH CLEANUP LEVELS IN THE RECORD OF DECISION

The ROD (except for no-action RODs) should describe how remedial alternatives will reduce risks by achieving cleanup levels through treatment or by eliminating exposures through engineering controls for the contaminated media.

In addition, the risk assessor should prepare/review the following information related to the selected alternative:

- Document short-term risks that may occur during remedy implementation
- Document risks that may remain after completion of the remedy (including residual risk from untreated waste remaining at the site)
- Determine the need for five-year reviews.

Refer to the ROD guidance (U.S. EPA, 1999a) for suggestions regarding presentation of risks associated with cleanup levels in the ROD (e.g., see Highlight 6-32).

## 5.3 RISK EVALUATION DURING REMEDIAL DESIGN AND REMEDIAL ACTION

The EPA risk assessor's role during remedial design and remedial action may be qualitative or quantitative depending on the site and phase of the project. During the remedial design, short-term and long-term risks may be assessed through refinement of previous analyses and identification of the need for engineering controls or other measures to mitigate risk.

During the remedial action, the EPA risk assessor is more likely to provide quantitative risk evaluation support. Short-term risk evaluation may address impacts to remediation workers and neighboring communities. Long-term risk evaluations typically focus on the following

- Whether cleanup levels specified in the ROD have been attained
- Whether residual risk after completion of the remedy ensures protectiveness.

## 5.4 RISK EVALUATION ASSOCIATED WITH EXPLANATIONS OF SIGNIFICANT DIFFERENCES (ESDs) AND AMENDED RODs

When conditions relevant to a site change following the signing of a ROD, it is sometimes necessary to prepare an ESD or amended ROD. Examples of conditions causing this situation may include, but are not limited to, the following:

- Toxicity values change
- Additional technology performance information becomes available
- ARARs change (e.g., Land Disposal Restrictions).

EPA risk assessor involvement with RPM evaluations of ESDs and Amended RODs focuses on evaluating whether cleanup levels are still protective when considering new ARARs, new parameters for risk and hazard calculations, new technology information, and other new information. Any new information and revised risk evaluations should be thoroughly documented.

## 5.5 RISK EVALUATION DURING FIVE-YEAR REVIEWS

CERCLA provides for reviews of certain remedies at least every five years to assure that human health and the environment are being protected by the remedial alternative implemented. EPA risk assessor involvement with RPM evaluations during Five-Year Reviews are generally quantitative and focus on the following three goals:

- Confirm that the remedy remains protective (including any engineering or institutional controls)

- Evaluate whether cleanup levels are still protective by considering new ARARs, new parameters for risk and hazard calculations, and other new information
- Evaluate whether cleanup has reduced risks to levels no longer requiring restricted site use and five-year reviews (U S EPA, 2001b)

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* This Reference Section is designed to not only give bibliographic information for documents referred to in the RAGS Part D text, but also to be a source of bibliographic information for documents that are relevant to risk assessment in general.