

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

Interim

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

NOTICE

This document provides guidance to EPA staff. The guidance is designed to communicate National policy on the planning, reporting and review of Superfund risk assessments. The document does not, however, 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. 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.

CONTENTS

	Page
NOTICE	ii
EXHIBITS	vi
DEFINITIONS	vii
ACRONYMS/ABBREVIATIONS	xii
ACKNOWLEDGMENTS	xiv
PREFACE	xv
1.0 INTRODUCTION	1-1
1.1 OVERVIEW OF PART D	1-1
1.1.1 Background	1-1
1.1.2 Elements of Part D Approach	1-1
1.2 APPLICABILITY OF PART D APPROACH	1-4
1.3 PROCESS IMPROVEMENTS RESULTING FROM PART D APPROACH	1-4
1.4 ORGANIZATION OF DOCUMENT	1-4
1.5 ADDITIONAL INFORMATION	1-7
2.0 RISK CONSIDERATIONS DURING PROJECT SCOPING	2-1
2.1 PLANNING	2-1
2.2 WORKPLAN DEVELOPMENT	2-2
2.2.1 RI/FS Workplan/Baseline Risk Assessment Workplan	2-2
2.2.2 SAP and QAPP	2-3
3.0 RISK ASSESSMENT DATA NEEDS AND TASKS DURING THE REMEDIAL INVESTIGATION	3-1
3.1 INTERIM DELIVERABLES	3-1

CONTENTS (Continued)

	Page
3.1.1	Standard Tables, Worksheets, and Supporting Information 3-2
3.1.2	Assessment of Confidence and Uncertainty 3-10
3.1.3	Probabilistic Analysis Information 3-10
3.2	DRAFT BASELINE RISK ASSESSMENT REPORT 3-11
3.3	FINAL BASELINE RISK ASSESSMENT REPORT 3-11
3.4	DATA TRANSFER TO CERCLIS 3 3-11
4.0	RISK EVALUATIONS DURING THE FEASIBILITY STUDY 4-1
4.1	INTRODUCTION 4-1
4.1.1	Remedial Action Objectives 4-1
4.1.2	Remediation Goals 4-1
4.1.3	Preliminary Remediation Goals 4-3
4.2	DEVELOP REMEDIAL ACTION OBJECTIVES 4-3
4.3	DEVELOP REMEDIATION GOALS 4-3
4.3.1	Identify Values Considered as Preliminary Remediation Goals 4-3
4.3.2	Select Preliminary Remediation Goals 4-4
4.4	SUMMARIZE RISKS AND HAZARDS ASSOCIATED WITH PRELIMINARY REMEDIATION GOALS 4-4
4.5	EVALUATE REMEDIAL TECHNOLOGIES AND ALTERNATIVES FOR RISK CONSIDERATIONS 4-4
4.5.1	Identification and Screening of Technologies and Alternatives 4-4
4.5.2	Detailed Analysis of Alternatives 4-5
5.0	RISK EVALUATIONS AFTER THE FEASIBILITY STUDY 5-1
5.1	RISK EVALUATION FOR THE PROPOSED PLAN 5-1
5.2	DOCUMENTATION OF RISKS IN THE RECORD OF DECISION 5-1
5.3	RISK EVALUATION DURING REMEDIAL DESIGN AND REMEDIAL ACTION 5-2

CONTENTS (Continued)

		Page
5.4	RISK EVALUATION ASSOCIATED WITH EXPLANATIONS OF SIGNIFICANT DIFFERENCES (ESDs) AND AMENDED RODs	5-2
5.5	RISK EVALUATION DURING FIVE-YEAR REVIEWS	5-2
REFERENCES		R-1
APPENDIX A	STANDARD TABLES	
APPENDIX B	INSTRUCTIONS FOR COMPLETION OF THE STANDARD TABLES	
APPENDIX C	DATA USEABILITY WORKSHEET	
ELECTRONIC MEDIA		

EXHIBITS

Exhibit	Page
1-1 RELATIONSHIP OF THE HUMAN HEALTH EVALUATION TO THE CERCLA PROCESS	1-2
1-2 GUIDELINES FOR PART D APPLICABILITY	1-5
1-3 PROCESS IMPROVEMENTS EXPECTED WITH PART D APPROACH	1-6
1-4 ROLE OF RISK ASSESSOR IN THE CERCLA REMEDIAL PROCESS	1-8
3-1 INTERIM DELIVERABLES FOR EACH SITE	3-12
3-2 STANDARDIZED RISK ASSESSMENT REPORTING	3-14
3-3 DATA USEABILITY WORKSHEET	3-15
4-1 EXAMPLE TABLES TO STANDARDIZE REPORTING OF FS RISK EVALUATIONS	4-6

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.
CERCLIS 3	The newest version of the Comprehensive Environmental Response, Compensation, and Liability Information System, EPA’s primary Superfund database. CERCLIS 3 enables Superfund staff nationwide to share comprehensive and reliable data across EPA and eventually with other federal partners and the public.
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.

DEFINITIONS (Continued)

Term	Definition
Exposure Medium	The contaminated environmental medium to which an individual is exposed. Includes the transfer of contaminants from one medium to another.
Exposure Pathway	The course a chemical 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.
Exposure Point	An exact location of potential contact between a person and a chemical within an exposure medium.
Exposure Point Concentration	The value that represents a conservative estimate of the chemical concentration available from a particular medium or route of exposure. See definitions for Medium EPC and Route EPC, which follow.
Exposure Route	The way a chemical 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) originally contaminated.
Medium EPC	The EPC, based on either a statistical derivation of measured data or modeled data. The Medium EPC differs from the Route EPC in that the Medium EPC does not consider the transfer of contaminants from one medium to another.

DEFINITIONS (Continued)

Term	Definition
Preliminary Remediation Goals (PRGs)	Initial clean-up goals that (1) are protective of human health and the environment and (2) comply with ARARs. They are developed early in the 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).
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 is 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, a 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.
Route EPC	The EPC, based on either a statistical derivation of measured data or based on modeled data, that was selected to represent the route-specific concentration for the exposure calculations. The Route EPC differs from the Medium EPC in that the Route EPC may consider the transfer of contaminants from one medium to another, where applicable for a particular exposure route.
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 and on the electronic media provided with this guidance document. Use of the Standard Tables will standardize the reporting of human health risk assessments. The Standard Table formats can not be altered (i.e., columns can not be added, deleted, or changed); however, rows and footnotes can be added as appropriate. Standardization of the Tables is needed to achieve Superfund program-wide reporting consistency and to accomplish electronic data transfer to the Superfund database.
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. Chapters 2 through 5 of Part D present the TARA.
Worksheets	Formats for documenting assumptions, input parameters, and conclusions regarding complex risk assessment issues. The Data Useability Worksheet (found in Exhibit 3-3) should be an Interim Deliverable for all sites. Worksheets addressing Lead and Radionuclides are under development and will be provided in a revision to RAGS Part D.

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
CERCLIS 3	Version 3 of Comprehensive Environmental Response Compensation and Liability Information System (CERCLIS)
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 Priority 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	<i>Risk Assessment Guidance for Superfund</i>
RAGS/HHEM	<i>Risk Assessment Guidance for Superfund: Volume I -- Human Health Evaluation Manual</i>
RAOs	Remedial Action Objectives
RfC	Reference Concentration
RfD	Reference Dose
RI/FS	Remedial Investigation/Feasibility Study

ACRONYMS/ABBREVIATIONS (Continued)

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
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 approach presented in this manual.

CDM Federal Programs Corporation provided technical assistance to EPA in the development of this manual, under contract No. 68-W9-0056.

RAGS PART D WORKGROUP

EPA HEADQUARTERS

Office of Emergency and Remedial Response:

James Konz
David Bennett

EPA REGIONAL OFFICES

Region 1:
Region 2:
Region 3:
Region 4:
Region 5:
Region 6:
Region 7:
Region 8:
Region 9:
Region 10:

Ann-Marie Burke
Marian Olsen
Jennifer Hubbard
Glenn Adams
Andrew Podowski
Ghassan Khoury
David Crawford
Chris Weis
Stan Smucker
Dana Davoli

PREFACE

Risk Assessment Guidance for Superfund: Volume I -- Human Health Evaluation Manual (RAGS/HHEM) Part D is the fourth part in the 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; and Part C addresses the human health risk evaluations of remedial alternatives. 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, and C, and in supplemental Office of Solid Waste and Emergency Response (OSWER) directives. 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 decision-makers.

This guidance does not discuss the standardization of ecological risk assessments, nor does it discuss the risk management decisions that are necessary at a CERCLA site (e.g., selection of final remediation goals).

This manual is being distributed as an interim document to allow for a period of field testing and evaluation. In addition, EPA is developing standardized approaches to plan, report and review:

- lead risks;
- radionuclide risks; and
- probabilistic analyses.

These will be issued as future revisions of RAGS Part D. In addition, EPA will provide standard tables for ecological evaluation.

RAGS/HHEM will be revised in the future, and new documents in appropriate print and electronic format will be issued.

Comments addressing usefulness, changes, and additional areas where guidance is needed should be addressed to the RAGS Part D website at <http://www.epa.gov/superfund/oerr/techres/ragsd/ragsd.html>, or to:

Senior Process Manager for Risk
RAGS Part D
U.S. Environmental Protection Agency
Office of Emergency and Remedial Response (5202G)
401 M Street, SW
Washington, DC 20460

