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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 concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA remedy selection process. The guidance is designed to implement national policy on these issues.

Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions 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 remedy selection decision 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.

Interested parties are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation, and the Agency welcomes public input on the document at any time. EPA may change this guidance in the future.

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EXHIBITS

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DEFINITIONS

These definitions are provided for purposes of this guidance and are intended to be consistent with existing Agency guidance and regualtions.

Term	Definition
Applicable or Relevant and Appropriate Requirements (ARARs)	As defined in the NCP, "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 Planning 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 Planning 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 Planning 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 targeted for possible remediation.

DEFINITIONS (Continued)

Term	Definition
Preliminary Remediation Goals (PRGs)	Generally, initial cleanup goals that (1) are protective of human health and the environment and (2) comply with ARARs. Pursuant to the NCP, they are developed early in the remedy selection process based on readily available information and should be modified to reflect results of the baseline risk assessment. They also should be used during analysis of remedial alternatives in the remedial investigation/feasibility study (RI/FS). Remedial goals, selected as part of the risk management decision, normally 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, 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.
Scenario Timeframe	The time period (current and/or future) being considered for the Exposure Pathway.

DEFINITIONS (Continued)

Term	Definition
Planning Tables	One of the Planning Tools under the RAGS Part D approach. The Planning 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 Planning Tables have been developed in Lotus® and Excel® for ease of use by risk assessors. For each site-specific risk assessment, the Planning Tables, related Worksheets, and Supporting Information should first be prepared as Interim Deliverables for EPA risk assessor review, and should later be included in the Draft and Final Baseline Risk Assessment Reports. The Planning Tables may be found in Appendix A. Use of the Planning Tables will standardize the reporting of human health risk assessments. The Planning 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.
Planning Tools	A basic element of the RAGS Part D approach. The Planning Tools have been developed to standardize the planning, reporting, and review of Superfund risk assessments. The three Planning Tools contained in the Part D approach include the Technical Approach for Risk Assessment (TARA), the Planning Tables, and Instructions for the Planning 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 Planning 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

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
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 participated in the Workgroup that developed the final RAGS Part D approach presented in this manual.

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RAGS PART D WORKGROUP

OFFICE OF EMERGENCY AND REMEDIAL RESPONSE:

Headquarters:	David Bennett
Headquarters:	Elizabeth Hofmann
Headquarters:	James Konz
Headquarters:	Karen Martin

EPA REGIONAL CONTACTS:

Region 1:	Sarah Levinson
Region 2:	Marian Olsen
Region 3:	Jennifer Hubbard
Region 4:	Glenn Adams
Region 5:	Andrew Podowski
Region 6:	Ghassan Khoury
Region 7:	Judy Facey
Region 8:	Jim Luey
Region 9:	Stan Smucker
Region 10:	Dana Davoli

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 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 Final guidance considers the comments received from users of the Revision 0 guidance and provides Planning 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 Planning Tables associated with certain sites.

In addition to Planning Table format changes, the Final guidance provides planning formats to document radionuclide and lead risk evaluations, neither of which was addressed in the Revision 0 guidance. The Final guidance also provides more robust and diverse examples than were included in Revision 0. These examples address comments and questions received from users of the Revision 0 guidance and are provided as suggested approaches to address complex situations. In all cases, the EPA regional risk assessor should be consulted to discuss the appropriate approach for a site.

This guidance does not discuss standardization of ecological risk assessments. EPA will provide planning 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 Final will be effective for all new CERCLA risk assessments. Consult the EPA risk assessor for applicability of the final guidance 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