Risk Assessment Guidance for Superfund:

Volume III - Part A, Process for Conducting Probabilistic Risk Assessment

EPA 540-R-02-002
OSWER 9285.7-45
PB2002 963302
www.epa.gov/superfund/RAGS3A/index.htm
December 2001

Superfund

Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment

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

Printed on Recycled Paper

DISCLAIMER

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 decision makers 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 objection 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 this document at any time. EPA may change this guidance in the future.

ABOUT THE REVISION

WHAT IT IS

EPA's *Process for Conducting Probabilistic Risk Assessment* is an update of the 1989 *Risk Assessment Guidance for Superfund (RAGS)*. It is Volume III, an update to the existing two-volume set of RAGS. Volume III: Part A provides policy and guidance on conducting probabilistic risk assessment for both human and ecological receptors.

WHO IT'S FOR

RAGS Volume III: Part A is written primarily for risk assessors. Risk assessment reviewers, remedial project managers, and risk managers involved in Superfund site cleanup activities will also benefit from this addition to RAGS.

WHAT'S NEW

RAGS Volume III: Part A provides guidance on applying probabilistic analysis to both human health and ecological risk assessment. New information and techniques are presented that reflect the views of EPA Superfund program. A tiered approach is described for determining the extent and scope of the modeling effort that is consistent with the risk assessment objectives, the data available, and the information that may be used to support remedial action decisions at Superfund hazardous waste sites.

RAGS Volume III: Part A contains the following information:

- For the risk assessor— updated policies and guidance; discussion and examples of Monte Carlo modeling techniques for estimating exposure and risk.

- For the risk manager and the remedial project manager—an introduction to PRA, a chapter on communicating methods and results of PRA with the public, and a chapter on the role of PRA in decision making.

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

1-D MCA	One-dimensional Monte Carlo analysis
2-D MCA	Two-dimensional Monte Carlo analysis
95% UCL	95% upper confidence limit
AM	Arithmetic mean
ARARs	Applicable or relevant and appropriate requirements
AT	Averaging time
AWQC	Ambient water quality criterion
BCa	Bias correction acceleration method
BMD	Benchmark dose
BMDS	Benchmark dose software
BMR	Benchmark Response
BTAG	Biological Technical Assistance Group
BW	Body weight
C	Concentration
CAG	Community advisory group
CDF	Cumulative distribution function
CI	Confidence interval
CIC	Community involvement coordinator
CIP	Community involvement plan
CLT	Central limit theorem
COC	Chemical of concern
CQR	Continuous quadratic regression
CSF	Cancer slope factor
CTE	Central tendency exposure
CV	Coefficient of variation
DI	Daily intake
DQO	Data quality objectives
EC_0	Exposure concentration that produces zero effect
EC_{20}	Concentration that causes a 20% effect
ECDF	Empirical cumulative distribution function
ED	Exposure duration
ED_{10}	Dose that causes a 10% effect
EDF	Empirical distribution function
EF	Exposure frequency
EPA	U.S. Environmental Protection Agency
EPC	Exposure point concentration
ERA	Ecological risk assessment
ERAF	Risk Assessment Forum
ERAGS	Ecological Risk Assessment Guidance for Superfund
EU	Exposure unit
EVIU	Expected value of including uncertainty
EVOI	Expected value of information
EVPI	Expected value of perfect information
EVSI	Expected value of sample information
GIS	Geographical Information Systems
GM	Geometric mean
GoF	Goodness-of-Fit
GSD	Geometric standard deviation
HEAST	Health effects assessment summary table
HHEM	Human Health Evaluation Manual
HI	Hazard Index

HQ	Hazard Quotient
IR	Iterative reduction
Irsd	Soil and dust ingestion rate
IRIS	Integrated Risk Information System
LADD	Life-time average daily intake
LCL	Lower confidence limit
LED_{10}	Lowest effect dose - lower confidence bound for dose that causes a 10% effect
LHS	Latin hypercube sampling
LOAEL	Lowest-observed-adverse-effect level
LOD	Limit of detection
LOEC	Lowest-observed-effect-concentration
MCA	Monte Carlo analysis
MCL	Maximum contaminant levels
MDC	Maximum detected concentration
MEE	Microexposure Event Analysis
MLE	Maximum Likelihood Estimation
MoMM	Method of Matching Moments
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NOAEL	No-observed-adverse-effect level
NOEC	No-observed-effect-concentration
OLS	Ordinary least squares
PBPK	Physiologically-based pharmacokinetic
PCBs	Polychlorinated biphenyls
pCi/g	Picocuries/gram
PDF	Probability density function
PDFu	Probability distribution for variability
PDFv	Probability distribution for uncertainty
PMF	Probability mass function
PPT	Parts per trillion
PRA	Probabilistic risk assessment
PRG	Preliminary remediation goal
PRP	Potentially responsible party
QAPP	Quality Assurance Project Plan
RAGS	Risk Assessment guidance for Superfund
RAL	Remedial action level
RBC	Risk based concentration
RCRA	Resource Conservation and Recovery Act
RfC	Reference concentration
RfD	Reference dose
RG	Remediation goal
RI/FS	Remedial Investigation/Feasibility Study
RME	Reasonable maximum exposure
RMSE	Root mean squared error
ROD	Record of decision
ROS	Rank order statistic
RPSS	Relative partial sum of squares
RPM	Remedial project manager
RSS	Regression sum of squares
SCM	Site conceptual model
SD	Standard deviation

SE	Standard error
SMDP	Scientific/Management Decision Point
SOW	Statement of Work
SR	Sensitivity ratio
SSD	Species sensitivity distribution
SSE	Sum of squares due to error
SSR	Sum of squares due to regression
SST	Sum of squares for total (regression plus error)
TAB	Technical Assistance to Brownfields Community
TAG	Technical assistance grant
TOSC	Technical outreach services for communities
TRV	Toxicity reference value
TSS	Total sum of squares
UCL	Upper confidence limit
VOI	Value of information

AUTHORS, CONTRIBUTORS, AND REVIEWERS

This manual was developed by EPA's Office of Emergency and Remedial Response. A number of individuals have reviewed and/or have been contributing authors of this document. Members of the EPA RAGS Volume III Workgroup, which was responsible for developing this document, included the following EPA headquarters and regional office staff.

RAGS VOLUME III WORKGROUP PARTICIPANTS

EPA HEADQUARTERS

Office of Emergency and Remedial Response	David A. Bennett S. Steven Chang David E. Cooper Janine Dinan Elizabeth Lee Hofmann
Office of Policy Economics and Innovation	Timothy M. Barry

EPA REGIONAL OFFICES

Region 1	Ann-Marie Burke	Region 5	Amy Mucha James Chapman
Region 2	Audrey Galizia Marian Olsen	Region 6	Maria L. Martinez
Region 3	Nancy Rios Jafolla	Region 8	Susan Griffin Gerry Henningsen Dale Hoff
Region 4	Ted W. Simon Sharon R. Thoms	Region 10	Joe Goulet

Technical assistance and production support was provided to EPA in the development of this guidance under Contract Numbers GS-10F-0137K and GS-35F-0555K.

An earlier draft of this document was peer reviewed by a panel of experts at a peer-review workshop held in November 2000. In addition, individuals in EPA and from the public provided valuable comments on earlier drafts of this guidance during the peer review process.

PREFACE

Risk Assessment Guidance for Superfund (RAGS) Volume III: Part A (hereafter referred to as RAGS Volume 3: Part A) provides technical guidance on the application of probabilistic risk assessment (PRA) methods to human health and ecological risk assessment in the U.S. Environmental Protection Agency (EPA) Superfund program. *RAGS Volume 3: Part A* supplements existing human health and ecological assessment guidance provided in the RAGS series. This guidance focuses on Monte Carlo analysis (MCA) as a method of quantifying variability and uncertainty in risk. Primarily geared toward the risk assessor, it is intended, both in content and format, to be most accessible to those readers who are familiar with risk assessment and basic statistical concepts. Chapters 1, 2, 6, and 7 are also directed towards risk managers. The term risk manager is used in this guidance to refer to individuals or entities that serve as the decision makers at hazardous waste sites. The term is used to emphasize the separation between risk assessment and risk management activities. Risk managers may include individual remedial project mangers (RPMs), site partnering teams, senior EPA managers (Section Chiefs, Branch Chiefs, or Division Directors), or other decision makers.

An attempt has been made in this document to define all relevant technical terms using plain language and to illustrate concepts with examples. An exhibit at the beginning of each chapter provides definitions of terms used in that chapter. In addition, a comprehensive definition of terms is provided in Appendix E. Other useful information has been presented in exhibits placed throughout each chapter. Bullets are used throughout the text to emphasize important concepts and policy statements related to the use of PRA. References are listed at the end of each chapter.

RAGS Volume 3: Part A was developed by the Superfund Probabilistic Risk Assessment Workgroup and the Ecological Risk Assessment Forum (ERAF); both are intra-Agency workgroups that have focused on improving the Risk Assessment Guidance for Superfund and implementing Superfund Reform activities. The guidance has undergone extensive review by Superfund and other programs within the Agency. In February 2000, a draft of the guidance was announced in the *Federal Register* to provide an opportunity for public comment (U.S. EPA, 2000a). In August 2000, a notice of peer review was announced in the *Federal Register* (U.S. EPA, 2000b), and in November 2000, *RAGS Volume 3: Part A* received a formal peer review from panelists outside the Agency.

The Agency may incorporate PRA under fund-lead and Potentially Responsible Party (PRP)-lead risk assessments. Implementation of successful PRAs requires careful planning. EPA strongly recommends that PRPs involve the Agency in all decisions regarding the planning, submittal, and technical details of any PRA. Coordinating with EPA early in the process will help ensure that PRAs conform to the recommended guidelines as part of the Superfund risk assessment process for protecting human and ecological health. PRPs should submit workplans for Agency review before initiating any PRA. Similarly, when EPA chooses to use PRA for an EPA-lead risk assessment, a PRA workplan will assist in directing site investigation and risk assessment activities, whether conducted by EPA or an EPA contractor. A workplan specifies contractor activities in the risk assessment and provides risk assessors and risk managers with an opportunity to obtain internal feedback from knowledgeable EPA staff, prior to initiating work on the assessment.

A tiered approach to PRA is advocated, which begins with a point estimate risk assessment. Important considerations include the time required to perform the PRA, the additional resources involved in developing the PRA, the quality and extent of data on exposure that will be used in the assessment, and the value added by conducting the PRA. Project scoping is an essential component of all risk assessments and is especially important in PRA.

Implementation of a PRA usually requires special computer software that may be commercially available or that may need to be custom-designed for a specific application. Although commercial software packages are noted in this guidance, any mention or use of a particular product in *RAGS Volume 3: Part A* does not constitute an endorsement of that product by the Agency.

1.0 WHAT IS THE PURPOSE OF RAGS VOLUME 3 PART A?

RAGS Volume 3: Part A addresses the technical and policy issues associated with the use of PRA in EPA Superfund program. This guidance builds upon basic concepts of risk assessment outlined in *RAGS Volume I* (U.S. EPA, 1989a; 2001), recent guidance for ecological risk assessment (U.S. EPA, 1992, 1994, 1997a, 1998a; 1999), and the Agency Probabilistic Analysis Policy document (U.S. EPA, 1997b). *RAGS Volume 3: Part A* addresses the use of PRA for both human health and ecological risk assessments. *RAGS Volume 3: Part A* was developed to provide risk assessors and risk managers with basic guidelines for incorporating PRA into Superfund site-specific risk assessments. It is not intended to be a detailed technical reference on PRA methods, however, it does direct the reader to appropriate literature on important technical subjects. A primary purpose of *RAGS Volume 3: Part A* is to help prevent misuse and misinterpretation of PRA.

2.0 WHAT IS PROBABILISTIC RISK ASSESSMENT AND HOW IS IT USED IN RISK CHARACTERIZATION?

PRA is a risk assessment that uses probability distributions to characterize variability or uncertainty in risk estimates. In a PRA, one or more variables in the risk equation is defined as a probability distribution rather than a single number. Similarly, the output of a PRA is a range or probability distribution of risks experienced by the receptors. The evaluation of variability and uncertainty is an important component of the risk characterization of all risk assessments. As stated in the 1995 Risk Characterization memorandum from Administrator Carol Browner (U.S. EPA, 1995),

> *... we must fully, openly, and clearly characterize risks. In doing so, we will disclose the scientific analyses, uncertainties, assumptions, and science policies which underlie our decisions... There is value in sharing with others the complexities and challenges we face in making decisions in the face of uncertainty.*

In addition, the 1997 EPA Policy for Use of Probabilistic Analysis in Risk Assessment (U.S. EPA, 1997b) states:

> ☞ *It is the policy of the U.S. Environmental Protection Agency that such probabilistic analysis techniques as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments.*

A more extensive general discussion of PRA can be found in Chapter 1 of the guidance. The use of PRA in Superfund remedial decision making is presented in Chapter 7 of the guidance.

3.0 WHAT ARE THE ADVANTAGES AND DISADVANTAGES OF PRA FOR REMEDIAL DECISIONS?

The primary advantage of PRA within the Superfund program is that it can provide a quantitative description of the degree of variability or uncertainty (or both) in risk estimates for both cancer and non-cancer health effects and ecological hazards. The quantitative analysis of uncertainty and variability can provide a more comprehensive characterization of risk than is possible in the point estimate approach.

Another significant advantage of PRA is the additional information and potential flexibility it affords the risk manager. Superfund remedy decisions are often based on an evaluation of the risk to the individual at the reasonable maximum exposure (RME) level (U.S. EPA, 1990). The RME represents the highest exposure reasonably likely to occur (U.S. EPA, 1989a). When using PRA, the risk manager can select the RME from the high-end range of percentiles of risk, generally between the 90^{th} and 99.9^{th} percentiles, referred to in this guidance as the *RME range*.

However, PRA may not be appropriate for every site. Disadvantages of PRA are that it generally requires more time, resources, and expertise on the part of the assessor, reviewer, and risk manager than a point estimate approach.

4.0 HOW IS *RAGS VOLUME 3, PART A* ORGANIZED?

Although the primary audience of this guidance is the risk assessor, Chapter 1 provides a basic overview of PRA for risk assessors and risk managers. The centerpiece of *RAGS Volume 3: Part A* is the tiered approach described in Chapter 2. The tiered approach is a framework that enables the risk manager to decide if and when to undertake a PRA and to determine the appropriate level of complexity for the PRA. Chapter 3 provides a description of using PRA for human health risk assessment. Chapter 4 discusses the issues of using PRA for ecological risk assessment. Chapter 5 presents a discussion of using PRA to determine preliminary remediation goals. Chapter 6 details issues associated with communicating risk estimates developed with PRA. Chapter 7 provides information for risk managers choosing to base remedial decisions on the results of a PRA.

Eight appendices to this guidance expand on technical aspects of topics important to PRA, such as sensitivity analysis and selecting and fitting probability distributions.

5.0 WHAT ARE THE KEY GUIDING CONCEPTS IN *RAGS VOLUME 3: PART A*?

(1) *Use a tiered approach to incorporating PRA into site risk assessments.*

(2) *Submit a workplan for Agency review prior to initiating work on a PRA.*

(3) *Perform a point estimate assessment prior to considering a PRA.*

(4) *While PRA can provide a useful tool to characterize and quantify variability and uncertainty in risk assessments, it is not appropriate for every site.*

(5) *PRA generally requires more time, resources, and expertise on the part of the assessor, reviewer, and risk manager than a point estimate risk assessment.*

(6) The decision to use PRA is site-specific and is based on the complexity of the problems at the site, the quality and extent of site-specific data, and the likely utility of the result.

(7) If the additional information provided from a PRA is unlikely to affect the risk management decision, then it may not be prudent to proceed with a PRA. However, if there is a clear value added from performing a PRA, then the use of PRA as a risk assessment tool generally should be considered despite the additional resources that may be needed.

(8) Communicating the results of a PRA will be more challenging than communicating the results of a point estimate risk assessment because PRA and its perspective will be new to most participants.

(9) If the decision is made to conduct a PRA, it is important to include community in the planning process. Communication on PRA may involve: providing the community with a basic understanding of the principles of PRA, discussing the proposed workplan and inviting comments on the proposed approach, discussing site-specific data, and communicating the final results and how they impact decisions for the site.

REFERENCES FOR PREFACE

U.S. EPA. 1989a. *Risk Assessment Guidance for Superfund* (RAGS): *Volume I. Human Health Evaluation Manual* (HHEM) *(Part A, Baseline Risk Assessment)*. Interim Final. Office of Emergency and Remedial Response, Washington, DC. EPA/540/1-89/002. NTIS PB90-155581.

U.S. EPA. 1990. National Oil and Hazardous Substances Pollution Contingency Plan. Final Rule. 40 CFR 300: *55 Federal Register*, 8666-8865, March 8.

U.S. EPA. 1992. *Final Guidelines for Exposure Assessment*. EPA/600/Z-92/001. *Federal Register,* 22888-22938. May 29.

U.S. EPA. 1994. *Role of Ecological Risk Assessment in the Baseline Risk Assessment.* Office of Solid Waste and Emergency Response, Washington, DC. OSWER Directive No. 9285.7-17.

U.S. EPA. 1995. *Memorandum from Carol Browner on Risk Characterization*. Office of the Administrator, Washington, DC. February 22.

U.S. EPA. 1997a. *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*. Interim Final. Environmental Response Team, Edison, NJ. EPA/540/R-97/006, OSWER Directive No. 9285.7-25. June.

U.S. EPA. 1997b. *Memorandum from Deputy Administrator Fred Hansen on the Use of Probabilistic Techniques (including Monte Carlo Analysis) in Risk Assessment, and Guiding Principles for Monte Carlo Analysis*. Office of Research and Development, Washington, DC. EPA/630/R-97/001. May 15.

U.S. EPA. 1998a. *Guidelines for Ecological Risk Assessment.* Risk Assessment Forum. Environmental Protection Agency, Washington DC. EPA/630/R-95/002F. April. *Federal Register* 63(93): 26846-26924. May 14.

U.S. EPA. 1999. *Ecological Risk Assessment and Risk Management Principles for Superfund Sites*. Final. Office of Solid Waste and Emergency Response, Washington, DC. OSWER Directive No. 9285.7-28P.

U.S. EPA. 2000a. *Superfund Probabilistic Risk Assessment to Characterize Uncertainty and Variability*. Washington, DC. *Federal Register* [FR Doc. 06-3492] 65(31): 7550-7552. February 15.

U.S. EPA. 2000b. *Peer Review for Superfund Probabilistic Risk Guidance*. Washington, DC. *Federal Register* [FR Doc. 00-21197] 65(162): 50694. August 21.

U.S. EPA. 2001. *Risk Assessment Guidance for Superfund*: *Volume I. Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments).* Office of Emergency and Remedial Response. Washington, DC. OSWER Directive No. 9285.7-47. December.