Publication 9285.7-01C
October 1991

Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives)

Interim

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

NOTICE

The policies set out in this document are intended solely as guidance; they are not final U.S. Environmental Protection Agency (EPA) actions. These policies are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on an analysis of specific site circumstances. The Agency also reserves the right to change this guidance at any time without public notice.

This guidance is based on policies in the Final Rule of 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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DEFINITIONS

Term	Definition
Applicable or Relevant and Appropriate Requirements (ARARs)	"Applicable" requirements are those clean-up standards, 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.
Exposure Pathway	The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also would be indicated.
Exposure Point	A location of potential contact between an organism and a chemical or physical agent.
Exposure Route	The way a chemical or physical agent comes in contact with an organism (i.e., by ingestion, inhalation, dermal contact).
Final Remediation Levels	Chemical-specific clean-up levels that are documented in the Record of Decision (ROD). They may differ from preliminary remediation goals (PRGs) because of modifications resulting from consideration of various uncertainties, technical and exposure factors, and all nine selection-of-remedy criteria outlined in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP).
Long-term Risks	Risks that remain after remedy implementation is complete (i.e., residual risks).
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 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).

DEFINITIONS (Continued)

Term	Definition
Remedial Alternative	An action considered in the feasibility study intended to reduce or eliminate significant risks to human health and/or the environment at a site. A range of remedial alternatives are considered in detail by the FS while the selection of a specific remedial alternative over others is documented in the ROD.
Remedial Action	The selected alternative that is documented in the ROD.
Risk-based Concentrations	Concentration levels for individual chemicals that correspond to a specific cancer risk level (e.g., 10^{-6}, 10^{-4}) or hazard quotient (HQ) or hazard index (HI) (e.g., less than or equal to 1). They are generally selected as preliminary or final remediation goals when ARARs are not available.
Short-term Risks	Risks that occur during implementation of a remedial alternative. Some "short-term" risks can occur over a period of many years (e.g., risk associated with air stripper emissions).

ACRONYMS/ABBREVIATIONS

Acronym/ Abbreviation	Definition
ACGIH	American Conference of Governmental Industrial Hygienists
AIC	Acute Inhalation Criteria
APCD	Air Pollution Control Device
ARARs	Applicable or Relevant and Appropriate Requirements
ATSDR	Agency for Toxic Substances and Disease Registry
CEGL	Continuous Exposure Guidance Level
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
ECAO	Environmental Criteria and Assessment Office
EEGL	Emergency Exposure Guidance Level
EPA	U.S. Environmental Protection Agency
HEAST	Health Effects Assessment Summary Tables
HHEM	Human Health Evaluation Manual
HI	Hazard Index
HQ	Hazard Quotient
IDLH	Immediately Dangerous to Life and Health
IRIS	Integrated Risk Information System
LOAEL	Lowest-observed-adverse-effect-level
MCL	Maximum Contaminant Level
MRL	Minimal Risk Level
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NIOSH	National Institute for Occupational Safety and Health
NOAEL	No-observed-adverse-effect-level
NRC	National Research Council

ACRONYMS/ABBREVIATIONS (Continued)

Acronym/ Abbreviation	Definition
ORD	Office of Research and Development
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Level
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
PRG	Preliminary Remediation Goal
QA/QC	Quality Assurance/Quality Control
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Level
RfC	Reference Concentration
RfD	Reference Dose
RI/FS	Remedial Investigation/Feasibility Study
RME	Reasonable Maximum Exposure
ROD	Record of Decision
RPM	Remedial Project Manager
RQ	Reportable Quantity
RREL	Risk Reduction Engineering Laboratory
SARA	Superfund Amendments and Reauthorization Act
SPEGL	Short-term Public Emergency Guidance Level
TLV-C	Threshold Limit Values - Ceiling
TLV-STEL	Threshold Limit Values - Short-term Exposure Limit
TLV-TWA	Threshold Limit Values - Time-weighted Average
TSC	Superfund Health Risk Technical Support Center

ACRONYMS/ABBREVIATIONS (Continued)

Acronym/ Abbreviation	Definition
TSCA	Toxic Substances Control Act
VOCs	Volatile Organic Compounds

ACKNOWLEDGEMENTS

This manual was developed by the Toxics Integration Branch (TIB) of EPA's Office of Emergency and Remedial Response, Hazardous Site Evaluation Division. A large number of EPA regional and headquarters managers and technical staff (see below) provided valuable input regarding the organization, content, and policy implications of the manual throughout its development.

ICF Incorporated provided technical assistance to EPA in the development of this manual, under Contract Nos. 68-01-7389, 68-W8-0098, and 68-03-3452. S. Cohen and Associates (SC&A) provided assistance in the development of Appendix D, under EPA Contract No. 68-D9-0170.

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PREFACE

Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (RAGS/HHEM) Part C is one of a three-part series. Part A addresses the baseline risk assessment; Part B addresses the development of risk-based preliminary remediation goals. Part C provides guidance on the human health risk evaluations of remedial alternatives that are conducted during the feasibility study, during selection and documentation of a remedy, and during and after remedy implementation. Part C provides general guidance to assist in site-specific risk evaluations and to maintain flexibility in the analysis and decision-making process. This guidance does not discuss the evaluation of ecological effects that takes place during remedy selection and implementation, nor does it discuss the risk management decisions that are necessary at a CERCLA site (e.g., selection of final remediation goals). The potential users of Part C are persons involved in the remedy selection and implementation process, including risk assessors, risk assessment reviewers, remedial project managers, and other decision-makers.

This manual is being distributed as an interim document to allow for a period of field testing and review. RAGS/HHEM will be revised in the future, and Parts A, B, and C will be incorporated into a single final guidance document. Additional information for specific subject areas is being developed for inclusion in a later revision. These areas include:

- development of short-term inhalation toxicity values;
- short-term worker health and safety issues; and
- determination of attainment of final remediation goals.

Comments addressing usefulness, changes, and additional areas where guidance is needed should be sent to:

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