

**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 |

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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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