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Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals)

Interim

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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.
Cancer Risk	Incremental probability of an individual's developing cancer over a lifetime as a result of exposure to a potential carcinogen.
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".
Exposure Parameters	Variables used in the calculation of intake (e.g., exposure duration, inhalation rate, average body weight).
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, as well as all nine selection-of-remedy criteria outlined in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP).

DEFINITIONS (Continued)

Term	Definition
Hazard Index (HI)	The sum of two or more hazard quotients for multiple substances and/or multiple exposure pathways.
Hazard Quotient (HQ)	The ratio of a single substance exposure level over a specified time period to a reference dose for that substance derived from a similar exposure period.
"Limiting" Chemical(s)	Chemical(s) that are the last to be removed (or treated) from a medium by a given technology. In theory, the cumulative residual risk for a medium may approximately equal the risk associated with the limiting chemical(s).
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).
Quantitation Limit (QL)	The lowest level at which a chemical can be accurately and reproducibly quantitated. Usually equal to the method detection limit multiplied by a factor of three to five, but varies for different chemicals and different samples.
Reference Dose (RfD)	The Agency's preferred toxicity value for evaluating potential noncarcinogenic effects in humans resulting from contaminant exposures at CERCLA sites. (See RAGS/HHEM Part A for a discussion of different kinds of reference doses and reference concentrations.)
Risk-based PRGs	Concentration levels set at scoping for individual chemicals that correspond to a specific cancer risk level of 10^{-6} or an HQ/HI of 1. They are generally selected when ARARs are not available.
Slope Factor (SF)	A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual's developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.
Target Risk	A value that is combined with exposure and toxicity information to calculate a risk-based concentration (e.g., PRG). For carcinogenic effects, the target risk is a cancer risk of 10^{-6}. For noncarcinogenic effects, the target risk is a hazard quotient of 1.

ACRONYMS/ABBREVIATIONS

Acronym/ Abbreviation	Definition
ARARs	Applicable or Relevant and Appropriate Requirements
CAA	Clean Air Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CWA	Clean Water Act
EAG	Exposure Assessment Group
ECAO	Environmental Criteria and Assessment Office Superfund Health Risk Technical Support Center
EF	Exposure Frequency
EPA	U.S. Environmental Protection Agency
FWQC	Federal Water Quality Criteria
HEAST	Health Effects Assessment Summary Tables
HHEM	Human Health Evaluation Manual
HI	Hazard Index
HQ	Hazard Quotient
HRS	Hazard Ranking System
IRIS	Integrated Risk Information System
LLW	Low-level Radioactive Waste
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NPL	National Priorities List
OSWER	Office of Solid Waste and Emergency Response
OERR	Office of Emergency and Remedial Response

ACRONYMS/ABBREVIATIONS (Continued)

Acronyms/ Abbreviation	Definition
PA/SI	Preliminary Assessment/Site Inspection
PEF	Particulate Emission Factor
PRG	Preliminary Remediation Goal
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
RfC	Reference Concentration
RfD	Reference Dose
RI/FS	Remedial Investigation/Feasibility Study
RME	Reasonable Maximum Exposure
ROD	Record of Decision
RPM	Remedial Project Manager
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act
SF	Slope Factor
TR	Target Risk
VF	Volatilization Factor
WQS	State Water Quality Standards

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- Office of General Counsel; and
- Exposure Assessment Group, Office of Research and Development.

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PREFACE

Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (RAGS/HHEM) Part B is one of a three-part series. Part A addresses the baseline risk assessment; Part C addresses human health risk evaluations of remedial alternatives. Part B provides guidance on using U.S. Environmental Protection Agency (EPA) toxicity values and exposure information to derive risk-based preliminary remedial goals (PRGs) for a Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) site. Initially developed at the scoping phase using readily available information, risk-based PRGs generally are modified based on site-specific data gathered during the remedial investigation/feasibility study (RI/FS). This guidance does not discuss the risk management decisions that are necessary at a CERCLA site (e.g., selection of final remediation goals). The potential users of Part B are those 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 goals for additional land uses and exposure pathways;
- development of short-term goals;
- additional worker health and safety issues; and
- determination of final remediation goals (and attainment).

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

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