United States Environmental Protection Agency | Office of Solid Waste and Emergency Response Washington, D.C. 20460 | Publication 9285.7-01CFS December 1991

EPA

Risk Assessment Guidance for Superfund: Volume I -- Human Health Evaluation Manual (Part C)

Office of Emergency and Remedial Response
Hazardous Site Evaluation Division, OS-230

Quick Reference Fact Sheet

The overarching mandate of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) program is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances. To help meet this mandate, the U.S. Environmental Protection Agency's (EPA's) Office of Emergency and Remedial Response (OERR) has developed a human health evaluation process as part of its remedial response program. EPA's *Human Health Evaluation Manual,* which describes the process of gathering information and assessing the risk to human health, and the *Environmental Evaluation Manual* comprise a two-volume set (Volumes I and II, respectively) called *Risk Assessment Guidance for Superfund* (RAGS). RAGS replaces two previous EPA guidance documents: the *Superfund Public Health Evaluation Manual* (SPHEM; 1986) and the *Draft Endangerment Assessment Handbook* (1985).

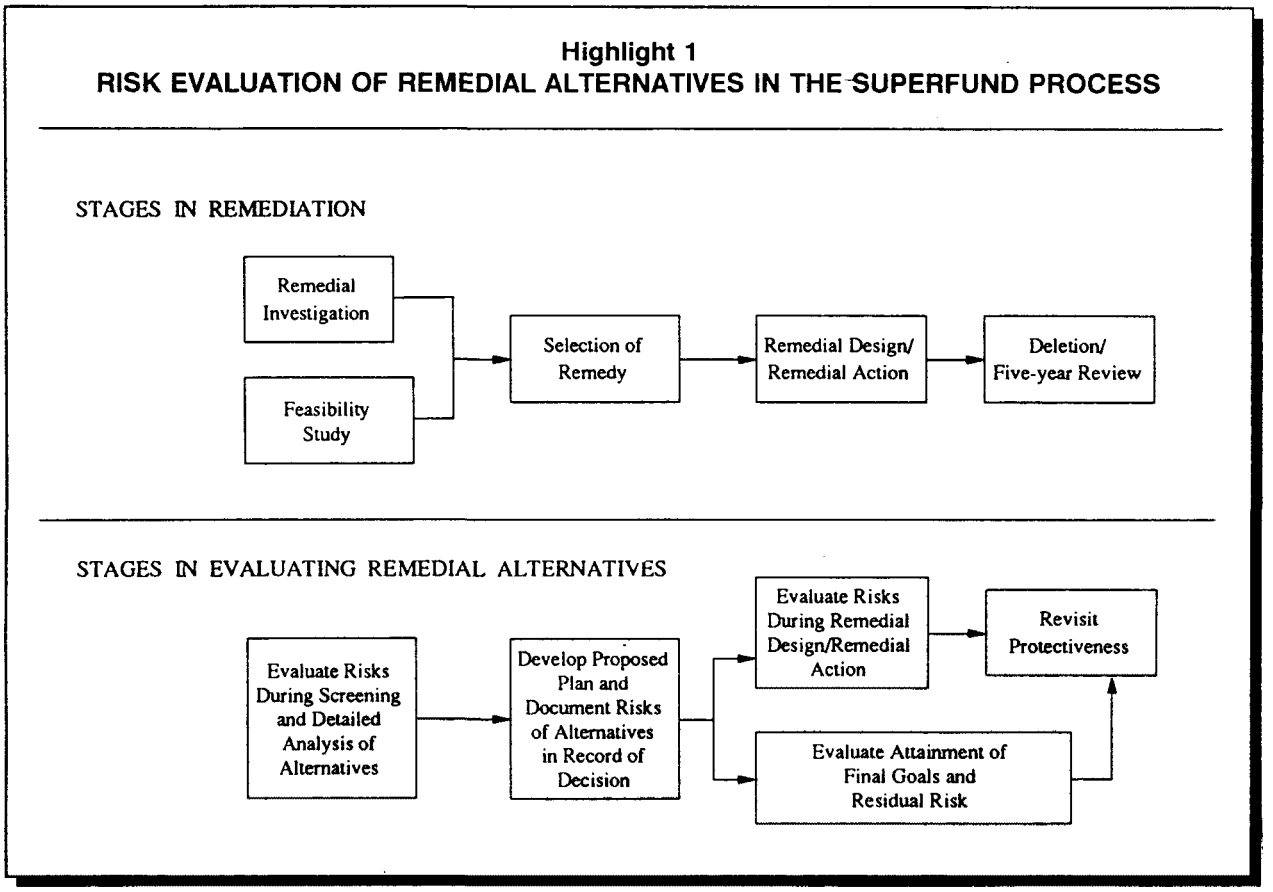
The *Human Health Evaluation Manual* (HHEM) has three main parts: *Part A*, which discusses the baseline risk assessment; *Part B, Development of Risk-based Preliminary Remediation Goals*; and *Part C, Risk Evaluation of Remedial Alternatives*. Because Part A contains detailed guidance on risk assessment activities such as data evaluation, exposure assessment, toxicity assessment, and risk characterization, it is necessary background for many of the evaluations discussed in Parts B and C. This fact sheet is designed to introduce remedial project managers (RPMs) and other personnel to the risk evaluation of remedial alternatives and to the information that is available in RAGS/HHEM Part C. RPMs should ensure that these procedures are used whenever considering human health risks of remedial alternatives.

OVERVIEW OF PART C: EVALUATING RISKS OF REMEDIAL ALTERNATIVES

Part C assists RPMs, risk assessors, site engineers, and others in using human health risk information to evaluate remedial alternatives. Part C discusses how to evaluate the long-term risks (i.e., residual risks) and short-term risks (i.e., risks during remedy implementation) associated with remedial alternatives. It also provides appendices with more detailed information about the types of releases expected from remedial technologies and about short-term toxicity values. Some consideration of risk is inherent during the remedial investigation/ feasibility study (RI/FS) and during activities that follow the RI/FS, including development of the proposed plan and record of decision (ROD), remedial design, remedy implementation, and five-year review. Risk evaluation of remedial alternatives is part of the overall FS process, as described in *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988). **Highlight 1** illustrates the relationship between the CERCLA process and the risk evaluations of remedial alternatives; **Highlight 2** summarizes the risk evaluations of remedial alternatives that take place.

The level of effort for risk evaluations of remedial alternatives is typically lower than for the baseline risk assessment and depends primarily on the site-specific questions that must be answered to select and implement a remedy that will be protective of human health. For many sites, a qualitative evaluation of the risks associated with remedial alternatives will be appropriate. For other sites, a more quantitative evaluation of risks may be needed. For example, if the relative residual risk associated with each remedial alternative (e.g., 10^{-6}, 10^{-5}, 10^{-4}) is an important factor in selecting an alternative, a more detailed evaluation of long-term risks may be needed. If the releases

Highlight 1
RISK EVALUATION OF REMEDIAL ALTERNATIVES IN THE SUPERFUND PROCESS



associated with implementation of a remedial alternative are not well-characterized or if residential populations are located nearby, a more detailed evaluation of short-term risks may be needed. **Highlight 3** lists additional factors to consider when determining the appropriate level of effort. Part C contains two case study examples that illustrate a qualitative and a quantitative risk evaluation of remedial alternatives.

EVALUATING LONG-TERM RISKS

What are long-term risks?

Long-term risks are those risks that remain after a remedial action is completed. Evaluating long-term risks involves considering the residual risk associated with an alternative and the ability of the alternative to maintain protection over time.

How are long-term risks evaluated?

The evaluation of residual risk typically involves a comparison of the concentrations a remedy has attained or is predicted to attain in an environmental medium with concentrations deemed by EPA to be protective of human health. In addition to this comparison, the ability of a remedy to maintain protection over time should be evaluated for alternatives that involve engineering or institutional controls. Failure of such controls could result in increased long-term risks, and therefore the likelihood of remedy failure and the magnitude of risks resulting from such a failure should be considered.

When are long-term risks evaluated?

Long-term risks should be evaluated at several points in the CERCLA process, including the:

- FS (screening and detailed analysis);
- proposed plan and ROD;
- remedial design;
- remedy implementation; and
- five-year reviews.

Most of the long-term risk evaluation will be conducted during the detailed analysis of the FS; however, additional information (e.g., treatability studies) may become available later and the evaluations performed during the FS may be revised. The long-term risks then must be documented in the ROD. During remedy

Highlight 2
SUMMARY OF RISK EVALUATIONS OF REMEDIAL ALTERNATIVES

STAGE	LEVEL OF EFFORT[a]		PRIMARY PURPOSE OF RISK EVALUATION[b]	
	Short-term Risk[c]	Long-term Risk	Short-term Risk[c]	Long-term Risk
Screening of Alternatives (Section 2.1)	Qualitative	Qualitative	Identify (and eliminate from consideration) alternatives with clearly unacceptable short-term risks.	Identify (and eliminate from consideration) alternatives with clearly unacceptable long-term risks.
Detailed Analysis of Alternatives (Section 2.2)	Qualitative or Quantitative[d]	Qualitative or Quantitative[d]	Evaluate short-term risks of each alternative to community and on-site remediation workers during implementation so that these risks can be compared among alternatives.	Evaluate long-term (residual) risk of each alternative and its ability to provide continued protection over time so that these risks can be compared among alternatives.
Proposed Plan (Section 3.1)	Qualitative or Quantitative[d]	Qualitative or Quantitative[d]	Refine previous analyses, as needed, based on newly developed information.	Refine previous analyses, as needed, based on newly developed information.
Record of Decision (Section 3.2)	Qualitative or Quantitative[d]	Qualitative or Quantitative[d]	Document short-term risks that may occur during remedy implementation.	Document risks that may remain after completion of remedy and determine need for five-year reviews.
Remedial Design (Section 3.3)	Qualitative or Quantitative[d]	Qualitative or Quantitative[d]	Refine previous analyses, as needed, and identify need for engineering controls or other measures to mitigate risks.	Refine previous analyses, as needed, and identify need for engineering controls or other measures to mitigate risks.
Remedial Action (Section 3.3)	Quantitative	Quantitative	Ensure protection of workers and community by monitoring emissions or exposure concentrations, as needed.	Evaluate whether remediation levels specified in ROD have been attained and evaluate residual risk after completion of remedy to ensure protectiveness.
Five-year Review (Section 3.4)	Generally not applicable	Quantitative	Generally not applicable.	Confirm that remedy (including any engineering or institutional controls) remains operational and functional and evaluate whether clean-up standards are still protective.

[a] Level of effort (i.e., qualitative or quantitative) refers only to the level of risk evaluation that is generally expected. Levels other than those presented here, or combinations of levels, are possible. See Part C and Highlight 3 of this fact sheet for additional discussion on level of effort.

[b] Purpose presented in this exhibit for each stage is only the primary purpose; other purposes may exist. See Part C for additional information.

[c] Short-term risk refers to risks that occur during remedy implementation.

[d] See Highlight 3 risk considerations for deciding whether a qualitative or quantitative risk evaluation is needed for these stages.

Highlight 3
FACTORS TO CONSIDER WHEN DECIDING WHETHER QUANTITATIVE RISK EVALUATION IS NEEDED

The decision of whether to conduct a quantitative or qualitative risk evaluation depends on (1) whether the relative short-term or long-term effectiveness of alternatives is an important consideration in selecting an alternative and (2) the "perceived risk" associated with the alternative. The perceived risk includes both the professional judgment of the site engineers and risk assessors and the concerns of neighboring communities. Some factors that generally lead to a higher perceived risk are as follows:

- close proximity of populations;
- use of an onsite incinerator;
- presence of highly or acutely toxic chemicals;
- technologies with high release potential, either planned or "accidental";
- high uncertainties in the nature of releases (e.g., amount or identity of contaminants released) such as might exist with use of certain innovative technologies;
- multiple contaminants and/or exposure pathways affecting the same individuals;
- multiple releases occurring simultaneously (e.g., from technologies operating in close proximity);
- multiple releases occurring from remedial actions at several operable units in close proximity; and
- releases occurring over long periods of time.

If consideration of these (or other) factors leads to a high perceived risk for an alternative, a more quantitative evaluation, including emission modeling and/or detailed treatability studies, may be helpful in the decision-making process. For example, if one alternative considered for a site involves extensive excavation in an area that is very close to residential populations, then a more quantitative evaluation of short-term risks may be needed to evaluate this alternative.

implementation, evaluation of long-term risks involves assessing attainment of the remediation goals. During five-year reviews, evaluation of long-term risks ensures that the remedy remains protective of human health.

EVALUATING SHORT-TERM RISKS

What are short-term risks?

The short-term risks associated with a remedial alternative are those risks that occur during implementation of the alternative. Because some remedies may take many years to complete, some "short-term" risks may actually occur over a relatively long period of time. The populations that may be subject to short-term risks are (1) people who live or work in the vicinity of the site and (2) workers who are involved in site remediation.

How are short-term risks evaluated?

Evaluating short-term risks involves the same basic steps as the baseline risk assessment: exposure assessment, toxicity assessment, and risk characterization. These steps generally are conducted in a less quantitative manner than for the baseline risk assessment, however. **Highlight 4** provides a summary of some of the differences between the baseline risk assessment and the assessment of short-term risks of remedial alternatives. Part C discusses both qualitative and quantitative evaluation of these short-term risks.

When are short-term risks evaluated?

Short-term risks should be evaluated at several times during the selection and implementation of a remedial alternative, including:

- FS (screening and detailed analysis);
- proposed plan and ROD;
- remedial design; and
- remedy implementation.

Because the short-term risks associated with a remedial alternative are a consideration in selecting an alternative, most of the analysis of short-term risks should be conducted during the FS, and the risks associated with the selected alternative should be documented in the ROD.

During design of the remedy, previous risk evaluations may be refined, as needed, and engineering controls or other measures to mitigate

Highlight 4
BASELINE RISK ASSESSMENT AND RISK EVALUATION OF REMEDIAL ALTERNATIVES

A risk evaluation of remedial alternatives follows the same general steps as a baseline risk assessment. Detailed guidance on each step is provided in RAGS/HHEM Part A, which must be reviewed and understood by the risk assessor before a risk evaluation of remedial alternatives is conducted. Note, however, that the baseline risk assessment typically is more quantitative and requires a higher level of effort than the risk evaluation of remedial alternatives. Other differences (and similarities) are listed below.

Evaluate Exposure (Part A -- Chapter 6)

- The source of releases for the baseline risk assessment is untreated site contamination, while the source of releases for the evaluation of remedial alternatives is the remedial action itself (plus any remaining waste).
- Exposure pathways associated with implementation of remediation technologies may include some pathways and populations that were not present (or of concern) under baseline conditions.
- The evaluation of short-term exposures associated with remedial alternatives may consider a number of different releases that occur over varying durations.

Evaluate Toxicity (Part A -- Chapter 7)

- The risk evaluation of remedial alternatives often involves less-than-lifetime exposures that require appropriate short-term toxicity values to characterize risk or hazard.
- The risk evaluation of remedial alternatives may include an analysis of chemicals that were not present under baseline conditions (i.e., created as a result of the remedial action).

Characterize Risks (Part A -- Chapter 8)

- A risk evaluation of remedial alternatives generally considers risks to on-site workers, as well as risks to the surrounding community.
- Additional uncertainties (e.g., predicting releases from remediation technologies) exist.

risks may be identified. If potential risks to the community are a concern or there is high uncertainty regarding these predicted risks, a strategy to monitor exposure concentrations during remedy implementation should be developed.

USING PART C APPENDICES

Part C includes four appendices that contain useful information for evaluating the risks associated with remedial alternatives.

Appendix A: Selected Remediation Technologies and Associated Potential Releases. Appendix A contains two exhibits designed to assist in identifying some of the potential releases that are associated with commonly used remedial technologies. Exhibit A-1 describes each process option for the technologies included in Exhibit A-2. Exhibit A-2 summarizes the releases to air and water and the treatment residuals associated with common remediation technologies.

Appendix B: Quantifying Potential Releases from Selected Remediation Technologies. Appendix B provides more detailed descriptions of the releases associated with several common remediation activities and examples of the considerations involved in quantifying technology-specific releases. It also contains lists of references that provide information on quantifying releases for soils handling, thermal destruction, and stabilization/solidification technologies, as well as references that pertain to a variety of remediation technologies.

Appendix C: Short-term Toxicity Values. Appendix C provides general background on exposure duration, a summary of existing short-term human health toxicity values, and information on where to obtain short-term toxicity values. Short-term toxicity values have been developed by a number of agencies and programs, and some of these values are not appropriate for use in characterizing risks associated with remedial alternatives. Therefore, EPA staff must call the Superfund Health Risk Technical Support Center (TSC) at FTS 684-7300 (513/569-7300) whenever short-term risks are to be characterized. The TSC will maintain an up-to-date database for these toxicity values.

Appendix D: Radiation Remediation Technologies. Appendix D contains two exhibits designed to assist in the process of using risk information to evaluate remediation technologies for sites

contaminated with radioactive substances. Exhibit D-1 summarizes the potential releases of radioactivity associated with a number of remediation technologies. Exhibit D-2 presents a qualitative estimate of the potential short-term and long-term risks associated with selected radiation remediation technologies.

RPM INVOLVEMENT

The RPM needs to have a comprehensive understanding of the risk evaluation of remedial alternatives in order to make decisions for risk management purposes. Part C includes a list of questions for RPMs on risks of remedial alternatives (presented in **Highlight 5**) and guidance on documenting the risk evaluations of remedial alternatives at appropriate points in the CERCLA process.

Highlight 5
QUESTIONS RPMs SHOULD ASK ABOUT THE RISKS OF REMEDIAL ALTERNATIVES

- Which alternatives will clearly not address the significant human exposure pathways identified in the baseline risk assessment?
- Which technologies can readily achieve PRGs in a given medium? What uncertainties are associated with this determination?
- Are the expected residual risks from one alternative significantly different from another?
- What other risk-based benefits are there in selecting one alternative over another?
- Will implementation of specific technologies create significant exposures or risks for the surrounding community?
- Is there a need for engineering controls or other measures to mitigate risks? Are such controls available, and what is their reliability?
- Does the remedial action result in hazardous substances remaining at the site such that five-year reviews are required?

NEED MORE HELP?

Regional Toxics Integration Coordinators

Regional Toxics Integration Coordinators (**Highlight 6**) can provide additional information concerning the risk evaluations of remedial alternatives.

Superfund Health Risk Technical Support Center

Regional EPA CERCLA staff must contact the Superfund Health Risk Technical Support Center of the Environmental Criteria and Assessment Office (ECAO) at FTS 684-7300 (513/569-7300) for guidance on short-term toxicity criteria. Requests for information from other users must be submitted in writing to the TSC and provide:

- CERCLA site name, site location, and 12-digit site number;
- name and phone number of the site RPM; and
- detailed description of the risk assessment related question.

Risk Reduction Engineering Laboratory

Risk Reduction Engineering Laboratory (RREL; Cincinnati, Ohio) personnel can provide site-specific technical services involving a variety of treatment technologies and Superfund response processes. Regional EPA CERCLA staff should direct questions regarding evaluations of and previous experience with remediation technologies and releases associated with remediation technologies to the Engineering and Treatment Technical Support Center at FTS 684-7406 (513/569-7406).

Where to Obtain Copies

EPA staff can obtain copies of Part C or additional copies of this fact sheet by calling EPA's Center for Environmental Research Information at FTS 684-7562 (513/569-7652). Others can obtain copies by contacting NTIS at 800/336-4700 (703/487-4650 in the Washington, DC area).

Highlight 6
SUPERFUND REGIONAL TOXICS INTEGRATION COORDINATORS

EPA Region	Toxics Integration Coordinator	Telephone
1	Sarah Levinson John F. Kennedy Federal Bldg. Boston, MA 02203	FTS 833-1504 617/223-5504
2	Peter Grevatt 26 Federal Plaza New York, NY 10278	FTS 264-6323 212/264-6323
3	Dr. Richard Brunker 841 Chestnut Street Philadelphia, PA 19107	FTS 597-0804 215/597-0804
4	Dr. Elmer Akin 345 Courtland Street, NE Atlanta, GA 30365	FTS 257-1586 404/347-1586
5	Erin Moran 230 S. Dearborn Street Chicago, IL 60604	FTS 353-1420 312/353-1420
6	Jon Rauscher First Interstate Bank Tower 1445 Ross Avenue Dallas, TX 75202	FTS 255-2198 214/655-2198
7	Dave Crawford 726 Minnesota Avenue Kansas City, KS 66101	FTS 276-7702 913/551-7702
8	Chris Weis 999 18th Street, Suite 500 Denver, CO 80202	FTS 330-7655 303/294-7655
9	Dan Stralka 75 Hawthorne Street San Francisco, CA 94105	FTS 484-2310 415/744-2310
10	Pat Cirone 1200 6th Avenue Seattle, WA 98101	FTS 399-1597 206/553-1597