CHAPTER 1

INTRODUCTION

This guidance has been developed by the U.S. Environmental Protection Agency (EPA) to assist remedial project managers (RPMs), risk assessors, site engineers, and others in using risk information at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites to both evaluate remedial alternatives during the feasibility study (FS) and to evaluate the human health risk associated with the selected remedial alternative during and after its implementation. Part C provides general guidance to assist in site-specific risk evaluations and to maintain flexibility in the decision-making process.

Risk assessment is one of many tools that RPMs use in selecting the best remedy for a site. Other important tools (not addressed in this guidance) involve the assessments of technical feasibility, applicable or relevant and appropriate requirements (ARARs), cost, and implementability.

This guidance is the third part (Part C) in the series *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual* (RAGS/HHEM). Part A of this guidance (EPA 1989g) describes how to conduct a site-specific baseline risk assessment; the information in Part A is necessary background for Part C. Part B (EPA 1991c) provides guidance for calculating risk-based concentrations that may be used, along with ARARs and other information, to develop preliminary remediation goals (PRGs) during project scoping. PRGs (and final remediation levels set in the Record of Decision [ROD]) can be used throughout the analyses in Part C to assist in evaluating the human health risks of remedial alternatives. Exhibit 1-1 illustrates the major correspondence of RAGS/HHEM activities with the steps in the CERCLA remedial process.

The steps for conducting a risk evaluation of remedial alternatives are discussed in general terms in Chapters 2 and 3; more detailed guidance for conducting short-term evaluations is provided in Appendices A through D. (See the box in the next column for a description of how the terms short-term risk and long-term risk differ in this guidance.) The remainder of this chapter:

SHORT-TERM RISK VS. LONG-TERM RISK

For the purposes of this guidance, short-term risks are those 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). In contrast, long-term risks are those that remain after remedy implementation is complete (i.e., residual risks).

- presents the scope and an overview of Part C;
- discusses the statutes, regulations, and guidance relevant to the evaluation of remedial alternatives;
- describes appropriate levels of effort for risk evaluations of remedial alternatives;
- discusses the importance of risk communication;
- addresses the role of the RPM and the need for documentation; and
- presents the organization of the remainder of this document.

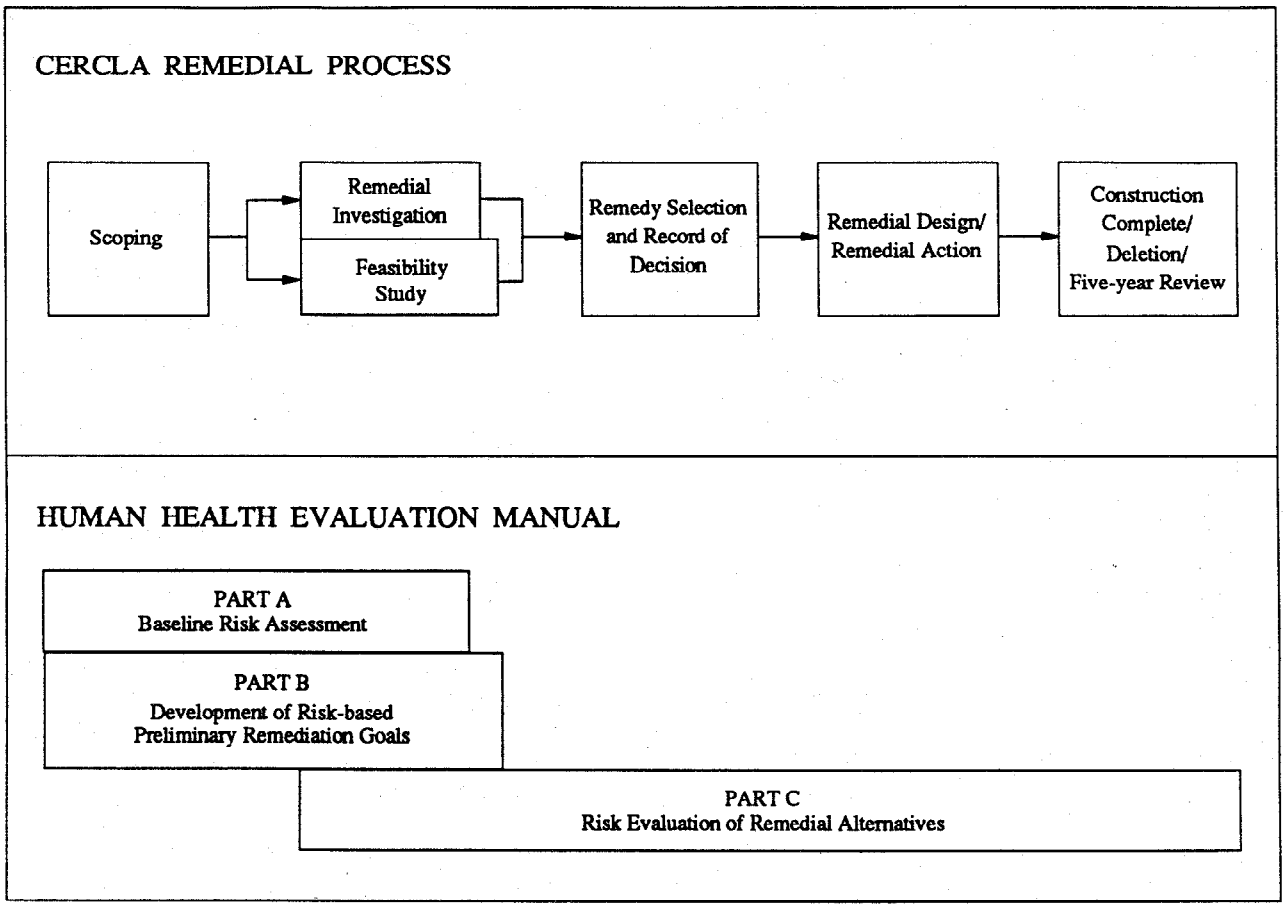
1.1 SCOPE AND OVERVIEW OF PART C

1.1.1 SCOPE

As discussed in Section 1.2 below, some of the nine criteria that are described in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) and that are used to evaluate remedial alternatives during the remedial investigation/feasibility study (RI/FS), involve a direct use of risk-related information. Several aspects of these criteria (e.g., short-term risks to workers and

EXHIBIT 1-1

RELATIONSHIP OF HUMAN HEALTH EVALUATION TO THE CERCLA PROCESS



surrounding community, long-term effectiveness) are discussed in detail in this guidance. Other criteria that do not directly involve health risk (e.g., implementability, cost) — with the exception of community acceptance — are mentioned briefly but are not discussed in detail.

Remedial alternatives, in addition to being evaluated for the degree to which they protect human health, are evaluated for their potential to protect ecological receptors. RAGS/HHEM Part C does not address ecological risk assessment (see the next box). However, ecological guidance specific to evaluating remedial alternatives in the CERCLA program will be developed following finalization of Agency guidance on ecological risk assessment.

EVALUATING ECOLOGICAL EFFECTS OF REMEDIAL ALTERNATIVES

Remedial actions, by their nature, can alter or destroy aquatic and terrestrial habitat. This potential for destruction or alteration of habitat and subsequent consequences must be evaluated so that it can be considered during the selection of a remedial alternative and during its implementation.

This document does not address the evaluation of ecological risks. Future guidance for ecological evaluations is planned, however. At present, ecological evaluations should be based on the best professional judgment of experienced ecologists and/or aquatic or environmental toxicologists.

The guidance in this document applies to sites contaminated with non-radioactive hazardous substances and those contaminated with radionuclides. Appendix D provides additional guidance specific to radionuclide sites.

Note that this guidance is limited to the use of risk assessment in evaluating remedial alternatives. Part C does not provide guidance on the risk management decisions that must be made when evaluating alternatives and selecting a remedy (e.g., balancing of the nine NCP criteria, selection of final remediation goals and levels) or engineering judgments that affect the evaluation of alternatives (e.g., determining whether an alternative is likely to achieve remediation goals). These issues are addressed in other guidance or in guidance that currently is being developed.

1.1.2 OVERVIEW

The process of evaluating remedial alternatives begins in the development and screening stage of the FS and extends into the detailed analysis stage. The major goal for the risk evaluation during these steps is to provide decision-makers with specific information that they may need in choosing among alternatives. Additional risk evaluations may need to be conducted during the proposed plan, during the design and implementation of the remedy, and after the remedy is complete (e.g., during "five-year reviews"). These activities are discussed below and throughout this guidance.

Exhibit 1-2 summarizes the levels of effort and purposes of the risk evaluations of remedial alternatives, while Exhibit 1-3 illustrates when these activities take place within the context of the CERCLA remedial process.

Identification and Screening of Technologies and Alternatives. During this stage, a range of remedial alternatives is identified, if necessary, and each alternative is evaluated with respect to effectiveness, implementability, and cost. This process may consist of two steps: (1) identification and screening of technologies and (2) development and screening of alternatives. These steps are often combined into a single step (as reflected in this guidance). Those alternatives that are clearly unfavorable relative to other alternatives in terms of effectiveness (e.g., very high perceived risk) or implementability, or that are grossly excessive in cost are dropped from consideration after this screening. Part of the evaluation of effectiveness involves human health risk (e.g., risks to the community and remediation workers), and Chapter 2 of this document provides guidance on evaluating these factors. RAGS/HHEM Part C does not discuss evaluating factors such as implementability and cost.

Detailed Analysis of Alternatives. During the detailed analysis stage, alternatives are evaluated according to each of the nine NCP evaluation criteria, and then are compared to each other. Both long-term effectiveness (i.e., residual risk) and short-term effectiveness (i.e., risk to the community and remediation workers during remedy implementation) are evaluated during the detailed analysis. Chapter 2 and Appendices A

EXHIBIT 1-2

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 the main text of this document for additional discussion on level of effort.

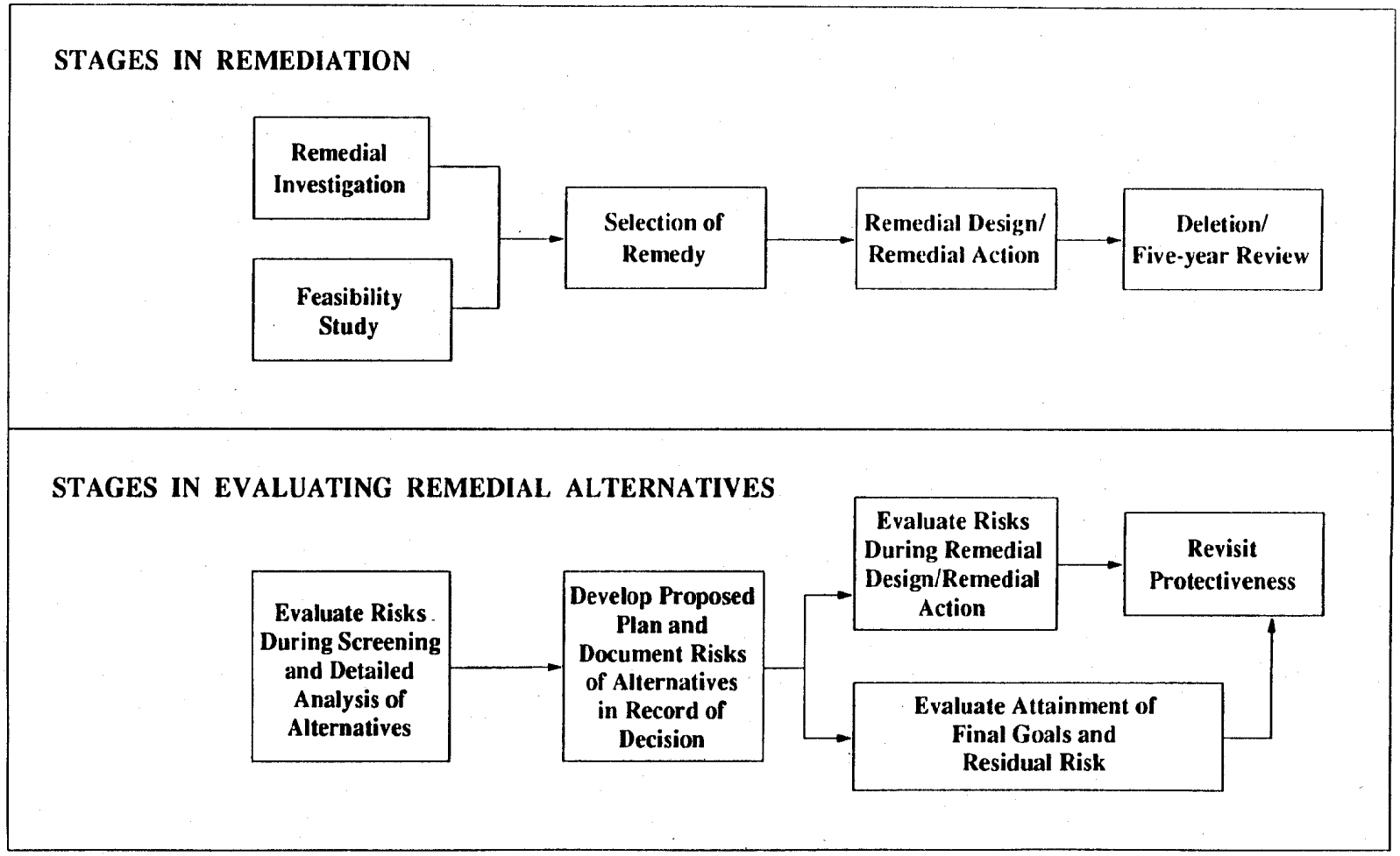
[b] Purpose presented in this exhibit for each stage is only the primary purpose; other purposes may exist. See the main text of this document for additional information.

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

[d] Text box in Section 2.2 lists considerations for deciding whether a qualitative or quantitative risk evaluation is needed for these stages.

EXHIBIT 1-3

RISK EVALUATION OF REMEDIAL ALTERNATIVES IN THE CERCLA PROCESS



through D of this document provide guidance on the evaluation of the risk-related aspects of long-term effectiveness (residual risk and permanence), and short-term effectiveness. (As with the screening of alternatives, Chapter 2 generally does not discuss evaluation of the other criteria, which do not directly involve human health risk considerations.) The resulting risk information is incorporated into the overall detailed analysis process described in the *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (RI/FS Guidance; EPA 1988c).

Proposed Plan and ROD. Risk evaluations are generally conducted during the development of the proposed plan and ROD only when new information concerning risks of the remedial alternatives is generated. Chapter 3 provides guidance on the evaluation of risks for the proposed plan and ROD stage.

Remedial Design/Remedial Action (RD/RA). Risk-related evaluations may also be conducted for some sites during implementation of the selected remedy. These activities, discussed briefly in Chapter 3, include: (1) refining risk evaluations as necessary when designing the remedy; (2) monitoring potential short-term health impacts on the community and workers; (3) assessing attainment of final remediation levels selected in the ROD; and (4) evaluating residual risk.

Five-year Review. Under the NCP, five-year reviews are required for sites as long as hazardous substances remain onsite above levels that allow unlimited use and unrestricted exposure, and are also conducted as a matter of policy for long-term remedial action sites even if no hazardous substances are expected to remain after completion of the action. Chapter 3 briefly addresses the consideration of risk during five-year reviews.

1.2 RELEVANT STATUTES, REGULATIONS, AND GUIDANCE

As discussed in RAGS/HHEM Part A, there is a hierarchy of requirements and guidance in CERCLA, beginning with the laws enacted by Congress, followed by the regulations, and then the guidance developed by EPA. This section addresses this hierarchy within the context of the risk evaluation of remedial alternatives.

1.2.1 CERCLA/SARA

CERCLA, commonly called Superfund, was enacted by Congress in 1980 in response to the dangers posed by sudden or otherwise uncontrolled releases of hazardous substances, pollutants, or contaminants into the environment. The Superfund Amendments and Reauthorization Act (SARA) was enacted in 1986. (All references to CERCLA in this guidance should be interpreted as "CERCLA as amended by SARA.")

Section 121 of CERCLA requires that remedies be protective of human health and the environment, satisfy ARARs, be cost-effective, and utilize permanent solutions and alternative treatment technologies to the maximum extent practicable. Section 121(c) of CERCLA requires a periodic review of remedial actions, at least every five years after initiation, for as long as hazardous substances that may pose a threat to human health or the environment remain at the site. The information in this manual provides guidance for evaluating the protectiveness of remedial alternatives at a site in terms of the human health-related aspects of these CERCLA requirements. Some considerations include protectiveness, effectiveness in terms of risk reduction, and degree of hazard for substances remaining at the site.

1.2.2 NCP

The NCP is the main set of regulations developed by EPA to implement CERCLA. The most recent NCP was published on March 8, 1990 (55 *Federal Register* 8666-8865) and is codified at 40 *Code of Federal Regulations* (CFR) Part 300. Section 300.430(e)(1) of the NCP describes a two-stage evaluation of remedial alternatives: a screening evaluation of a range of alternatives, if necessary, followed by a detailed analysis of the most promising alternatives. The NCP also describes activities that follow selection and implementation of the selected remedial alternative.

Screening. NCP section 300.430(e)(7) indicates that, if necessary and to the extent sufficient information is available, alternatives should be screened out if determined to be ineffective, not implementable, or grossly excessive in cost. Some aspects of effectiveness involve considerations of human health risk and are discussed in this guidance.

Detailed Analysis. The NCP establishes nine criteria in section 300.430(e)(9)(iii) to use in evaluating alternatives in detail and in selecting a remedy. Parts of three of these criteria — overall protection of human health and the environment, long-term effectiveness and permanence, and short-term effectiveness — directly relate to risks and therefore are the focus of this guidance. The actual selection of a remedy for any given site ultimately is based on consideration of the nine criteria. This guidance also discusses the importance of risk communication to the community as it relates to the criterion of community acceptance.

Five-year Reviews. NCP section 300.430(f)(4)(ii) provides that if a remedial alternative is selected that results in hazardous substances (or pollutants or contaminants) remaining at the site above levels that allow for unrestricted exposure and unlimited use, such remedy should be reviewed at least every five years after initiation of the selected remedial alternative.

1.2.3 OTHER RELEVANT GUIDANCE

Three CERCLA program documents are important background for the guidance presented in this document — RAGS/HHEM Parts A and B (EPA 1989g; EPA 1991c), and the RI/FS Guidance (EPA 1988c). Parts A and B provide guidance on conducting a baseline risk assessment and on developing risk-based concentrations, respectively, that should be used in evaluating remedial alternatives. The activities conducted during a risk evaluation of remedial alternatives are somewhat similar to the activities conducted during a baseline risk assessment. (Chapter 2 discusses in more detail the similarities and differences.) The RI/FS Guidance describes the major activities and analyses that are conducted during the RI/FS. See the references at the end of this document for other relevant background guidance.

1.3 LEVEL OF EFFORT

The level of effort for risk evaluations of remedial alternatives depends primarily on the site-specific questions that must be answered in order to select and implement a remedy. In addition, site-specific factors such as the complexity of the site, the number of alternatives considered for the site, the available resources, and the amount of available data may affect the level of effort. In most cases, a qualitative rather than a detailed quantitative evaluation of both long-term and short-term risks is all that is needed to select the most appropriate alternative. A quantitative risk evaluation of remedial alternatives will not need to be conducted for all sites. In all cases, the baseline risk assessment provides much of the risk-related information needed for the detailed analysis of alternatives, especially for those alternatives that involve limited or no action.

For many sites, the risk evaluations of remedial alternatives during the FS are conducted in a qualitative manner. That is, the risk evaluations during both the screening and detailed analysis stages for these sites will not be at all quantitative. At other sites, a more quantitative analysis of the long-term and/or short-term risks associated with the remedial alternatives may be needed during the detailed analysis. In these situations, the risk evaluation generally needs to incorporate more site-specific information.

A guiding principle is that the risk evaluation should be tailored to provide the RPM with specific information that he or she needs for supporting the selection or design of a remedy (e.g., the relative risks associated with alternatives, the alternatives that best meet the remediation goals). Because of the differences in information needs and available data for sites, in the complexity of sites, and in available methods, models, and resources for evaluation, all of the components of this guidance will not be applicable to all sites.

Chapter 2 provides some additional factors to consider when deciding on the level of effort to use for the risk evaluation of remedial alternatives.

1.4 IMPORTANCE OF RISK COMMUNICATION

As noted earlier, while overall protection of human health and the environment is one of the threshold criteria established by the NCP for use in evaluating alternatives and selecting a remedy, community acceptance of the remedy is a modifying criterion (NCP section 300.430(e)(9)(iii)). The CERCLA program encourages and promotes public participation during all phases of the decision-making process at CERCLA sites. Just as risk information is used by RPMs and other EPA staff to assist in evaluation of remedial alternatives during the FS and to evaluate the selected remedial alternative during and after its

implementation, risk information also will be employed by the public in their acceptance of a selected remedy. Good communication of the risks of the remedy to the public is crucial to the community's acceptance of the remedy.

There is no single procedure for good risk communication. The actual mechanism used and the messages delivered will vary from site to site and will depend upon the public, their level of concern, the complexity of the site, the contaminants of concern, and the proposed remedial alternative. RPMs are encouraged to work with the risk assessor and community relations coordinator for the site to develop the appropriate means to communicate risks from the remedial alternative or any residual risks. RPMs should consider using fact sheets, public meetings, and the release of draft documents or "risk communication" summaries as vehicles for risk communication. *Community Relations in Superfund: A Handbook* (EPA 1988a) offers guidance on planning and conducting CERCLA community relations activities.

Regardless of the vehicles chosen for risk communication, the following rules, from *Seven Cardinal Rules of Risk Communication* (EPA 1988f), should be kept in mind.

- Accept and involve the public as a legitimate partner.
- Plan carefully and evaluate your efforts.
- Listen to the public's specific concerns.
- Be honest, frank, and open.
- Coordinate and collaborate with other credible sources.
- Meet the needs of the media.
- Speak clearly and with compassion.

As provided under the NCP, risk communication, public participation, and community relations at CERCLA sites begin well before the remedy selection phase. This is important, as communities near CERCLA sites may begin with a degree of outrage that must be addressed before effective communication can begin. Community relations, public involvement, and good risk communication continue throughout the RI/FS process. A well-informed public will be better able to comment on — and provide input to — technical decisions. Establishing credibility through community relations, public participation, and effective risk communication practices early in the CERCLA process leads to greater community acceptance of the selected remedy.

1.5 MANAGEMENT AND DOCUMENTATION

One role of an RPM in the risk evaluation of remedial alternatives is to make risk management decisions. The RPM must have a comprehensive understanding of the risk evaluation in order to make these decisions. The first box on the next page provides questions that RPMs and other decision-makers should ask about the risks of remedial alternatives at their sites. The second box provides guidance on where to document the evaluations addressed in RAGS/HHEM Part C.

1.6 ORGANIZATION OF THE DOCUMENT

The remainder of this guidance is organized into two additional chapters and four appendices, as follows:

- Chapter 2: Risk Evaluation During the Feasibility Study;
- Chapter 3: Risk Evaluation After the Feasibility Study;
- Appendix A: Selected Remediation Technologies and Associated Potential Releases;
- Appendix B: Guidance for Quantifying Potential Releases from Selected Remediation Technologies;
- Appendix C: Short-term Toxicity Values; and
- Appendix D: Radiation Remediation Technologies.

In addition, several boxes, such as those below, provide useful information. A second kind of box, a "shadow" box, provides case studies. These boxes are presented at the end of Chapter 2.

QUESTIONS RPMs SHOULD ASK ABOUT HUMAN HEALTH RISKS OF REMEDIAL ALTERNATIVES

- Which technologies can readily achieve all preliminary remediation goals (PRGs) in a given medium? What uncertainties are involved in this determination?
- Which alternatives will clearly not address the significant human exposure pathways identified in the baseline risk assessment?
- Are the expected residual risks or short-term risks from one alternative significantly different from another?
- What other risk-based benefits (e.g., shorter time to achieving goals) are realized by selecting one alternative over another?
- Will implementation of specific technologies create new chemicals of concern or new significant exposures or risks for the surrounding community?
- Is there a need for engineering controls or other measures to mitigate risks during implementation? Are such controls available? How reliable are these controls?
- Does the remedial alternative result in hazardous substances remaining at the site such that a five-year review or reviews would be required?

DOCUMENTATION OF RISK EVALUATIONS

- The risk evaluation conducted during the development and screening of alternatives (Section 2.1) and during the detailed analysis of alternatives (Section 2.2) should be documented in the FS.
- The proposed plan (Section 3.1) should contain a summary of the risk evaluations for the alternatives, including any new risk information identified during development of the proposed plan.
- The ROD (Section 3.2) should contain the results of the risk evaluations of the alternatives and the preferred alternative, including any results developed since the proposed plan.
- Any significant changes identified during RD/RA (Section 3.3) in the risk evaluations should be documented (e.g., in a memorandum).
- Each five-year review (Section 3.4) should contain a statement on protectiveness and, if necessary, a recalculation of risk and/or a new risk assessment.