CHAPTER 1

INTRODUCTION

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA, or "Superfund"), establishes a national program for responding to releases of hazardous substances into the environment.[1] The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) is the regulation that implements CERCLA.[2] Among other things, the NCP establishes the overall approach for determining appropriate remedial actions at Superfund sites. The overarching mandate of the Superfund program is to protect human health and the environment from current and potential threats posed by uncontrolled hazardous substance releases, and the NCP echoes this mandate.

To help meet this Superfund mandate, EPA's Office of Emergency and Remedial Response has developed a human health evaluation process as part of its remedial response program. The process of gathering and assessing human health risk information described in this manual is adapted from well-established chemical risk assessment principles and procedures (NAS 1983; CRS 1983; OSTP 1985). It is designed to be consistent with EPA's published risk assessment guidelines (EPA 1984; EPA 1986a-e; EPA 1988a; EPA 1989a) and other Agency-wide risk assessment policy. The *Human Health Evaluation Manual* revises and replaces the *Superfund Public Health Evaluation Manual* (EPA 1986f).[3] It incorporates new information and builds on several years of Superfund program experience conducting risk assessments at hazardous waste sites. In addition, the *Human Health Evaluation Manual* together with the companion *Environmental Evaluation Manual* (EPA 1989b) replaces EPA's 1985 *Endangerment Assessment Handbook*, which should no longer be used (see Section 2.2.1).

The goal of the Superfund human health evaluation process is to provide a framework for developing the risk information necessary to assist decision-making at remedial sites. Specific objectives of the process are to:

- provide an analysis of baseline risks[4] and help determine the need for action at sites;
- provide a basis for determining levels of chemicals that can remain onsite and still be adequately protective of public health;
- provide a basis for comparing potential health impacts of various remedial alternatives; and
- provide a consistent process for evaluating and documenting public health threats at sites.

The human health evaluation process described in this manual is an integral part of the remedial response process defined by CERCLA and the NCP. The risk information generated by the human health evaluation process is designed to be used in the remedial investigation/feasibility study (RI/FS) at Superfund sites. Although risk information is fundamental to the RI/FS and to the remedial response program in general, Superfund site experience has led EPA to balance the need for information with the need to take action at sites quickly and to streamline the remedial process. Revisions proposed to the NCP in 1988 reflect EPA program management principles intended to promote the efficiency and effectiveness of the remedial response process. Chief among these principles is a bias for action. EPA's *Guidance for*

Conducting Remedial Investigations and Feasibility Studies Under CERCLA (EPA 1988b) also was revised in 1988 to incorporate management initiatives designed to streamline the RI/FS process and to make information collection activities during the RI more efficient. The *Risk Assessment Guidance for Superfund*, of which this *Human Health Evaluation Manual* is Volume I,[5] has been developed to reflect the emphasis on streamlining the remedial process. The *Human Health Evaluation Manual* is a companion document to the RI/FS guidance. It provides a basic framework for developing health risk information at Superfund sites and also gives specific guidance on appropriate methods and data to use. Users of the *Human Health Evaluation Manual* should be familiar with the RI/FS guidance, as well as with other guidances referenced throughout later chapters of this manual.

The *Human Health Evaluation Manual* is addressed primarily to the individuals actually conducting human health evaluations for sites (frequently contractors to EPA, other federal agencies, states, or potentially responsible parties). It also is targeted to EPA staff responsible for review and oversight of risk assessments (e.g., technical staff in the regions) and those responsible for ensuring an adequate evaluation of human health risks (i.e., remedial project managers, or RPMs). Although the terms risk assessor and risk assessment reviewer are used in this manual, it is emphasized that they generally refer to teams of individuals in appropriate disciplines (e.g., toxicologists, chemists, hydrologists, engineers). It is recommended that an appropriate team of scientists and engineers be assembled for the human health evaluation at each specific site. It is the responsibility of RPMs, along with the leaders of human health evaluation teams, to match the scientific support they deem appropriate with the resources at their disposal.

Individuals having different levels of scientific training and experience are likely to use the manual in designing, conducting, and reviewing human health evaluations. Because assumptions and judgments are required in many parts of the analysis, the individuals conducting the evaluation are key elements in the process. The manual is not intended to instruct non-technical personnel how to perform technical evaluations, nor to allow professionals trained in one discipline to perform the work of another.

KEY PLAYERS IN SUPERFUND SITE RISK ASSESSMENT/ RISK MANAGEMENT

Risk Assessor. The individual or team of individuals who actually organizes and analyzes site data, develops exposure and risk calculations, and prepares human health evaluation (i.e., risk assessment) reports. Risk assessors for Superfund sites frequently are contractors to EPA, other federal agencies, states, or potentially responsible parties.

Risk Assessment Reviewer. The individual or team of individuals within an EPA region who provides technical oversight and quality assurance review of human health evaluation activities.

Remedial Project Manager (RPM). The individual who manages and oversees all RI/FS activities, including the human health evaluation, for a site. The RPM is responsible for ensuring adequate evaluation of human health risks and for determining the level of resources to be committed to the human health evaluation.

Risk Manager. The individual or group of individuals who serves as primary decision-maker for a site, generally regional Superfund management in consultation with the RPM and members of the technical staff. The identity of the risk manager may differ from region to region and for sites of varying complexity.

The *Human Health Evaluation Manual* admittedly cannot address all site circumstances. Users of the manual must exercise technical and management judgment, and should consult with EPA regional risk assessment contacts and appropriate headquarters staff when encountering unusual or particularly complex technical issues.

The first three chapters of this manual provide background information to help place the human health evaluation process in the context of the Superfund remedial process. This chapter (Chapter 1) summarizes the human health evaluation process during the RI/FS. The three main parts of this process -- baseline risk assessment, refinement of

preliminary remediation goals, and remedial alternatives risk evaluation -- are described in detail in subsequent chapters. Chapter 2 discusses in a more general way the role of risk information in the overall Superfund remedial program by focusing on the statutes, regulations, and guidance relevant to the human health evaluation. Chapter 2 also identifies and contrasts Superfund studies related to the human health evaluation. Chapter 3 discusses issues related to planning for the human health evaluation.

1.1 OVERVIEW OF THE HUMAN HEALTH EVALUATION PROCESS IN THE RI/FS

Section 300.430 of the proposed revised NCP reiterates that the purpose of the remedial process is to implement remedies that reduce, control, or eliminate risks to human health and the environment. The remedial investigation and feasibility study (RI/FS) is the methodology that the Superfund program has established for characterizing the nature and extent of risks posed by uncontrolled hazardous waste sites and for developing and evaluating remedial options. The 1986 amendments to CERCLA reemphasized the original statutory mandate that remedies meet a threshold requirement to protect human health and the environment and that they be cost-effective, while adding new emphasis to the permanence of remedies. Because the RI/FS is an analytical process designed to support risk management decision-making for Superfund sites, the assessment of health and environmental risk plays an essential role in the RI/FS.

This manual provides guidance on the human health evaluation activities that are conducted during the RI/FS. The three basic parts of the RI/FS human health evaluation are:

(1) baseline risk assessment (described in Part A of this manual);

(2) refinement of preliminary remediation goals (Part B); and

(3) remedial alternatives risk evaluation (Part C).

Because these risk information activities are intertwined with the RI/FS, this section describes those activities in the context of the RI/FS process. It relates the three parts of the human health evaluation to the stages of the RI/FS, which are:

- project scoping (before the RI);
- site characterization (RI);
- establishment of remedial action objectives (FS);
- development and screening of alternatives (FS); and
- detailed analysis of alternatives (FS).

Although the RI/FS process and related risk information activities are presented in a fashion that makes the steps appear sequential and distinct, in practice the process is highly interactive. In fact, the RI and FS are conducted concurrently. Data collected in the RI influences the development of remedial alternatives in the FS, which in turn affects the data needs and scope of treatability studies and additional field investigations. The RI/FS should be viewed as a flexible process that can and should be tailored to specific circumstances and information needs of individual sites, not as a rigid approach that must be conducted identically at every site. Likewise, the human health evaluation process described here should be viewed the same way.

Two concepts are essential to the phased RI/FS approach. First, initial data collection efforts develop a general understanding of the site. Subsequent data collection effort focuses on filling previously unidentified gaps in the understanding of site characteristics and gathering information necessary to evaluate remedial alternatives. Second, key data needs should be identified as early in the process as possible to ensure that data collection is always directed toward providing information relevant to selection of a remedial action. In this way, the overall site characterization

effort can be continually scoped to minimize the collection of unnecessary data and maximize data quality.

The RI/FS provides decision-makers with a technical evaluation of the threats posed at a site, a characterization of the potential routes of exposure, an assessment of remedial alternatives (including their relative advantages and disadvantages), and an analysis of the trade-offs in selecting one alternative over another. EPA's interim final *Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA* (EPA 1988b) provides a detailed structure for the RI/FS. The RI/FS guidance provides further background that is helpful in understanding the place of the human health evaluation in the RI/FS process. The role that risk information plays in these stages of the RI/FS is described below; additional background can be found in the RI/FS guidance and in a summary of the guidance found in Chapter 2. Exhibit 1-1 illustrates the RI/FS process, showing where in the process risk information is gathered and analyzed.

1.1.1 PROJECT SCOPING

The purpose of project scoping is to define more specifically the appropriate type and extent of investigation and analysis that should be undertaken for a given site. During scoping, to assist in evaluating the possible impacts of releases from the site on human health and the environment, a conceptual model of the site should be established, considering in a qualitative manner the sources of contamination, potential pathways of exposure, and potential receptors. (Scoping is also the starting point for the risk assessment, during which exposure pathways are identified in the conceptual model for further investigation and quantification.)

PROJECT SCOPING

Program experience has shown that scoping is a very important step for the human health evaluation process, and both the health and environmental evaluation teams need to get involved in the RI/FS during the scoping stage. Planning for site data collection activities is necessary to focus the human health evaluation (and environmental evaluation) on the minimum amount of sampling information in order to meet time and budget constraints, while at the same time ensuring that enough information is gathered to assess risks adequately. (See Chapter 3 for information on planning the human health evaluation.)

The preliminary characterization during project scoping is initially developed with readily available information and is refined as additional data are collected. The main objectives of scoping are to identify the types of decisions that need to be made, to determine the types (including quantity and quality) of data needed, and to design efficient studies to collect these data. Potential site-specific modeling activities should be discussed at initial scoping meetings to ensure that modeling results will supplement the sampling data and effectively support risk assessment activities.

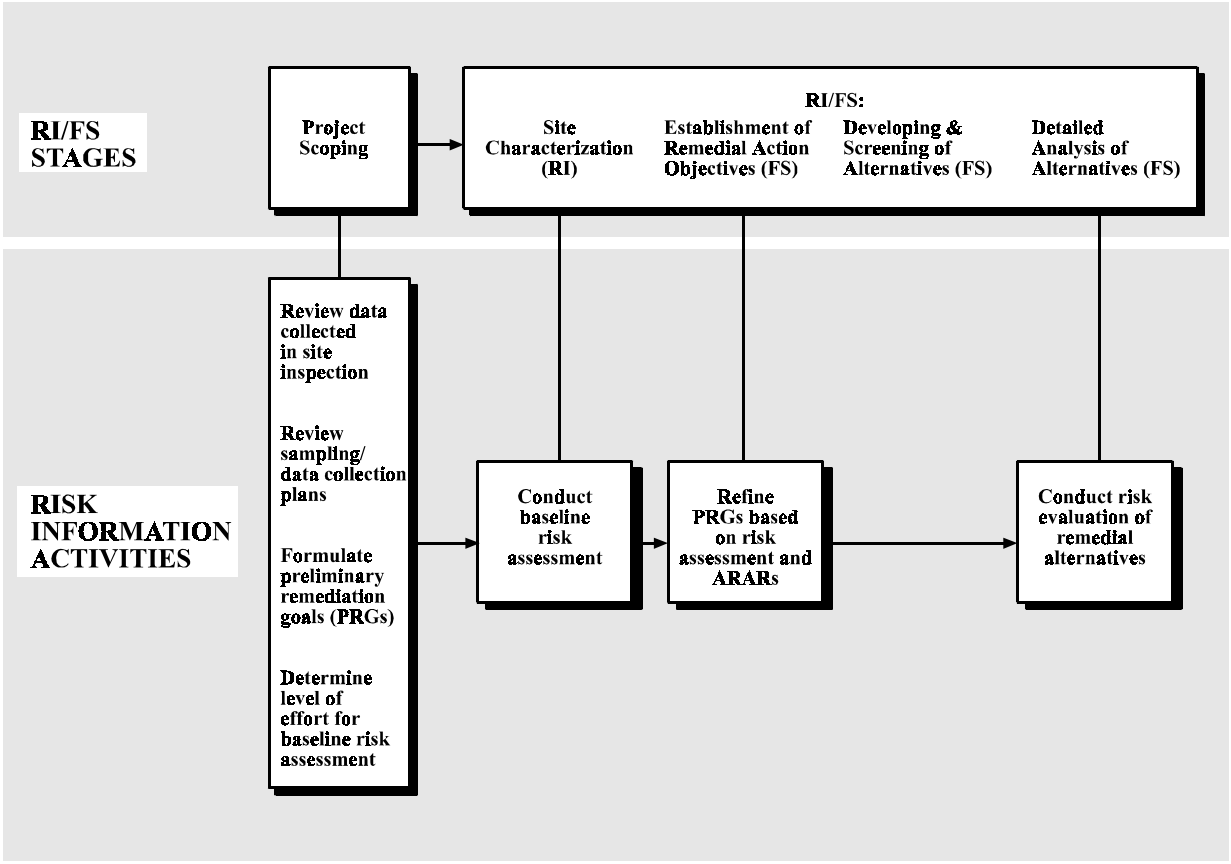
1.1.2 SITE CHARACTERIZATION (RI)

During site characterization, the sampling and analysis plan developed during project scoping is implemented and field data are collected and analyzed to determine the nature and extent of threats to human health and the environment posed by a site. The major components of site characterization are:

- collection and analysis of field data to characterize the site;
- development of a baseline risk assessment for both potential human health effects and potential environmental effects; and
- treatability studies, as appropriate.

Part of the human health evaluation, the baseline risk assessment (Part A of this manual) is an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action). The baseline risk assessment contributes to the site characterization

EXHIBIT 1-1
RISK INFORMATION ACTIVITIES IN THE RI/FS PROCESS



and subsequent development, evaluation, and selection of appropriate response alternatives. The results of the baseline risk assessment are used to:

- help determine whether additional response action is necessary at the site;
- modify preliminary remediation goals;
- help support selection of the "no-action" remedial alternative, where appropriate; and
- document the magnitude of risk at a site, and the primary causes of that risk.

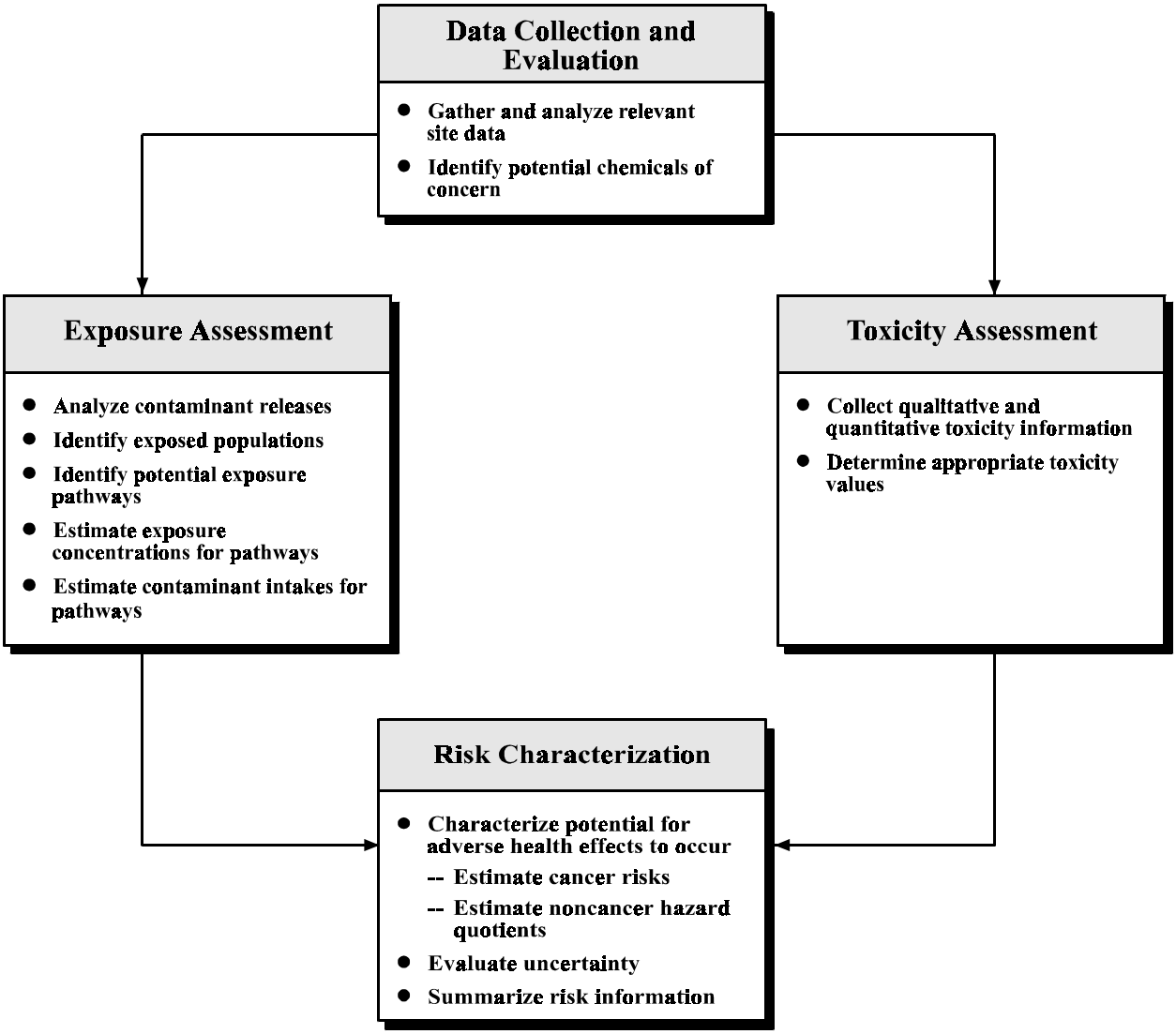
Baseline risk assessments are site-specific and therefore may vary in both detail and the extent to which qualitative and quantitative analyses are used, depending on the complexity and particular circumstances of the site, as well as the availability of applicable or relevant and appropriate requirements (ARARs) and other criteria, advisories, and guidance. After an initial planning stage (described more fully in Chapter 3), there are four steps in the baseline risk assessment process: data collection and analysis; exposure assessment; toxicity assessment; and risk characterization. Each step is described briefly below and presented in Exhibit 1-2.

Data collection and evaluation involves gathering and analyzing the site data relevant to the human health evaluation and identifying the substances present at the site that are the focus of the risk assessment process. (Chapters 4 and 5 address data collection and evaluation.)

An exposure assessment is conducted to estimate the magnitude of actual and/or potential human exposures, the frequency and duration of these exposures, and the pathways by which humans are potentially exposed. In the exposure assessment, reasonable maximum estimates of exposure are developed for both current and future land-use assumptions. Current exposure estimates are used to determine whether a threat exists based on existing exposure conditions at the site. Future exposure estimates are used to provide decision-makers with an understanding of potential future exposures and threats and include a qualitative estimate of the likelihood of such exposures occurring. Conducting an exposure assessment involves analyzing contaminant releases; identifying exposed populations; identifying all potential pathways of exposure; estimating exposure point concentrations for specific pathways, based both on environmental monitoring data and predictive chemical modeling results; and estimating contaminant intakes for specific pathways. The results of this assessment are pathway-specific intakes for current and future exposures to individual substances. (Chapter 6 addresses exposure assessment.)

The toxicity assessment component of the Superfund baseline risk assessment considers: (1) the types of adverse health effects associated with chemical exposures; (2) the relationship between magnitude of exposure and adverse effects; and (3) related uncertainties such as the weight of evidence of a particular chemical's carcinogenicity in humans. Typically, the Superfund site risk assessments rely heavily on existing toxicity information developed on specific chemicals. Toxicity assessment for contaminants found at Superfund sites is generally accomplished in two steps: hazard identification and dose-response assessment. The first step, hazard identification, is the process of determining whether exposure to an agent can cause an increase in the incidence of an adverse health effect (e.g., cancer, birth defect). Hazard identification also involves characterizing the nature and strength of the evidence of causation. The second step, dose-response evaluation, is the process of quantitatively evaluating the toxicity information and characterizing the relationship between the dose of the contaminant administered or received and the incidence of adverse health effects in the exposed population. From this quantitative dose-response relationship, toxicity values are derived that can be used to estimate the incidence of adverse effects occurring in humans at different exposure levels. (Chapter 7 addresses toxicity assessment.)

EXHIBIT 1-2
PART A: BASELINE RISK ASSESSMENT



The risk characterization summarizes and combines outputs of the exposure and toxicity assessments to characterize baseline risk, both in

quantitative expressions and qualitative statements. During risk characterization, chemical-specific toxicity information is compared against both measured contaminant exposure levels and those levels predicted through fate and transport modeling to determine whether current or future levels at or near the site are of potential concern. (Chapter 8 addresses risk characterization.)

The level of effort required to conduct a baseline risk assessment depends largely on the complexity of the site. In situations where the results of the baseline risk assessment indicate that the site poses little or no threat to human health or the environment and that no further (or limited) action will be necessary, the FS should be scaled-down as appropriate.

The documents developed during site characterization include a brief preliminary site characterization summary and the draft RI report, which includes either the complete baseline risk assessment report or a summary of it. The preliminary site characterization summary may be used to assist in identification of ARARs and may provide the Agency for Toxic Substances and Disease Registry (ATSDR) with the data necessary to prepare its health assessment (different from baseline risk assessment or other EPA human health evaluation activities; see Chapter 2). The draft RI report is prepared after the completion of the baseline risk assessment, often along with the draft FS report.

1.1.3 FEASIBILITY STUDY

The purpose of the feasibility study is to provide the decision-maker with an assessment of remedial alternatives, including their relative strengths and weaknesses, and the trade-offs in selecting one alternative over another. The FS process involves developing a reasonable range of alternatives and analyzing these alternatives in detail using nine evaluation criteria. Because the RI and FS are conducted concurrently, this development and analysis of alternatives is an interactive process in which potential alternatives and remediation goals are continually refined as additional information from the RI becomes available.

Establishing protective remedial action objectives. The first step in the FS process involves developing remedial action objectives that address contaminants and media of concern, potential exposure pathways, and preliminary remediation goals. Under the proposed revised NCP and the interim RI/FS guidance, preliminary remediation goals typically are formulated first during project scoping or concurrent with initial RI activities (i.e., prior to completion of the baseline risk assessment). The preliminary remediation goals are therefore based initially on readily available chemical-specific ARARs (e.g., maximum contaminant levels (MCLs) for drinking water). Preliminary remediation goals for individual substances are refined or confirmed at the conclusion of the baseline risk assessment (Part B of this manual addresses the refinement of preliminary remediation goals). These refined preliminary remediation goals are based both on risk assessment and on chemical-specific ARARs. Thus, they are intended to be protective and to comply with ARARs. The analytical approach used to develop these refined goals involves:

- identifying chemical-specific ARARs;
- identifying levels based on risk assessment where chemical-specific ARARs are not available or situations where multiple contaminants or multiple exposure pathways make ARARs not protective;
- identifying non-substance-specific goals for exposure pathways (if necessary); and
- determining a refined preliminary remediation goal that is protective of human health for all substance/exposure pathway combinations being addressed.

Development and screening of alternatives. Once remedial action objectives have been developed, general response actions, such as treatment, containment, excavation, pumping, or other actions that may be taken to satisfy those objectives should be developed. In the process of

developing alternatives for remedial action at a site, two important activities take place. First, volumes or areas of waste or environmental media that need to be addressed by the remedial action are determined by information on the nature and extent of contamination, ARARs, chemical-specific environmental fate and toxicity information, and engineering analyses. Second, the remedial action alternatives and associated technologies are screened to identify those that would be effective for the contaminants and media of interest at the site. The information developed in these two activities is used in assembling technologies into alternatives for the site as a whole or for a specific operable unit.

The Superfund program has long permitted remedial actions to be staged through multiple operable units. Operable units are discrete actions that comprise incremental steps toward the final remedy. Operable units may be actions that completely address a geographical portion of a site or a specific site problem (e.g., drums and tanks, contaminated ground water) or the entire site. Operable units include interim actions (e.g., pumping and treating of ground water to retard plume migration) that must be followed by subsequent actions to fully address the scope of the problem (e.g., final ground-water operable unit that defines the remediation goals and restoration timeframe). Such operable units may be taken in response to a pressing problem that will worsen if unaddressed, or because there is an opportunity to undertake a limited action that will achieve significant risk reduction quickly. The appropriateness of dividing remedial actions into operable units is determined by considering the interrelationship of site problems and the need or desire to initiate actions quickly. To the degree that site problems are interrelated, it may be most appropriate to address the problems together. However, where problems are reasonably separable, phased responses implemented through a sequence of operable units may promote more rapid risk reduction.

In situations where numerous potential remedial alternatives are initially developed, it may be necessary to screen the alternatives to narrow the list to be evaluated in detail. Such screening aids in streamlining the feasibility study while ensuring that the most promising alternatives are being considered.

Detailed analysis of alternatives. During the detailed analysis, each alternative is assessed against specific evaluation criteria and the results of this assessment arrayed such that comparisons between alternatives can be made and key trade-offs identified. Nine evaluation criteria, some of which are related to human health evaluation and risk, have been developed to address statutory requirements as well as additional technical and policy considerations that have proven to be important for selecting among remedial alternatives. These evaluation criteria, which are identified and discussed in the interim final RI/FS guidance, serve as the basis for conducting the detailed analyses during the FS and for subsequently selecting an appropriate remedial action. The nine evaluation criteria are as follows:

(1) overall protection of human health and the environment;
(2) compliance with ARARs (unless waiver applicable);
(3) long-term effectiveness and permanence;
(4) reduction of toxicity, mobility, or volume through the use of treatment;
(5) short-term effectiveness;
(6) implementability;
(7) cost;
(8) state acceptance; and
(9) community acceptance.

Risk information is required at the detailed analysis stage of the RI/FS so that each alternative can be evaluated in relation to the relevant NCP remedy selection criteria.

The detailed analysis must, according to the proposed NCP, include an evaluation of each alternative against the nine criteria. The first two criteria (i.e., overall protectiveness and compliance with ARARs) are threshold determinations and must be met before a remedy can be selected. Evaluation of the overall protectiveness of an alternative during the RI/FS should focus on how a specific alternative achieves protection over time and how site risks are reduced.

The next five criteria (numbers 3 through 7) are primary balancing criteria. The last two (numbers 8 and 9) are considered modifying criteria, and risk information does not play a direct role in the analysis of them. Of the five primary balancing criteria, risk information is of particular importance in the analysis of effectiveness and permanence. Analysis of long-term effectiveness and permanence involves an evaluation of the results of a remedial action in terms of residual risk at the site after response objectives have been met. A primary focus of this evaluation is the effectiveness of the controls that will be applied to manage risk posed by treatment residuals and/or any untreated wastes that may be left on the site, as well as the volume and nature of that material. It should also consider the potential impacts on human health and the environment should the remedy fail. An evaluation of short-term effectiveness addresses the impacts of the alternative during the construction and implementation phase until remedial response objectives will be met. Under this criterion, alternatives should be evaluated with respect to the potential effects on human health and the environment during implementation of the remedial action and the length of time until protection is achieved.

1.2 OVERALL ORGANIZATION OF THE MANUAL

The next two chapters present additional background material for the human health evaluation process. Chapter 2 discusses statutes, regulations, guidance, and studies relevant to the Superfund human health evaluation. Chapter 3 discusses issues related to planning for the human health evaluation. The remainder of the manual is organized by the three parts of the human health evaluation process:

- the baseline risk assessment is covered in Part A of the manual (Chapters 4 through 10);
- refinement of preliminary remediation goals is covered in Part B of the manual (not included as part of this interim final version); and
- the risk evaluation of remedial alternatives is covered in Part C of the manual (not included as part of this interim final version).

Chapters 4 through 8 provide detailed technical guidance for conducting the steps of a baseline risk assessment, and Chapter 9 provides documentation and review guidelines. Chapter 10 contains additional guidance specific to baseline risk assessment for sites contaminated with radionuclides. Sample calculations, sample table formats, and references to other guidance are provided throughout the manual. All material is presented both in technical terms and in simpler text. It should be stressed that the manual is intended to be comprehensive and to provide guidance for more situations than usually are relevant to any single site. Risk assessors need not use those parts of the manual that do not apply to their site.

Each chapter in Part A includes a glossary of acronyms and definitions of commonly used terms. The manual also includes two appendices: Appendix A provides technical guidance for making absorption adjustments and Appendix B is an index.

ENDNOTES FOR CHAPTER 1

1. References made to CERCLA throughout this document should be interpreted as meaning "CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA)."

2. 40 CFR Part 300. Proposed revisions to the NCP were published on December 21, 1988 (53 Federal Register 51394).

3. The term "public health evaluation" was introduced in the previous risk assessment guidance (EPA 1986f) to describe the assessment of chemical releases from a site and the analysis of public health threats resulting from those releases, and Superfund site risk assessment studies often are referred to as public health evaluations, or PHEs. The term "PHE" should be replaced by whichever of the three parts of the revised human health evaluation process is appropriate: "baseline risk assessment," "documentation of preliminary remediation goals," or "risk evaluation of remedial alternatives."

4. Baseline risks are risks that might exist if no remediation or institutional controls were applied at a site.

5. Volume II of the *Risk Assessment Guidance for Superfund* is the *Environmental Evaluation Manual* (EPA 1989b), which provides guidance for the analysis of potential environmental (i.e., not human health) effects at sites.

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