CHAPTER 2

STATUTES, REGULATIONS, GUIDANCE, AND STUDIES RELEVANT TO THE HUMAN HEALTH EVALUATION

This chapter briefly describes the statutes, regulations, guidance, and studies related to the human health evaluation process. The descriptions focus on aspects of these documents most relevant to human health evaluations and show how recent revisions to the documents bear upon the human health evaluation process. Section 2.1 describes the following documents that govern the human health evaluation:

- the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, or Superfund) and the Superfund Amendments and Reauthorization Act of 1986 (SARA);
- the National Oil and Hazardous Substances Pollution Contingency Plan (National Contingency Plan, or NCP);
- Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA (RI/FS guidance);
- CERCLA Compliance with Other Laws Manual (ARARs guidance); and
- Superfund Exposure Assessment Manual (SEAM).

Exhibit 2-1 shows the relationship of these statutes, regulations, and guidances governing human health evaluation. In addition, Section 2.2 identifies and briefly describes other Superfund studies related to, and sometimes confused with, the RI/FS human health evaluation. The types of studies discussed are:

- endangerment assessments;
- ATSDR health assessments; and
- ATSDR health studies.

2.1 STATUTES, REGULATIONS, AND GUIDANCE GOVERNING HUMAN HEALTH EVALUATION

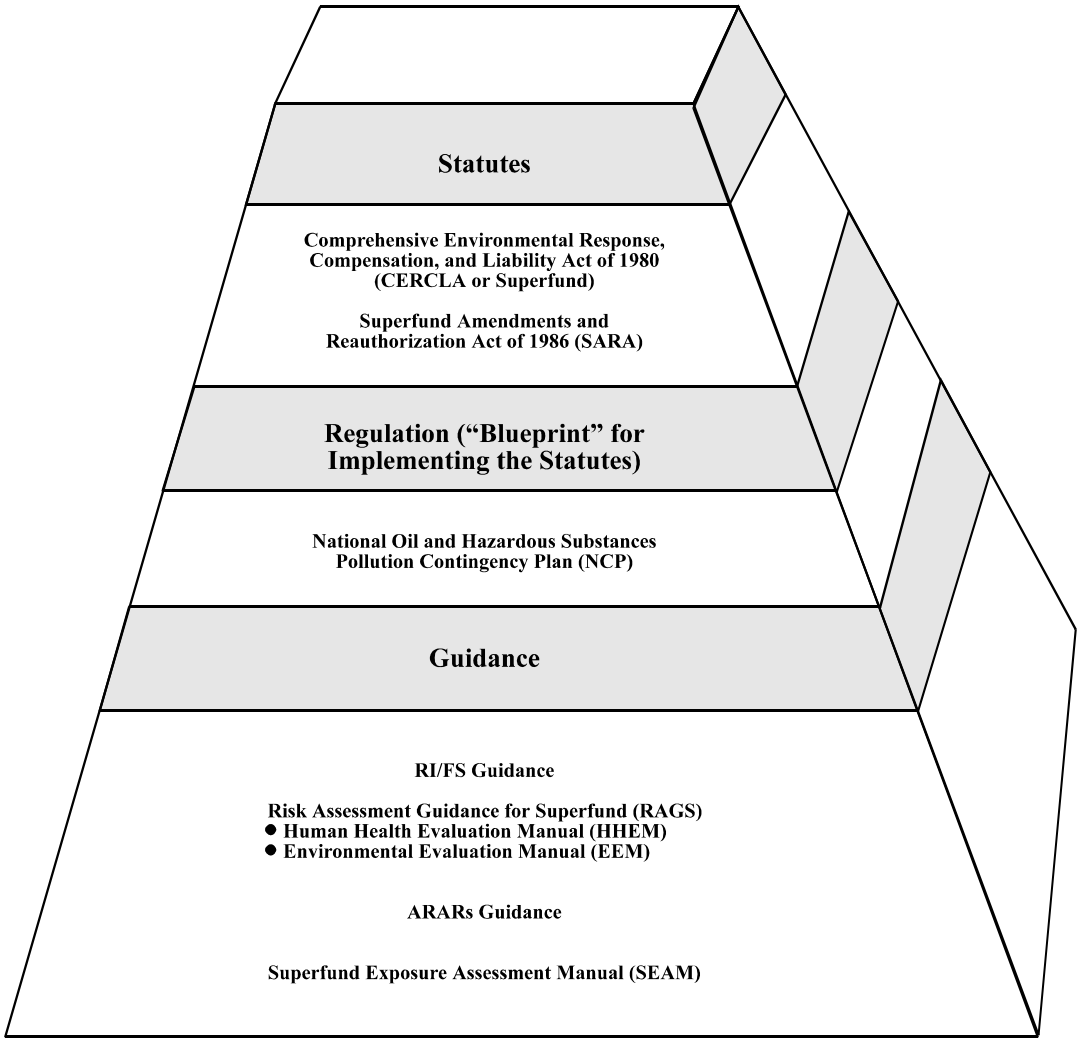
This section describes the major Superfund laws and program documents relevant to the human health evaluation process.

2.1.1 CERCLA AND SARA

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. 9601 et seq.), commonly called Superfund, in response to the dangers posed by sudden or otherwise uncontrolled releases of hazardous substances, pollutants, or contaminants into the

EXHIBIT 2-1

RELATIONSHIP OF DOCUMENTS GOVERNING HUMAN HEALTH EVALUATION



environment. CERCLA authorized $1.6 billion over five years for a comprehensive program to clean up the worst abandoned or inactive waste sites in the nation. CERCLA funds used to establish and administer the cleanup program are derived primarily from taxes on crude oil and 42 different commercial chemicals.

The reauthorization of CERCLA is known as the Superfund Amendments and Reauthorization Act (SARA), and was signed by the President on October 17, 1986. (All further references to CERCLA in this appendix should be interpreted as "CERCLA as amended by SARA.") These amendments provided $8.5 billion for the cleanup program and an additional $500 million for cleanup of leaks from underground storage tanks. Under SARA, Congress strengthened EPA's mandate to focus on permanent cleanups at Superfund sites, involve the public in decision processes at sites, and encourage states and federally recognized Indian tribes to actively participate as partners with EPA to address these sites. SARA expanded EPA's research, development (especially in the area of alternative technologies), and training responsibilities. SARA also strengthened EPA's enforcement authority. The changes to CERCLA sections 104 (Response Authorities) and 121 (Cleanup Standards) have the greatest impact on the RI/FS process.

Cleanup standards. Section 121 (Cleanup Standards) states a strong preference for remedies that are highly reliable and provide long-term protection. In addition to the requirement for remedies to be both protective of human health and the environment and cost-effective, other remedy selection considerations in section 121(b) include:

- a preference for remedial actions that employ (as a principal element of the action) treatment that permanently and significantly reduces the volume, toxicity, or mobility of hazardous substances, pollutants, and contaminants;

- offsite transport and disposal without treatment as the least favored alternative where practicable treatment technologies are available; and

- the need to assess the use of alternative treatment technologies or resource recovery technologies and use them 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, pollutants, or contaminants that may pose a threat to human health or the environment remain at the site. If during a five-year review it is determined that the action no longer protects human health and the environment, further remedial actions will need to be considered.

Section 121(d)(2)(A) of CERCLA incorporates into law the CERCLA Compliance Policy, which specifies that Superfund remedial actions meet any federal standards, requirements, criteria, or limitations that are determined to be legally applicable or relevant and appropriate requirements (i.e., ARARs). Also included is the new provision that state ARARs must be met if they are more stringent than federal requirements. (Section 2.1.4 provides more detail on ARARs.)

Health-related authorities. Under CERCLA section 104(i)(6), the Agency for Toxic Substances and Disease Registry (ATSDR) is required to conduct a health assessment for every site included or proposed for inclusion on the National Priorities List. The ATSDR health assessment, which is fairly qualitative in nature, should be distinguished from the EPA human health evaluation, which is more quantitative. CERCLA section 104(i)(5)(F) states that:

> the term "health assessments" shall include preliminary assessments of the potential risk to human health posed by individual sites and facilities, based on such factors as the nature and extent of contamination, the existence of potential pathways of human exposure (including ground or surface water contamination, air emissions, and food chain contamination), the size and potential susceptibility of the community within the likely pathways of exposure, the comparison of expected human exposure levels to the short-term and long-term health effects associated with identified hazardous substances and any available recommended exposure or tolerance limits for

such hazardous substances, and the comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure. The Administrator of ATSDR shall use appropriate data, risk assessments, risk evaluations and studies available from the Administrator of EPA.

There are purposeful differences between an ATSDR health assessment and traditional risk assessment. The health assessment is usually qualitative, site-specific, and focuses on medical and public health perspectives. Exposures to site contaminants are discussed in terms of especially sensitive populations, mechanisms of toxic chemical action, and possible disease outcomes. Risk assessment, the framework of the EPA human health evaluation, is a characterization of the probability of adverse effects from human exposures to environmental hazards. In this context, risk assessments differ from health assessments in that they are quantitative, chemical-oriented characterizations that use statistical and biological models to calculate numerical estimates of risk to health. However, both health assessments and risk assessments use data from human epidemiological investigations, when available, and when human toxicological data are unavailable, rely on the results of animal toxicology studies.

2.1.2 NATIONAL CONTINGENCY PLAN (NCP)

The National Contingency Plan provides the organizational structure and procedures for preparing for and responding to discharges of oil and releases of hazardous substances, pollutants, and contaminants. The NCP is required by section 105 of CERCLA and by section 311 of the Clean Water Act. The current NCP (EPA 1985) was published on November 20, 1985, and a significantly revised version (EPA 1988a) was proposed December 21, 1988 in response to SARA. The proposed NCP is organized into the following subparts:

- Subpart A -- Introduction
- Subpart B -- Responsibility and Organization for Response
- Subpart C -- Planning and Preparedness
- Subpart D -- Operational Response Phases for Oil Removal
- Subpart E -- Hazardous Substance Response
- Subpart F -- State Involvement in Hazardous Substance Response
- Subpart G -- Trustees for Natural Resources
- Subpart H -- Participation by Other Persons
- Subpart I -- Administrative Record for Selection of Response Action
- Subpart J -- Use of Dispersants and Other Chemicals

Subpart E, Hazardous Substance Response, contains a detailed plan covering the entire range of authorized activities involved in abating and remedying releases or threats of releases of hazardous substances, pollutants, and contaminants. It contains provisions for both removal and remedial response. The remedial response process set forth by the proposed NCP is a seven-step process, as described below. Risk information plays a role in each step.

Site discovery or notification. Releases of hazardous substances, pollutants, or contaminants identified by federal, state, or local government agencies or private parties are reported to the National Response Center or EPA. Upon discovery, such potential sites are screened to identify release situations warranting further remedial response consideration. These sites are entered into the CERCLA Information System (CERCLIS). This computerized system serves as a data base of site information and tracks the change in status of a site through the response process. Risk information is used to determine which substances are hazardous and, in some cases, the quantities that constitute a release that must be reported (i.e., a reportable quantity, or RQ, under CERCLA section 103(a)).

Preliminary assessment and site inspection (PA/SI). The preliminary assessment involves

collection and review of all available information and may include offsite reconnaissance to evaluate the source and nature of hazardous substances present and to identify the responsible party(ies). At the conclusion of the preliminary assessment, a site may be referred for further action, or a determination may be made that no further action is needed. Site inspections, which follow the preliminary assessment for sites needing further action, routinely include the collection of samples and are conducted to help determine the extent of the problem and to obtain information needed to determine whether a removal action is warranted. If, based on the site inspection, it appears likely that the site should be considered for inclusion on the National Priorities List (NPL), a listing site inspection (LSI) is conducted. The LSI is a more extensive investigation than the SI, and a main objective of the LSI is to collect sufficient data about a site to support Hazard Ranking System (HRS) scoring. One of the main objectives of the PA/SI is to collect risk-related information for sites so that the site can be scored using the HRS and priorities may be set for more detailed studies, such as the RI/FS.

Establishing priorities for remedial action. Sites are scored using the HRS, based on data from the PA/SI/LSI. The HRS scoring process is the primary mechanism for determining the sites to be included on the NPL and, therefore, the sites eligible for Superfund-financed remedial action. The HRS is a numerical scoring model that is based on many of the factors affecting risk at a site. A revised version of the HRS (EPA 1988b) was proposed December 23, 1988.

Remedial investigation/feasibility study (RI/FS). As described in Section 1.1, the RI/FS is the framework for determining appropriate remedial actions at Superfund sites. Although RI/FS activities technically are removal actions and therefore not restricted to sites on the NPL (see sections 101(23) and 104(b) of CERCLA), they most frequently are undertaken at NPL sites. Remedial investigations are conducted to characterize the contamination at the site and to obtain information needed to identify, evaluate, and select cleanup alternatives. The feasibility study includes an analysis of alternatives based on the nine NCP evaluation criteria. The human health evaluation described in this manual, and the environmental evaluation described elsewhere, are the guidance for developing risk information in the RI/FS.

Selection of remedy. The primary consideration in selecting a remedy is that it be protective of human health and the environment, by eliminating, reducing, or controlling risks posed through each pathway. Thus, the risk information developed in the RI/FS is a key input to remedy selection. The results of the RI/FS are reviewed to identify a preferred alternative, which is announced to the public in a Proposed Plan. Next, the lead agency reviews any resulting public comments on the Proposed Plan, consults with the support agencies to evaluate whether the preferred alternative is still the most appropriate, and then makes a final decision. A record of decision (ROD) is written to document the rationale for the selected remedy.

Remedial design/remedial action. The detailed design of the selected remedial action is developed and then implemented. The risk information developed previously in the RI/FS helps refine the remediation goals that the remedy will attain.

Five-year review. Section 121(c) of CERCLA requires a periodic review of remedial actions, at least every five years after initiation of such action, for as long as hazardous substances, pollutants, or contaminants that may pose a threat to human health or the environment remain at the site. If it is determined during a five-year review that the action no longer protects human health and the environment, further remedial actions will need to be considered.

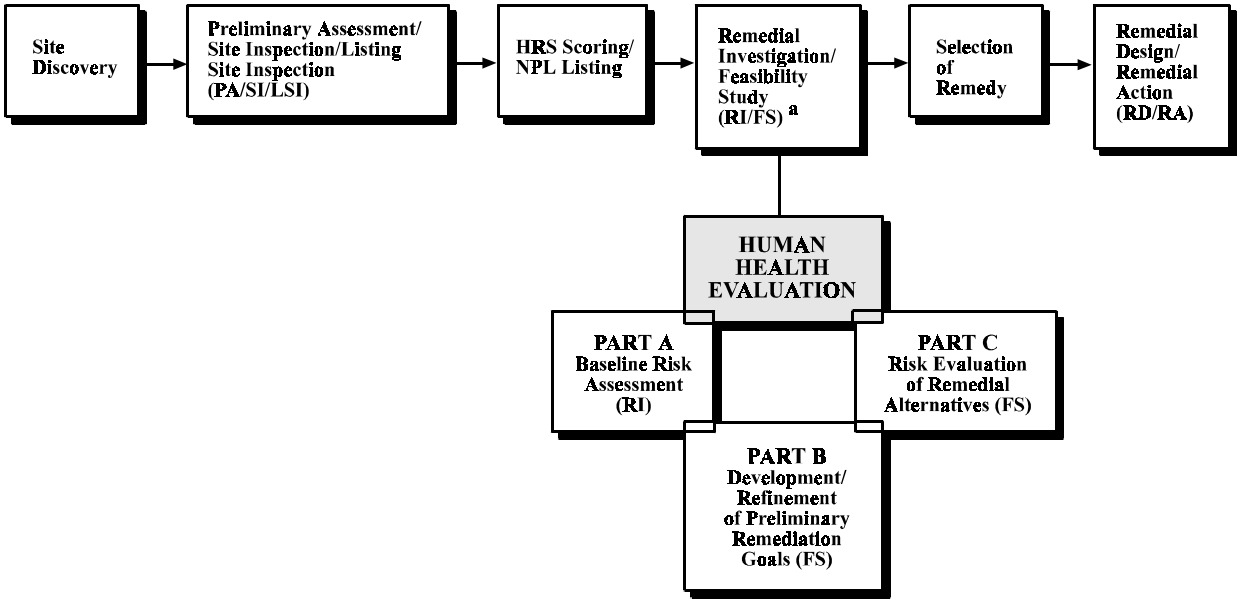
Exhibit 2-2 diagrams the general steps of the Superfund remedial process, indicating where in the process the various parts of the human health evaluation are conducted.

2.1.3 REMEDIAL INVESTIGATION/ FEASIBILITY STUDY GUIDANCE

EPA's interim final Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA (EPA 1988c) provides a detailed

EXHIBIT 2-2

ROLE OF THE HUMAN HEALTH EVALUATION IN THE SUPERFUND REMEDIAL PROCESS



[a] The RI/FS can be undertaken prior to NPL listing.

structure for conducting field studies to support remedial decisions and for identifying, evaluating, and selecting remedial action alternatives under CERCLA. This 1988 guidance document is a revision of two separate guidances for remedial investigations and for feasibility studies published in 1985. These guidances have been consolidated into a single document and revised to:

- reflect new emphasis and provisions of SARA;
- incorporate aspects of new or revised guidance related to RI/FSs;
- incorporate management initiatives designed to streamline the RI/FS process; and
- reflect experience gained from previous RI/FS projects.

The RI/FS consists of the following general steps:

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

Because Section 1.1 describes each of these steps, focusing on the role that risk information plays in the RI/FS, a discussion of the steps is not repeated here. The RI/FS guidance provides the context into which the human health evaluation fits and should be used in conjunction with this manual.

2.1.4 ARARS GUIDANCE

The interim final CERCLA *Compliance with Other Laws Manual* (EPA 1988d; EPA 1989a), or ARARs guidance, was developed to assist in the selection of onsite remedial actions that meet the applicable or relevant and appropriate requirements (ARARs) of the Resource Conservation and Recovery Act (RCRA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Clean Air Act (CAA), and other federal and state environmental laws, as required by CERCLA section 121. Part I of the manual discusses the overall procedures for identifying ARARs and provides guidance on the interpretation and analysis of RCRA requirements. Specifically:

- Chapter 1 defines "applicable" and "relevant and appropriate," provides matrices listing potential chemical-specific, location-specific, and action-specific requirements from RCRA, CWA, and SDWA, and provides general procedures for identifying and analyzing requirements;
- Chapter 2 discusses special issues of interpretation and analysis involving RCRA requirements, and provides guidance on when RCRA requirements will be ARARs for CERCLA remedial actions;
- Chapter 3 provides guidance for compliance with CWA substantive (for onsite and offsite actions) and administrative (for offsite actions) requirements for direct discharges, indirect discharges, and dredge and fill activities;
- Chapter 4 provides guidance for compliance with requirements of the SDWA that may be applicable or relevant and appropriate to CERCLA sites; and
- Chapter 5 provides guidance on consistency with policies for ground-water protection.

The manual also contains a hypothetical scenario illustrating how ARARs are identified and used, and an appendix summarizing the provisions of RCRA, CWA, and SDWA.

Part II of the ARARs guidance covers the Clean Air Act, other federal statutes, and state requirements. Specifically:

- Chapter 1 provides an introduction to Part II of the guidance, and also includes extensive summary tables;

- Chapter 2 describes Clean Air Act requirements and related RCRA and state requirements;

- Chapters 3 and 4 provide guidance for compliance with several other federal statutes;

- Chapter 5 discusses potential ARARs for sites contaminated with radioactive substances;

- Chapter 6 addresses requirements specific to mining, milling, or smelting sites; and

- Chapter 7 provides guidance on identifying and complying with state ARARs.

2.1.5 SUPERFUND EXPOSURE ASSESSMENT MANUAL

The *Superfund Exposure Assessment Manual* (EPA 1988e), which was developed by the Superfund program specifically as a companion document to the original Superfund Public Health Evaluation Manual (EPA 1986), provides RPMs and regional risk assessors with the guidance necessary to conduct exposure assessments that meet the needs of the Superfund human health risk evaluation process. Specifically, the manual:

- provides an overall description of the integrated exposure assessment as it is applied to uncontrolled hazardous waste sites; and

- serves as a source of reference concerning the use of estimation procedures and computer modeling techniques for the analysis of uncontrolled sites.

The analytical process outlined in the *Superfund Exposure Assessment Manual* provides a framework for the assessment of exposure to contaminants at or migrating from uncontrolled hazardous waste sites. The application of both monitoring and modeling procedures to the exposure assessment process is outlined in the manual. This process considers all contaminant releases and exposure routes and assures that an adequate level of analytical detail is applied to support the human health risk assessment process.

The exposure assessment process described in the *Superfund Exposure Assessment Manual* is structured in five segments:

(1) analysis of contaminant releases from a subject site into environmental media;

(2) evaluation of the transport and environmental fate of the contaminants released;

(3) identification, enumeration, and characterization of potentially exposed populations;

(4) integrated exposure analysis; and

(5) uncertainty analysis.

Two recent publications from EPA's Office of Research and Development, the *Exposure Factors Handbook* (EPA 1989b) and the *Exposure Assessment Methods Handbook* (EPA 1989c), provide useful information to supplement the Superfund Exposure Assessment Manual. All three of these key exposure assessment references should be used in conjunction with Chapter 6 of this manual.

2.2 RELATED SUPERFUND STUDIES

This section identifies and briefly describes other Superfund studies related to, and sometimes confused with, the RI/FS human health evaluation. It contrasts the objectives and methods and clarifies the relationships of these other studies with RI/FS health risk assessments. The types of studies discussed are endangerment assessments, ATSDR health assessments, and ATSDR health studies.

2.2.1 ENDANGERMENT ASSESSMENTS

Before taking enforcement action against parties responsible for a hazardous waste site, EPA must determine that an imminent and substantial endangerment to public health or the environment

exists as a result of the site. Such a legal determination is called an endangerment assessment. For remedial sites, the process for analyzing whether there may be an endangerment is described in this Human Health Evaluation Manual and its companion Environmental Evaluation Manual. In the past, an endangerment assessment often was prepared as a study separate from the baseline risk assessment. With the passage of SARA and changes in Agency practice, the need to perform a detailed endangerment assessment as a separate effort from the baseline risk assessment has been eliminated.

For administrative orders requiring a remedial design or remedial action, endangerment assessment determinations are now based on information developed in the site baseline risk assessment. Elements included in the baseline risk assessment conducted at a Superfund site during the RI/FS process fully satisfy the informational requirements of the endangerment assessment. These elements include the following:

- identification of the hazardous wastes or hazardous substances present in environmental media;
- assessment of exposure, including a characterization of the environmental fate and transport mechanisms for the hazardous wastes and substances present, and of exposure pathways;
- assessment of the toxicity of the hazardous wastes or substances present;
- characterization of human health risks; and
- characterization of the impacts and/or risks to the environment.

The human health and environmental evaluations that are part of the RI/FS are conducted for purposes of determining the baseline risks posed by the site, and for ensuring that the selected remedy will be protective of human health and the environment. The endangerment assessment is used to support litigation by determining that an imminent and substantial endangerment exists. Information presented in the human health and environmental evaluations is basic to the legal determination of endangerment.

In 1985, EPA produced a draft manual specifically written for endangerment assessment, the Endangerment Assessment Handbook. EPA has determined that a guidance separate from the Risk Assessment Guidance for Superfund (Human Health Evaluation Manual and Environmental Evaluation Manual) is not required for endangerment assessment; therefore, the Endangerment Assessment Handbook will not be made final and should no longer be used.

2.2.2 ATSDR HEALTH ASSESSMENTS

CERCLA section 104(i), as amended, requires the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct health assessments for all sites listed or proposed to be listed on the NPL. A health assessment includes a preliminary assessment of the potential threats that individual sites and facilities pose to human health. The health assessment is required to be completed "to the maximum extent practicable" before completion of the RI/FS. ATSDR personnel, state personnel (through cooperative agreements), or contractors follow six basic steps, which are based on the same general risk assessment framework as the EPA human health evaluation:

(1) evaluate information on the site's physical, geographical, historical, and operational setting, assess the demographics of nearby populations, and identify health concerns of the affected community(ies);

(2) determine contaminants of concern associated with the site;

(3) identify and evaluate environmental pathways;

(4) identify and evaluate human exposure pathways;

(5) identify and evaluate public health implications based on available medical and toxicological information; and

(6) develop conclusions concerning the health threat posed by the site and make recommendations regarding further public health activities.

The purpose of the ATSDR health assessment is to assist in the evaluation of data and information on the release of toxic substances into the environment in order to assess any current or future impact on public health, develop health advisories or other health-related recommendations, and identify studies or actions needed to evaluate and prevent human health effects. Health assessments are intended to help public health and regulatory officials determine if actions should be taken to reduce human exposure to hazardous substances and to recommend whether additional information on human exposure and associated risks is needed. Health assessments also are written for the benefit of the informed community associated with a site, which could include citizen groups, local leaders, and health professionals.

Several important differences exist between EPA human health evaluations and ATSDR health assessments. EPA human health evaluations include quantitative, substance-specific estimates of the risk that a site poses to human health. These estimates depend on statistical and biological models that use data from human epidemiologic investigations and animal toxicity studies. The information generated from a human health evaluation is used in risk management decisions to establish cleanup levels and select a remedial alternative.

ATSDR health assessments, although they may employ quantitative data, are more qualitative in nature. They focus not only on the possible health threats posed by chemical contaminants attributable to a site, but consider all health threats, both chemical and physical, to which residents near a site may be subjected. Health assessments focus on the medical and public health concerns associated with exposures at a site and discuss especially sensitive populations, toxic mechanisms, and possible disease outcomes. EPA considers the information in a health assessment along with the results of the baseline risk assessment to give a complete picture of health threats. Local health professionals and residents use the information to understand the potential health threats posed by specific waste sites. Health assessments may lead to pilot health effects studies, epidemiologic studies, or establishment of exposure or disease registries.

EPA's Guidance for Coordinating ATSDR Health Assessment Activities with the Superfund Remedial Process (EPA 1987) provides information to EPA and ATSDR managers for use in coordinating human health evaluation activities. (Section 2.1, in its discussion of CERCLA, provides further information on the statutory basis of ATSDR health assessments.)

2.2.3 ATSDR HEALTH STUDIES

After conducting a health assessment, ATSDR may determine that additional health effects information is needed at a site and, as a result, may undertake a pilot study, a full-scale epidemiological study, or a disease registry. Three types of pilot studies are predominant:

(1) a symptom/disease prevalence study consisting of a measurement of self-reported disease occurrence, which may be validated through medical records if they are available;

(2) a human exposure study consisting of biological sampling of persons who have a potentially high likelihood of exposure to determine if actual exposure can be verified; and

(3) a cluster investigation study consisting of an investigation of putative disease clusters to determine if the cases of a disease are excessively high in the concerned community.

A full-scale epidemiological study is an analytic investigation that evaluates the possible causal relationships between exposure to hazardous substances and disease outcome by testing a scientific hypothesis. Such an epidemiological study is usually not undertaken unless a pilot study reveals widespread exposure or increased prevalence of disease.

ATSDR, in cooperation with the states, also may choose to follow up the results of a health assessment by establishing and maintaining national

registries of persons exposed to hazardous substances and persons with serious diseases or illness. A registry is a system for collecting and maintaining, in a structured record, information on specific persons from a defined population. The purpose of a registry of persons exposed to hazardous substances is to facilitate development of new scientific knowledge through identification and subsequent follow-up of persons exposed to a defined substance at selected sites.

Besides identifying and tracking of exposed persons, a registry also is used to coordinate the clinical and research activities that involve the registrants. Registries serve an important role in assuring the uniformity and quality of the collected data and ensuring that data collection is not duplicative, thereby reducing the overall burden to exposed or potentially exposed persons.

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